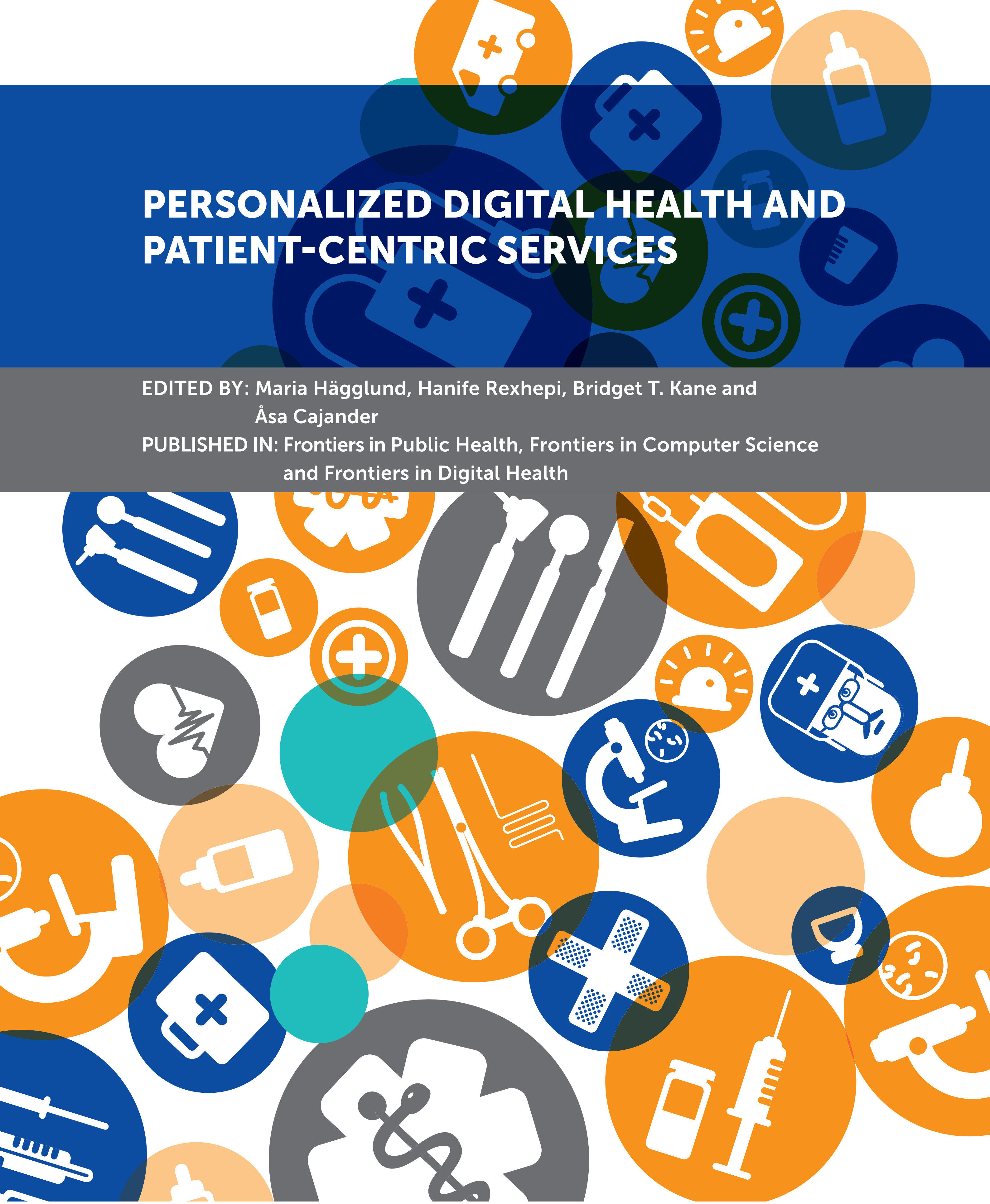

PERSONALIZED DIGITAL HEALTH AND PATIENT-CENTRIC SERVICES

EDITED BY: Maria Hägglund, Hanife Rexhepi, Bridget T. Kane and
Åsa Cajander

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PERSONALIZED DIGITAL HEALTH AND PATIENT-CENTRIC SERVICES

Topic Editors:
Maria Hägglund, Uppsala University, Sweden
Hanife Rexhepi, University of Skövde, Sweden
Bridget T. Kane, Karlstad University, Sweden
Åsa Cajander, Uppsala University, Sweden

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Editorial: Personalized Digital Health and Patient-Centric Services

Maria Hägglund[1]*, *Åsa Cajander*[2], *Hanife Rexhepi*[3] *and Bridget Kane*[4]

[1] Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden, [2] Department of Information Technology, Uppsala University, Uppsala, Sweden, [3] School of Informatics, University of Skövde, Skövde, Sweden, [4] Information Systems, Karlstad University Business School, Karlstad, Sweden

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Editorial on the Research Topic

Personalized Digital Health and Patient-Centric Services

Preventing medical errors and improving patient health outcomes are challenges faced by healthcare systems worldwide. Digitalization and the development of eHealth solutions are essential to enhance the quality of care and empower patients to engage actively in managing their health, and collaboration with healthcare services. By adapting these solutions to the individual patient's needs, we can achieve personalized digital health. Digital health and eHealth are often used interchangeably, and there is no real agreement on the scope or overlap of the concepts. In this editorial, we use the concepts as synonyms. Over recent years, efforts have been made to develop digital health services that aim to improve the effectiveness and efficiency of healthcare through innovative approaches and strengthen the opportunities for self-care, self-management, and patient participation. These eHealth services are increasing as a result of the patient empowerment and patients' rights movements that campaign for easy access to medical data (Wiljer et al., 2008; Wass and Vimarlund, 2018; Bärkås et al., 2021), patient participation in their care (Riggare et al., 2019a), and in the design and improvement of the healthcare systems including eHealth services (Riggare et al., 2021).

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Ann Borda,
The University of Melbourne, Australia

****Correspondence:***
Maria Hägglund
maria.hagglund@kbh.uu.se

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PATIENTS' ONLINE ACCESS TO HEALTH INFORMATION

Patients use the Internet to find health-related information and learn about their specific conditions and general health (Riggare et al., 2019a). Oldenburg et al. explore how an educational website can be used to encourage patients to discuss preventative interventions with their physicians, harnessing the power of the Internet and social media to improve health. Similarly, Beaton et al. propose the design of a comprehensive educational resource for adults experiencing concussion symptoms, to help them recover and return to work.

In recent years, an international trend has emerged to give patients online access to their electronic health records (EHRs) (Essén et al., 2018; Hägglund et al., 2019). Patient Accessible EHRs (PAEHRs) describe EHRs shared with patients through an online patient portal (Wiljer et al., 2008; Moll et al., 2018; Kristiansen et al., 2019). PAEHRs can include access to clinical notes, often called open notes (Delbanco et al., 2010, 2012; Leveille et al., 2012), laboratory results and medications. In this special issue, papers cover aspects including design and acceptance of technology (Davis), implementation challenges (Cijvat et al.), and the impact that the practice of sharing clinical notes with patients may have on clinicians' documentation practices (Blease et al.). Using Normalization Process Theory (May and Finch, 2009; May et al., 2009), Davis concludes that a personal health record supporting shared decision-making makes sense and is positive to the different stakeholders participating in their study. Davis identifies more varied opinions regarding how such a tool would become used in everyday practice, where patients are more positive and healthcare professionals more skeptical. Cijvat et al. confirm that implementation can be challenging, comparing the implementation of PAEHRs in Sweden and the Netherlands. The main barriers identified in both countries are resistance from healthcare professionals (Huvila et al., 2013; Cajander and Grünloh, 2019), and technical barriers. Facilitators vary across the two contexts, but both countries describe stakeholder engagement (including patients and healthcare professionals) and strong leadership as critical success factors.

Moreover, Blease et al. discuss how patients' access to notes can have both positive and negative effects on healthcare professionals documentation. Survey studies suggest that some healthcare professionals make an effort to write clearly and with less derogatory language (DesRoches et al., 2020), using the note as an extension of the patient visit, whereas others write fewer clinical details and even leave out important information (Petersson and Erlingsdottir, 2018; Kristiansen et al., 2019; Moll and Cajander, 2020). Poor documentation practices may lead to patient safety risks, a topic that is also addressed by Bjerkan et al. In their focus group study, Bjerkan et al. identify barriers to high-quality documentation on technical, organizational, social and individual levels. It would be interesting to explore further how patient access to their documentation could be used to encourage improved documentation practices, and act as an additional patient safety tool (Chimowitz et al., 2018).

SELF-MANAGEMENT AND ONLINE TREATMENTS

Over recent years, technologies for self-monitoring and self-tracking have emerged, allowing patients to collect a wide range of health-related data outside the clinic (Lupton, 2017; Sharon, 2017; Riggare and Hägglund, 2018; Riggare et al., 2019b). These technologies can educate patients about their health, help them manage their illness and help identify actionable insights. Despite positive outcomes, it is unclear how patient-generated data can be integrated into clinical practice (Hägglund et al., 2016). Hung et al. propose a solution for managing patient-generated data sharing with the aim of supporting collaborative self-care, allowing users with chronic and complex health management needs to have fine-grained control over sharing their patient-generated health data (PGHD) with a care team.

Self-management is important for most people with chronic health issues (Riggare and Hägglund, 2018; Riggare et al., 2019b). Issom et al. explore patients' use of a chatbot to support self-management of adults and young adults with sickle cell disease (SCD), a genetic blood disorder that causes several comorbidities that can be acute, chronic, and potentially lethal. In contrast to patients with SCD, many chronic conditions are more common in the older age groups, and in Wannheden et al.'s study 76% of the respondents are over 50 years old. Wannheden et al. explore how using a digital tool for self-monitoring and communication with healthcare satisfies or frustrates basic psychological needs. They found that individual preferences differ and that personalization of these types of tools is essential. In contrast, Lobo et al. addresses the needs of stroke family caregivers. They conclude that future research needs to focus on improving user participation and proper understanding of the user practices and needs, as well as technical and organizational implementation.

In addition to self-management of chronic conditions, digital solutions for disease prevention and health promotion are increasingly common. The COVID-19 pandemic has caused concerns for numerous reasons, such as isolation and physical inactivity during lock-downs. Martyushev-Poklad and Yankevich review the patent landscape of automated systems for personalized health management, and conclude that few solutions exist today that support all aspects of human health. Ollier et al. designed a pandemic lifestyle care intervention and presented their study protocol in this special issue. In order to maintain physical activity, mobility and balance are essential for older adults and might impact their well-being and independence. Early identification of functional impairment may enable early risk-of-fall assessments and preventive measures and Backåberg et al. explore whether the skeleton avatar technique can predict the results of functional tests of mobility and balance. Backåberg et al. conclude that the technique can successfully predict the results of some of the functional tests and could in the future provide the means for a simple, easy, and accessible assessment of functional ability among older adults.

Access to care can be a challenge for many patients, and digitalization has proven a means to bridge that gap. Rauen et al. compare the outcome of Internet cognitive behavioral therapy (ICBT) with or without additional face-to-face outpatient psychotherapy in adult patients with moderate to severe depressive disorder. Patients who receive other face-to-face psychotherapy demonstrate slightly better outcomes after 6 months, and Rauen et al. conclude that ICBT is suitable for psychiatric treatment, although additional face-to-face outpatient psychotherapy helps stabilize long-term outcomes. Considering the increasing use of digital health in psychiatry, Blease et al. surveyed postgraduate clinical psychology students to explore their familiarity and formal exposure to topics related to artificial intelligence and machine learning during their studies, and conclude that although the students have a wide range of opinions on the topic, they receive limited formal education.

Whittaker et al. explore whether pulmonary rehabilitation can be delivered successfully online. A pilot study (26 patients and four family carers) provided pulmonary rehabilitation support via mobile phone, including exercise prescription and support. Twenty of the 30 study participants recommend the tool to others, suggesting that personal preferences play a significant role in the acceptance of technology.

TELEMEDICINE/ONLINE CONSULTATIONS

Online consultations and telemedicine with doctors and nurses are also rapidly gaining popularity but at the same time, questions are raised as to whether it is possible to provide good quality care through virtual online consultations. One can speculate about the patient experience with using these services, the contexts in which telemedicine works well, and where other forms of consultations work better.

An exciting study presented in this special issue relates to opioid use disorders and telemedicine (Cole et al.). Cole et al.

conclude that telemedicine is a viable alternative for providing care and works incredibly well in rural areas. They maintain that telemedicine can lower barriers to accessing mental healthcare such as stigma, the guilt of addiction, and anxiety surrounding an in-person meeting with a healthcare professional. Cole et al. also developed a patient satisfaction survey that serves as a measure and provides advice in evaluating patients' satisfaction regarding the quality of care provided via telemedicine.

As with many other areas in eHealth services, the pandemic has been a driver of implementation and use of self-management and online treatments. Foti et al.'s study of telemedicine induced by the pandemic for Inflammatory rheumatic disease shows positive results, and the successful implementation of telemedicine. During the lockdown, ∼80% of outpatient appointments were telemedicine, and outpatient clinic face-to-face consultations were limited to urgent patients. Another exciting survey study in this special issue looks into telemedicine during the lockdown. Reicher et al. show positive experiences from patients, and the majority also state that they will continue using telemedicine in the future.

Interestingly, one-third of Reicher et al.'s respondents changed their minds about telemedicine during the lockdown. These findings are intriguing in light of telemedicine's non-use, which is addressed in another paper on this special issue (Landgren and Cajander). Landgren and Cajander show that before the pandemic in Sweden, there was a mistrust for services for political reasons, a deficiency in knowledge of available services, and a lack of perceived usefulness. Landgren and Cajander show that personal relations and continuity are more crucial than time or travel comforts. Indeed, to prevent digital exclusion, caregivers need to offer information, encouragement, or tools for the elderly and design-for-all needs to be a prerequisite in the design process.

DISCUSSION AND CONCLUSION

Digital health innovations serve society and support the sustainability of healthcare systems. Implementing these technologies is usually expensive with limited success, creating new challenges for healthcare professionals, patients, healthcare providers, and healthcare organizations (Chaudhry et al., 2006; Cajander et al., 2020; Moll and Cajander, 2020). In this special issue, we explore dimensions related to eHealth services that increase transparency, access to both care and data, and reports on how patients, family caregivers, and healthcare professionals' interactions can be impacted.

The pandemic has increased the use of eHealth services for patients, as several studies in this special topic conclude (Cole et al.; Foti et al.; Ollier et al.). Many patients and healthcare professionals who were hesitant to use eHealth services now see the need to learn, implement and adapt telemedicine and other eHealth services to their needs. The pandemic has lowered the barrier to user adoption, and the perceived usefulness of digital e-services for patients seems to have increased significantly. Interesting future research could look into the sustainability of these changes. To what degree will telemedicine continue being used after the pandemic, in which contexts is telemedicine most valuable and what specific populations have used these digital technologies during the pandemic? Another exciting avenue of research is the effects on healthcare professionals' work environment, decision-making, and quality of care.

Despite the undeniable importance of eHealth services to many patients, some choose not to use them (Landgren and Cajander). Part of the explanation for this is that e-services for patients are still not being designed inclusively and in an accessible way. Indeed, Internet use generally (Johansson et al., 2021) and eHealth services for patients as designed today increase the digital divide in society. As we grow older, we are likely to increasingly need healthcare and potentially eHealth services. Hence, the elderly are more likely to consider eHealth services valuable and directed toward them, but research shows that the correlation between age and use of patient accessible health records is not linear (Huvila et al., 2018). Nevertheless, many experience the technology as inherently difficult to use (Huvila et al., 2021). We should not forget that at the same time as eHealth services for patients increase the digital divide; they also close it for people who are hesitant to physically attend for healthcare due to anxiety, stigma etc., as pointed out by Cole et al. and Rauen et al.

In summary, the publications in this special issue show how personalized digital health solutions can successfully be used by patients and healthcare providers to improve prevention, self-management and access to healthcare—if they are designed to meet the individual patient's needs and preferences.

AUTHOR CONTRIBUTIONS

All authors were actively involved in editing the special Research Topic, and have contributed to the editorial text. All authors contributed to the article and approved the submitted version.

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ORIGINAL RESEARCH
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Internet Cognitive Behavioral Therapy With or Without Face-to-Face Psychotherapy: A 12-Weeks Clinical Trial of Patients With Depression

Katrin Rauen[1], Stefan Vetter[2], Amanda Eisele[1,3], Ewelina Biskup[4,5], Aba Delsignore[6], Michael Rufer[2] and Steffi Weidt[2]*

[1] Department of Geriatric Psychiatry, Psychiatric Hospital Zurich, University of Zurich, Zurich, Switzerland, [2] Department of Psychiatry, Psychotherapy, and Psychosomatics, Psychiatric Hospital Zurich, University of Zurich, Zurich, Switzerland, [3] Department of Neurology, University Hospital Zurich, Zurich, Switzerland, [4] Department of Advanced Biomedical Sciences, Frederico II University of Naples, Naples, Italy, [5] College of Fundamental Medicine, Shanghai University of Medicine and Health Sciences, Shanghai, China, [6] Faculty of Medicine, University of Zurich, Zurich, Switzerland

Edited by:
Maria Hägglund,
Beth Israel Deaconess Medical Center and Harvard Medical School, United States

Reviewed by:
Hemant Ghayvat,
Fudan University, China
Maria Vittoria Bulgheroni,
Ab.Acus, Italy

***Correspondence:**
Steffi Weidt
steffi.weidt@puk.zh.ch

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Depressive disorders are a curable, global health problem. However, most patients remain untreated, and more and more patients use internet-based interventions, but it is unclear whether it is beneficial for ongoing face-to-face psychotherapy. Thus, we compared the outcome of internet cognitive behavioral therapy (ICBT) with (ICBT+) or without (ICBT) additional face-to-face outpatient psychotherapy in adult patients with moderate to severe depressive disorder. For this longitudinal interventional clinical trial (NCT02112266), 168 of 252 online recruited adults with depressive symptoms received ICBT+ ($n = 96$) or ICBT ($n = 72$). Demographics (sex, age, age at first depressive episode, years of education, duration of depressive symptoms) were assessed and compared between groups. All patients underwent ICBT for 12 weeks. Quality of life (QoL) and severity of depressive symptoms were assessed within each group at three time points [baseline (T0), postinterventional after ICBT at 12 weeks (T1), and for follow-up at 6 months (T2)] using the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) global score to assess QoL as primary and the Beck Depression Inventory (BDI-II) to assess self-rated depressive symptoms as secondary outcome variables, respectively. Differences were assessed between groups using t test and over time using repeated-measures analysis of variance. Data of intention-to-treat analysis are given as mean ± SD. Group differences were assumed at $p < 0.05$. Partial η^2 is given as effect size. Demographic data, QoL, and depressive symptoms did not differ between groups (ICBT+/ICBT) at baseline (T0). Patients of both groups suffered from moderate to severe depressive disorders and gained improved QoL scores (WHOQOL-BREF-global: $p < 0.001$, $\eta^2 = 0.16$), as well as experienced decreased depressive symptoms (BDI-II:

$p < 0.001$, $\eta^2 = 0.2$) after 12 weeks of ICBT compared to baseline. Patients without additional face-to-face outpatient psychotherapy lost QoL—albeit not significant—and had increased depressive symptoms (BDI: $p = 0.02$, $\eta^2 = 0.04$) at 6 months' follow-up. Thus, ICBT is suitable for psychiatric treatment, although additional face-to-face outpatient psychotherapy helps stabilizing long-term outcome.

Keywords: depression, ICBT, face-to-face psychotherapy, QoL, BDI-II, WHOQOL-BREF, trial

INTRODUCTION

Depressive disorders are a major, though curable, global health problem that remarkably hampers patient's quality of life (QoL). The World Health Organization (WHO) has ranked major depression worldwide the third cause of burden, and it is estimated to be the primary cause by 2030 (1, 2). The lifetime risk is 15–18%, and women are twice as often affected as men (3, 4). However, prior to puberty, affective disorders are equally distributed between sexes, but notably, this sex- and gender-related difference in the prevalence of depression occurs during adolescence and remains stable over the life span, indicating besides genetic factors a role of sex hormones and/or gender-related educational issues for the pathogenesis (5, 6). Depression is similarly prevalent in high- vs. middle- and low-income countries indicating that causes go far beyond modern lifestyle and poverty (2, 7, 8). Nevertheless, a remarkable number of patients remain undiagnosed (9–11), and almost half remain untreated (12, 13). Reasons for not seeking professional help are unawareness with failure of recognizing depressive symptoms, the limited capacities of therapists, and the persisting tenacious stigma of mental disorders (10, 12–14). This treatment gap is especially relevant in the young, thereby increasing the risk of progression in terms of recurrence and aggravation of episodes in adulthood, and endures despite the large body of effective non-pharmacological and pharmacological treatment (10, 15–17).

Psychotherapy effectively tackle mild to moderate depressive disorders, whereas moderate to severe depression needs a combined approach of pharmacotherapy and psychotherapy (18). To date, cognitive behavioral therapy (CBT) is the most evidence-based psychotherapy for depression (13, 19), and patients often prefer non-pharmacological rather than pharmacological or combined approaches. Recently, online therapies gained more attention to close the current treatment gap for depressive disorders (13, 20, 21). Internet-based cognitive behavioral interventions, such as the internet cognitive behavioral therapy (ICBT), improve mild to moderate depressive symptoms and have been shown to be beneficial when compared to usual care either by the general practitioner or a psychotherapist without grading of the evidence [Grading of Recommendations Assessment, Development and Evaluation (GRADE) not conducted] and in comparison to waiting-list patients with moderate evidence (GRADE moderate) (22). However, there is also the contrary opinion and evidence that ICBT might be inferior regarding individual and face-to-face outpatient CBT (21). Nevertheless, the evidence of ICBT improving severe depressive symptoms is rare (23), and to our knowledge, ICBT has not yet been compared to ICBT plus face-to-face psychotherapy in moderate to severe depression (22). Thus, evidence regarding QoL outcome and relief of symptoms in moderate to severe depressive patients has not yet been fully explored.

Quality of life is a suitable and increasingly applied subjective outcome measure to assess patient's well-being over time. The WHO defines QoL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad-ranging concept with complex interactions with a person's physical health, psychological state, personal beliefs, social relationships, and their relationship to salient features of their environment," (24) thereby emphasizing the relevance of internal and environmental factors and its interplay for good QoL.

Currently, more and more internet-based interventions are available and are used by patients with or without ongoing face-to-face psychotherapy. Nevertheless, it is unclear whether these internet-based interventions are favorable or even unfavorable due to different therapy approaches at the same time. Therefore, we investigated the outcome of ICBT with or without additional face-to-face outpatient psychotherapy in adult patients with a moderate to severe depressive disorder.

PATIENTS AND METHODS

Study Design and Patients

This longitudinal interventional preregistered clinical trial (NCT02112266) was conducted online. A multipronged approach included several recruitment strategies, namely, announcements on depressive disorder websites, postings in online self-help forums, and notices in chat rooms for depressive symptoms. Patients were enrolled online from April 2014 until March 2016. After the presurvey, potentially eligible subjects received a participation code. All online questionnaires were programmed using QuestBack Unipark (25). After final study inclusion, patients were assigned to the ICBT group receiving exclusively the ICBT online therapy or to the ICBT+ group receiving ICBT plus additional face-to-face outpatient

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Abbreviations: BDI-II, Beck Depression Inventory, 2nd version; CBT, Cognitive Behavioral Therapy; GRADE, Grading of Recommendations Assessment, Development and Evaluation; ICBT, Internet Cognitive Behavioral Therapy; ICBT+, Internet Cognitive Behavioral Therapy plus additional face-to-face outpatient psychotherapy; η^2, Partial eta squared (effect size); QoL, Quality of Life; SD, Standard Deviation; WHO, World Health Organization; WHOQOL-BREF, World Health Organization Quality of Life Questionnaire.

psychotherapy. All patients underwent ICBT for 12 weeks without study site visits, thus from T0 until T1. Therefore, time points of assessments were at baseline (T0), after 12 weeks of the ICBT treatment (T1), and at 6 months after the start of the ICBT treatment for one follow-up (T2). Demographics (sex, age, age at first depressive episode, years of education, duration of depressive symptoms) were assessed and compared between groups at baseline (T0). Changes of QoL as primary outcome were measured by the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) global score. Depressive symptoms were quantified with the BDI-II as secondary outcome. Primary and secondary outcomes were assessed over time at three time points, that is, at baseline (T0), after the intervention of ICBT at 12 weeks (T1), and at 6 months' follow-up (T2). The study was approved by the local ethics committee of the Canton of Zurich in Switzerland (KEK-ZH-Nr. 2013-0542). It was conducted in full accordance with the Declaration of Helsinki, with all subjects providing their electronic informed consent prior to participation and the EQUATOR/CONSORT standards.

Inclusion and Exclusion Criteria

Patients aged 18–65 years of both sexes (female/ male) were eligible for study inclusion if depressive symptoms were at least moderate to severe with a BDI-II equal to or >20 and <40, and symptoms persisted at least for 2 weeks. German language was required. Exclusion criteria were very severe depression according to a BDI-II of beyond 40, suicidal ideation, alcohol or drug dependency, history of psychotic symptoms, history of bipolar disorder, current inpatient care, or semiresidential treatment.

Intervention

Both groups received the ICBT over 12 weeks, developed by makora AG (www.makora.ch). Subjects were allocated to this internet intervention, including eight different modules, which were released every week. All modules were based on psychoeducation and exercises for the following topics: (1) symptom recognition, (2) identification of reasons for depressive symptoms, (3) increasing positive activation, (4) thought observation, (5) thought identification, (6) error in reasoning resolving, (7) social activity improving, and (8) relapse preventing. There was no personal study support other than technical. However, subjects received automatic e-mails when (i) they did not finish an ICBT module, (ii) did not log in into the program for more than 7 days, and (iii) a new module was released to work on. After the 12 weeks of ICBT, thus between the end of the ICBT (T1) and the follow-up at 6 months (T2), subjects could use the ICBT program without any restrictions. During this period, they received no more automatic e-mails but were occasionally reminded that they were taking part in a study. There were neither recommendations nor restrictions during the 3-months period from the end of the structured and guided ICBT (T1) to the follow-up, thus at 6 months after the start of the trial (T2). Therefore, all participants were able to continue or discontinue ICBT in accordance to their individual motivation and preferences, and patients of the ICBT+ group could follow their individual needs regarding the face-to-face psychotherapy.

Demographics and Outcome Measures

Sociodemographic and clinical data were obtained through structured questions about sex (female/male), age, age at first depressive episode, years of education, and duration of depressive symptoms and were compared between groups at baseline (T0).

The WHOQOL-BREF in its German version was used to assess QoL for primary outcome over time within and between groups (26). The WHOQOL-BREF is a validated patient-reported outcome instrument assessing the patient's global health and well-being within the recall period of 2 weeks and has been developed to provide a validated short form covering 26 items and all facets of the WHOQOL-100—one of the most applied QoL assessments. Despite its significant reduction in questions compared to the WHOQOL-100, the WHOQOL-BREF is a sound, cross-culturally valid instrument with good to excellent psychometric properties with the advantage of quick completion (26, 27). The WHOQOL-BREF generates a QoL profile of four domains, namely, physical health, psychological, social relationships, environment, and two further items, that is, the individual's overall perception and the global health with a score from 0 to 100 representing worst and best QoL, respectively.

The BDI-II was used for secondary outcome measures assessing depressive symptoms over time within and between groups. The BDI-II is a self-assessment and can be completed within 5 to 10 min (28, 29). The questionnaire consists of 21 items, each rated on a 4-point scale ranging from 0 to 3, representing no to severe symptoms within the past 2 weeks. Responses were summed, yielding a score between 0 and 63, with higher scores indicating severest depressive symptoms. In detail, a score from 0 to 8 represents no clinical signs of depression; a score of 9 to 13, minimal; a score of 14 to 19, mild; a score of 20–28, moderate; and a score of 29–63, severe depression. The BDI-II is reliable with a Cronbach α of 0.93 for depressed patients and has a good internal and external test validity with $r = 0.72$–0.89 and $r = 0.68$–0.70, respectively. Instruments' responsiveness is along reliability and validity one out of the three measurement properties to determine the quality of a health-related patient-reported outcome and represents the capability to detect the patient status' changes over time (30, 31)

Statistics

Descriptive statistics were used to characterize subjects regarding demographics and therapy characteristics of the ICBT and the ICBT+ group. Differences (demographics, WHOQOL-BREF global score, BDI-II) at baseline were assessed per group using t test for independent samples and over time using repeated-measures analysis of variance. Intention-to-treat analysis with first observations carried forward was conducted for the dependent variables WHOQOL-BREF global score and the BDI-II. Group (ICBT vs. ICBT+) served as the between-subject variable, with time (pre, post, follow-up) as the within-subject factor. Data are given as mean ± SD.

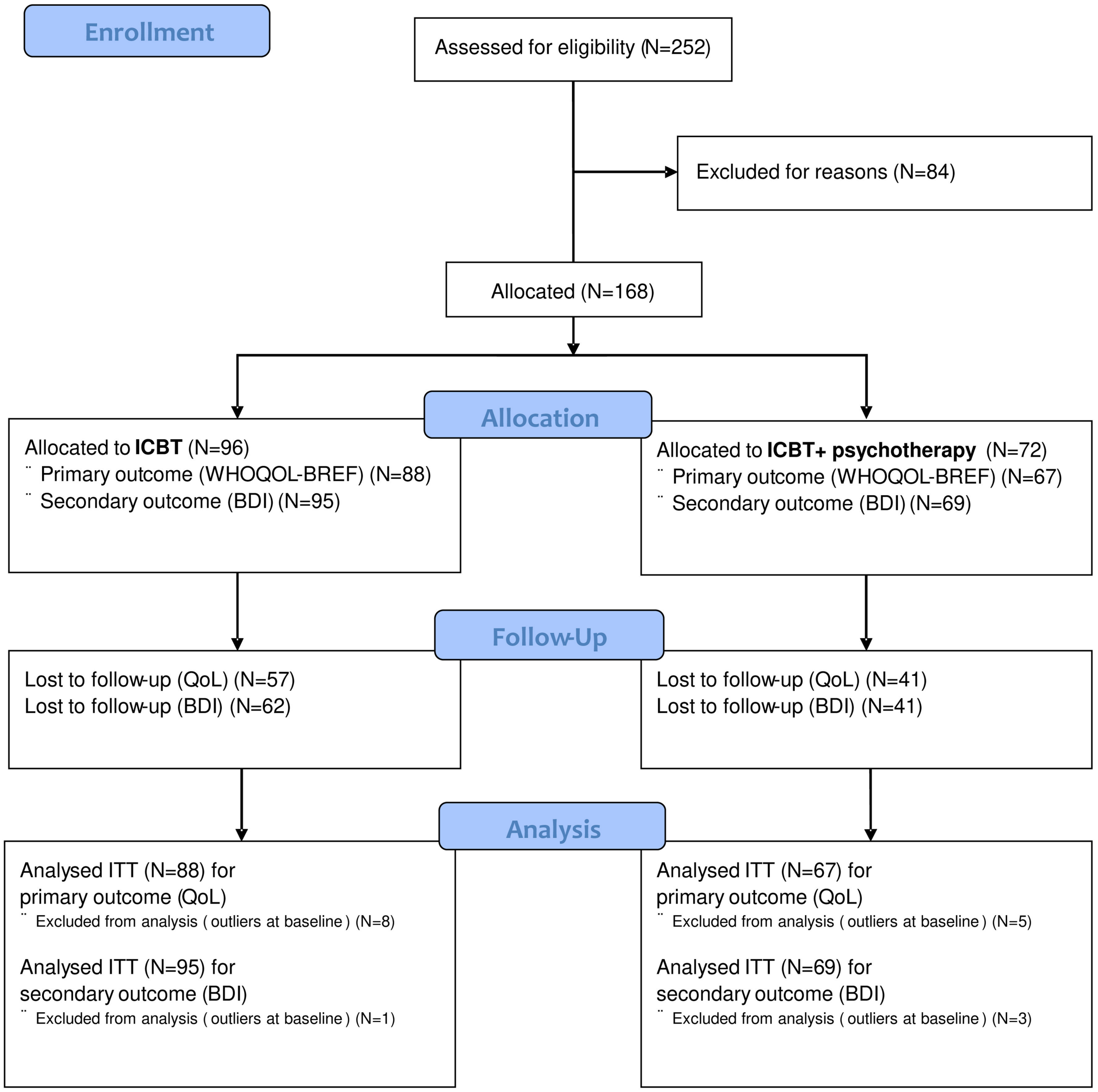

FIGURE 1 | Flowchart of enrollment and analysis for ICBT.

Outliers were removed if data exceeded more than 2 SD. Group differences were assumed at $p < 0.05$. To determine effect sizes, a partial η^2 was calculated, indicating a small ($\eta^2 \geq 0.01$), medium ($\eta^2 \geq 0.06$), or large effect ($\eta^2 \geq 0.14$) (32). Statistical calculations were performed using SPSS (version 25.0; IBM, Armonk, New York, USA). Graphs were illustrated using Prism8 (GraphPad Software, San Diego, CA, USA) (33).

RESULTS

Two hundred fifty-two online recruited adults with depressive symptoms were assessed for eligibility (**Figure 1**). Eighty-four patients were excluded according to the exclusion criteria: current suicidal ideation ($n = 26$), inpatient treatment ($n = 2$), alcohol or drug dependency ($n = 7$), psychotic symptoms ($n = 2$), bipolar disorder ($n = 4$), not given e-mail address ($n = 27$), and not willing to participate ($n = 16$). Thus, 168 of 252 (67%) received participant codes to enter the online therapy. Of those, 96 (57%) had no outpatient psychotherapy and were allocated to the ICBT group, whereas 72 had outpatient treatment for their depressive disorder and were assigned to the ICBT+ group. After removal of eight and five outliers, respectively, 88 patients of the ICBT and 67 patients of the ICBT+ group were analyzed for their primary outcome (WHOQOL-BREF global score). For secondary outcome (BDI-II), 95 patients of the ICBT, and 69 patients of the ICBT+ group were analyzed after removing one and three outliers, respectively.

TABLE 1 | Demographics at baseline.

Demographics	ICBT group ($N = 96$)	ICBT + psychotherapy ($N = 72$)	*p*-value[#]
Sex (females/males) (%)	76%/24%	79%/21%	0.71
Age in years (mean ± SD)	35.4 ± 11.5	37.5 ± 11.9	0.26
Age at first depressive episode in years (mean ± SD)	21.0 ± 9.6	21.7 ± 14.3	0.73
Years of education (mean ± SD)	14.6 ± 5.4	15.9 ± 5.0	0.11
Depressive symptoms in weeks (mean ± SD)	68.2 ± 159.7	73.4 ± 151.0	0.83

[#] *t-test after Shapiro-Wilk-Test for normality.*

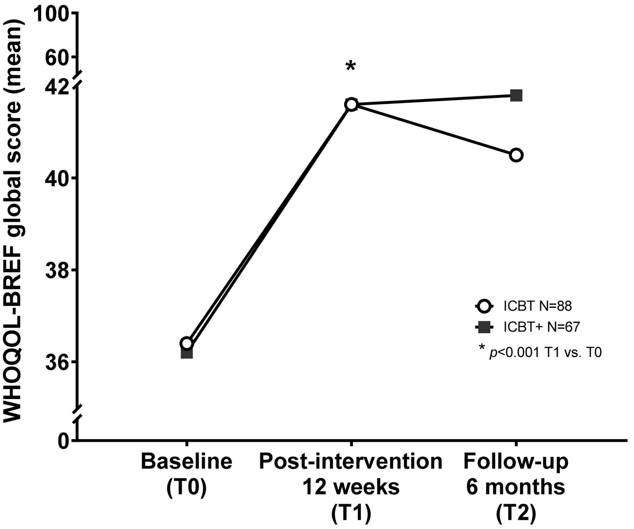

FIGURE 2 | Internet cognitive behavioral therapy and quality of life outcome. Internet cognitive behavioral therapy (ICBT) is suitable to improve quality of life (QOL) measured by the WHOQOL-BREF global score within 12 weeks of treatment ($p < 0.001$, $\eta^2 = 0.16$). Patients who received additional face-to-face outpatient psychotherapy (ICBT+) were able to stabilize their gained QoL up to 6 months after the start of the intervention, whereas patients without additional face-to-face psychotherapy slightly lost QoL, although not significant. *indicates the significant longitudinal improvement of QoL between baseline (T0) and after 12 weeks of treatment (T1), and thus between T0 and T1 within both groups.

Demographics and Therapy Characteristics

Demographics, namely sex (female/ male), age, age at first depressive episode, years of education, and duration of depressive symptoms, were assessed at baseline and did not differ between groups, that is, the ICBT ($n = 96$) and the ICBT+ ($n = 72$) group (**Table 1**).

The ICBT and ICBT+ groups did not statistically differ regarding (i) the total time spent for ICBT, (ii) the total counts of logins, (iii) the counts of logins between T0 and T1, and (iv) the counts of logins between T1 and T2. In detail, total time spent for ICBT was on average in the ICBT group 4.5 ± 6.3 h (mean ± SD) and in the ICBT+ group 5.7 ± 9.3 h ($p = 0.36$). The total count of logins was on average 11.5 ± 12.6 within the ICBT group compared to 12.7 ± 14.8 ($p = 0.62$) within the ICBT+ group. Between T0 and T1, subjects of the ICBT group had 10.7 ± 11.4 compared to 11.3 ±12.3 logins of the ICBT+ subjects ($p = 0.79$). During T1 and T2, the count of logins was 0.78 ± 1.8 within the ICBT and 1.1 ± 2.9 within the ICBT+ group ($p = 0.46$), representing the low tendency to continue the ICBT, that is, only 19 and 15 subjects, respectively. Frequencies of face-to-face psychotherapy within the ICBT+ group were as follows: 43.7% of subjects received face-to-face psychotherapy at least once per week, 42.3% one to two times per month, and 14.1% less frequent.

Quality-of-Life Outcome

The WHOQOL-BREF global scores did not differ between groups (ICBT: $n = 88$/ ICBT+: $n = 72$) at baseline (36.4 ± 13.9/36.2 ± 11.9; $p = 0.94$) (**Figure 2** and **Table 2**). Intention-to-treat analysis comparing WHOQOL-BREF global scores at T0 and T1 revealed significant improved QoL within groups ($p < 0.001$) with a large effect size indicated by a partial $\eta^2 = 0.16$, but without group differences ($p = 0.87$; $\eta^2 < 0.01$). Subjects of the ICBT group reported reduced QoL at 6 months (T2) compared to the end of the ICBT at 12 weeks (T1), albeit this observation was not significant within groups ($p = 0.62$, $\eta^2 < 0.01$) or between groups ($p = 0.49$, $\eta^2 < 0.01$).

Depressive Symptoms

The BDI-II scores did not differ between groups (ICBT: $n = 95$/ ICBT+: $n = 69$) at baseline (27.4 ± 7.7/27.6 ± 7.1; $p = 0.97$) (**Figure 3** and **Table 3**). Intention-to-treat analysis comparing BDI-II scores at T0 and T1 underlines reduced depressive symptoms in both groups with $p < 0.001$ indicated by a large effect size with a partial $\eta^2 = 0.2$. Subjects of the ICBT group showed slight deterioration of depressive symptoms, with higher BDI-II scores compared to those subjects of the ICBT+ group at 6 months (T2) and compared to the end of the ICBT at 12 weeks (T1) ($p = 0.02$, $\eta^2 = 0.04$). Thus, BDI-II scores differed within groups over time from T0 to T1, and between groups over time from T1 to T2, indicating a beneficial effect of additional face-to-face outpatient psychotherapy.

DISCUSSION

This longitudinal interventional clinical trial included adult patients aged 18–65 years of both sexes with moderate to severe depressive disorders investigating QoL outcome measured by the WHOQOL-BREF global score for primary and changes of self-assessed depressive symptoms measured by the BDI-II for secondary outcome. Demographics and outcome measures, that is, QoL and BDI scores, did not differ at baseline between the two investigated groups, that is, the ICBT and ICBT+ groups, the latter having received additional face-to-face outpatient psychotherapy, whereas the ICBT group received solely the online treatment of eight modules on psychoeducation and exercises. Patients of both groups, namely, ICBT and ICBT+, reported improved QoL and had reduced self-assessed depressive symptoms after 12 weeks (T1) of online

TABLE 2 | Influence of ICBT on quality of life outcome.

Primary outcome	Baseline (T0)		Post-intervention 12 weeks (T1)		Follow-up 6 months (T2)		Group difference	Differences over time within groups	
	ICBT ($N = 88$)	ICBT+ ($N = 67$)	ICBT ($N = 88$)	ICBT+ ($N = 67$)	ICBT ($N = 88$)	ICBT+ ($N = 67$)	ICBT vs. ICBT+	T0 vs. T1	T1 vs. T2
WHOQOL-BREF global (mean ± SD)	36.4 ± 13.9	36.2 ± 11.9	41.6 ± 18.0	41.6 ± 15.0	40.5 ± 18.1	41.8 ± 16.4	$p = 0.87$ $\eta^2 < 0.01$	$p < 0.001$ $\eta^2 = 0.16$	$p = 0.62$ $\eta^2 < 0.01$

ITT analysis (N = 155) General linear models (repeated measures).
η^2: effect size partial eta squared ($\geq$ 0.01 small effect, $\geq$ 0.06 medium effect, $\geq$ 0.14 large effect).

treatment with or without additional face-to-face outpatient psychotherapy, and this result did not differ between the two groups. At follow-up (T2), namely, 6 months after the trial's start, there was a trend that patients receiving additional face-to-face outpatient psychotherapy (ICBT+) were able to stabilize their QoL, whereas lack of face-to-face outpatient psychotherapy (ICBT) might result in reduced QoL over time. In terms of self-assessed depressive symptoms at 6 months' follow-up, patients receiving exclusively online treatment slightly deteriorated, whereas patients with additional face-to-face outpatient psychotherapy further improved over time and reported significantly fewer depressive symptoms compared to the ICBT patients. These results suggest that additional face-to-face outpatient psychotherapy may have helped stabilizing outcome over time. Internet cognitive behavioral therapy can help improve QoL and depressive symptoms especially for those patients having limited access to psychotherapy and/or being afraid of psychiatry-related stigma, thereby being supportive to overcome lack of treatment capacities or stigma of psychiatric consultations.

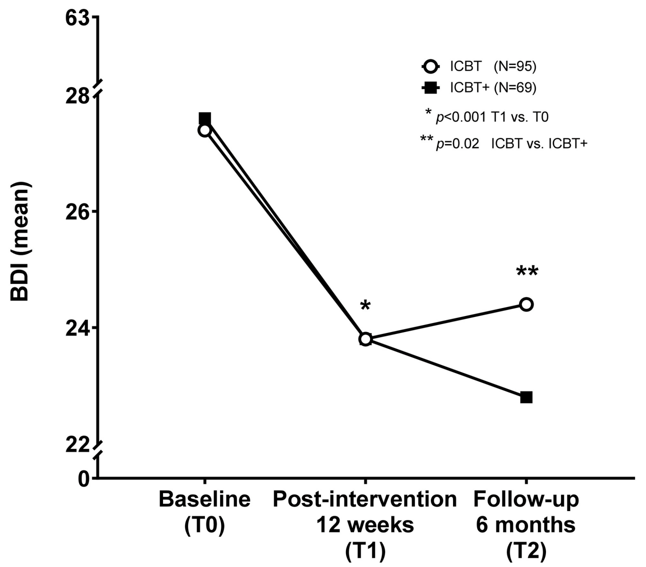

FIGURE 3 | Internet cognitive behavioral therapy and depressive symptoms. Internet cognitive behavioral therapy (ICBT) is suitable to improve depressive symptoms measured by the Beck Depression Inventory in its revised version (BDI-II) within 12 weeks of treatment ($p < 0.001$, $\eta^2 = 0.2$). Patients who received additional face-to-face outpatient psychotherapy (ICBT+) further improved and reported fewer depressive symptoms, whereas those without additional psychotherapy deteriorate up to 6 months after the intervention ($p = 0.02$, $\eta^2 = 0.04$). Thus, ICBT with additional face-to-face outpatient psychotherapy seems to be beneficial for patients to reduce depressive symptoms in the long run. *indicates the significant longitudinal decrease of depressive symptoms between baseline (T0) and after 12 weeks of treatement (T1), and thus between T0 and T1 within both groups. **indicates the significant difference between ICBT and ICBT+ groups with respect to time from T1 to T2, thus the end of the guided ICBT treatment for both groups and the 6 months follow up with significant less depressive symptoms in patients having received ICBT plus face-to-face psychotherapy.

Demographics

The participating patients most probably suffered from recurrent depressive disorders with onset during their adolescence and were within their third life decade with a female-to-male ratio of 4:1. From the literature, it is well-known that first episodes of depressive disorders occur from midadolescence to mid-40s, with almost half of patients experiencing first depression before the age of 20 years with peaks in the second and third decades of life (2); thus, our study cohort is well in line with the literature regarding age at study participation and age at first depressive episode. Regarding the female-to-male ratio, our study cohort had three times more women than men; thus, women are overrepresented in our study compared to the prevalence of depression mostly given in the literature (2–4, 6, 34). However, socioeconomic factors play a role for depression, and significant cross-national variations with higher percentage of women, thus comparable to our cohort, have been reported (35). As the prevalence of depression changes between females and males during adolescence and remains stable over the life span, the biological sex due to hormonal changes and differences of brain structures as well as gender-related factors are relevant (6, 35). It is especially noteworthy that the association of higher education with better mental health is significantly more relevant for women than for men in Europe (35). Why most probably an overrepresented number of women participated in our study remains unclear, but it can be speculated that females rather than males recognize depressive symptoms and might be more self-aware of symptoms, and thus seeking help more frequently. Future research should focus on how to better reach males and younger participants suffering from depression (e.g., with specific advertisement for online treatment for these subgroups). Based on our results, specific suggestions for additional face-to-face outpatient psychotherapy might be offered to participants during the ICBT training.

TABLE 3 | Impact of ICBT on depressive symptoms.

Secondary outcome	Baseline (T0)		Post-intervention 12 weeks (T1)		Follow-up 6 months (T2)		Group difference	Differences over time within groups	
	ICBT ($N = 95$)	ICBT+ ($N = 69$)	ICBT ($N = 95$)	ICBT+ ($N = 69$)	ICBT ($N = 95$)	ICBT+ ($N = 69$)	ICBT vs. ICBT+	T0 vs. T1	T1 vs. T2
BDI (mean ± SD)	27.4 ± 7.7	27.6 ± 7.1	23.8 ± 10.4	24.0 ± 9.6	24.4 ± 10.6	22.8 ± 10.6	$p = 0.77$ $\eta^2 < 0.01$	$p < 0.001$ $\eta^2 = 0.2$	$p = 0.35$ $\eta^2 < 0.01$

ITT analysis (N = 164) General linear models (repeated measures).
η^2: effect size partial eta squared (≥ 0.01 small effect, ≥ 0.06 medium effect, ≥ 0.14 large effect).

Quality of Life and Depression

Quality of life was connotatively hampered by moderate to severe depression in our patients and was significantly improved in both groups by ICBT. However, norm values of QoL measured by the WHOQOL-BREF have been described beyond a score of 70 (36), albeit norm data for the global score are missing. However, the international validation of the WHOQOL-BREF included 11,830 subjects and revealed mean values of 3–4 on the 5-point scale for the general QoL and general health with moderate correlations with the four domains, that is, physical, psychological, social, and environment of the WHOQOL-BREF (27, 37). Furthermore, other commonly used health-related QoL scores, e.g., the SF-36, have well-reported norm values for, e.g., the German population with mean scores of approximately 50 on a scale ranging from 0 to 100, the latter representing best QoL (38). Thus, most probably QoL of our patient cohort was still hampered after ICBT with or without additional face-to-face outpatient psychotherapy. Most likely, this impeded QoL is influenced by the long average duration of depressive symptoms; that is, patients of our cohort have cumulatively suffered more than 4 years from depressive symptoms. A second major reason might be the early onset of depression during adolescence; thus, our participating patients may live in a disadvantageous environment or even have experienced an adverse life event; hence, epigenetic factors might play a role and might limit treatment success (2, 39, 40).

Depressive symptoms abated from an initially moderate to severe to a lower moderate level over the 12 weeks of ICBT with or without additional face-to-face outpatient psychotherapy. The follow-up period of 6 months revealed a further decrease of depressive symptoms in patients having additional face-to-face outpatient psychotherapy, whereas those patients without significantly deteriorated—albeit patients of both groups remained moderate depressive over the period of 6 months. Therefore, additional face-to-face psychotherapy is strongly recommended for improved long-term results. However, our results emphasize the need for more intense and better therapies including physical activities, environmental approaches, and pharmacotherapy for chronic depressive patients amenable to online therapies as overall results are quite disappointing.

Cognitive Behavioral Therapy and Depression

Cognitive behavioral therapy is the most widely available and best evident psychotherapy to treat patients with depression (2, 41). Yet, approximately half of patients do not have access to treatment because of unawareness of the disease, lacking capacities of psychotherapists, or the persisting stigma of mental health disorders (10, 12–14). Thus, a large body of internet-based therapies is available. Previous studies recommend ICBT to improve mild to moderate depression, but treatment success merely persisted over a short period of time; namely, from 6 to 24 months after the ICBT, no group differences were obvious when compared to an active control condition (42). This previous reported unsatisfactory long-term effect of ICBT is well in line with our current results. Therefore, we suggest that future studies need to evaluate patients' behavioral and environmental long-term changes and the effort and time invested in the online treatment after structured and guided ICBT is applied. Why the effect of ICBT remained relatively small in our cohort cannot fully be explained. Nevertheless, the usually rapid effect of ICBT can be hampered by personality disorders (21, 42). As our patient cohort experienced first depressive episodes during adolescence with a high probability of chronic depression, it is possible that at least part of the cohort suffers from a personality disorder with negative impact on outcome. One major problem in treatment of mental disorders is the patient's individual engagement as up to one-third of patients discontinue treatment, and of those who entered continuation phase, 40% break off (13, 20, 43).

Limitations

There are several limitations of our study that warrant discussion. First, data on previous and current therapies including pharmacotherapy were not available or incomplete (43), which limits the interpretability and the discussion of our results. Second, details on the additional face-to-face outpatient psychotherapy including the total amount of treatment hours, the therapeutic focus, and the patient's individual capabilities to change maladaptive behaviors or detrimental cognitive beliefs were incomplete or not assessed. These factors need future considerations not only because patients with depression having received twice-weekly compared to once-weekly psychotherapy are suggested to have an improved outcome (44), but also to better anticipate the face-to-face psychotherapeutic effect beyond its frequency. Third, data on the total time spent on face-to-face or ICBT treatment during the treatment and follow-up period are incomplete, a weakness that is known from the literature and needs to be assessed in future studies (45). Fourth, loss to follow-up was quite high, although representing the common and well-known problem of depressive patients' motivation and engagement for treatment continuum (43, 44). Fifth, we did not analyze a control group without any treatment or included a waiting group; therefore, it cannot fully be excluded that time influenced at least part of the patient's improvement (41). However, there is evidence that ICBT is superior over control groups and is not only an alternative to watchful waiting (46, 47). Furthermore, application of ICBT is superior to waiting-list groups with a moderate evidence level (GRADE moderate) (22), and guided ICBT can be as effective as face-to-face CBT (48). Sixth, we did not assess environmental factors that might interfere with treatment effects and need to be included in future studies.

Future Perspectives

Digital health is rapidly nascent, and a variety of future perspectives need considerations. First, the most important direction that needs to be tackled is the use of (i) chatbots using artificial intelligence and machine learning rather than decision trees, (ii) embodied conversational avatars, or even (iii) hackathons that have the potential to increase patients' therapy adherence, responsiveness, beneficial behavioral patterns, and social interactions to overcome depression and to pave the way to personalized medicine in mental health (49–57). Second, objective outcome measurements are important to emphasize the beneficial effect of online therapy trials using neuroimaging, e.g., diffusion tensor imaging and functional magnetic resonance imaging, which can help to elucidate microstructural changes in the white matter tracts of the interhemispheric and frontal-subcortical neural circuits that are impaired in depression (58), or to depict the striatal hypoactivation of the reward neuronal network within unipolar depression when anticipating and consuming rewards (59), or epigenetic and modifiable factors, e.g., the dense DNA methylation status of the glucocorticoid receptor gene (NR3C1), which is associated with early life stress and disposes to major depression disorder (60). Third, environmental factors such as previous and current negative life conditions, marital status, manifestation, and duration of dysfunctional beliefs might play a role for therapy adherence in ICBT (61); thus, we advocate to include besides emerging digital strategies and objective measures more environmental factors in future studies.

CONCLUSION

During ICBT, QoL and depressive symptoms improved in patients suffering from moderate to severe depression. At 6 months' follow-up, patients having received ICBT and additional face-to-face outpatient psychotherapy were able to stabilize their improved QoL in contrast to diminished QoL in patients with sole ICBT and reported significantly reduced depressive symptoms at the lower border of moderate severity, compared to slight deterioration of the ICBT patients. These results suggest additional face-to-face outpatient psychotherapy may help stabilize outcome over time, and structured and guided ICBT supports patients having limited access to face-to-face psychotherapy and/or being afraid of psychiatry-related stigma. For long-time effects, the continuous treatment of structured and guided ICBT and/or additional face-to-face psychotherapy is recommended.

DATA AVAILABILITY STATEMENT

All relevant data for this study are included in the article. The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation, to any qualified researcher.

ETHICS STATEMENT

The study was approved by the local ethics committee of the Canton of Zurich in Switzerland (KEK-ZH-Nr. 2013-0542). The participants provided their electronic informed consent prior to participation in this study.

AUTHOR CONTRIBUTIONS

SW conceptualized, initiated, designed, and supervised the entire study. KR conceptualized the data analysis, supervised the statistical data analysis, gave important, intellectual content, interpreted the data, wrote the abstract for the pre-submission, wrote the manuscript, and illustrated graphs and tables. SV revised the manuscript and gave important, intellectual content. AE performed the statistical analysis, revised the final manuscript. EB revised the manuscript and gave important, intellectual content in terms of sex- and gender related aspects. AD helped to initiate and design the study, revised the final manuscript. MR helped to initiate and design the study, revised the final manuscript and gave important intellectual content. All authors approved the final version of the manuscript and agreed to be accountable for the content of the work.

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Management of Patients With Inflammatory Rheumatic Diseases: Telemedicine and Rheumatologists Challenged in the Era of COVID-19

*Rosario Foti, Giorgio Amato, Roberta Foti and Elisa Visalli**

Rheumatology Unit, San Marco Hospital Policlinico, University of Catania, Catania, Italy

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****Correspondence:***
Elisa Visalli
elivisa21@gmail.com

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INTRODUCTION

In March 2020, a new disease called COVID-19 caused by a novel member of the Coronaviridae family named SARS-CoV-2 (severe acute respiratory coronavirus 2 syndrome) was declared pandemic (1).

In this context, the management of patients with immune-rheumatic diseases is absolutely crucial. These conditions share treatments with immunosuppressive agents such as corticosteroids and synthetic or biological disease-modifying drugs (2, 3), but despite a slight increase in infections is documented, unjustified discontinuation of immunosuppressants in rheumatic disorders is not recommended (4). Discontinuation of therapy may lead to disease flares (2) with systemic inflammation and immunological disruption that can potentially increase susceptibility to infections in rheumatic diseases (5). Therefore, a medical reassessment could be necessary, and it may further increase the patient's infectious risk due to moving around and being in the hospital.

In response to these needs, profound changes have been introduced in our organization (6), and telemedicine could play an important role in public health emergencies (7). Telemedicine is the remote delivery of healthcare services and clinical practices through medical data transmission via information and communication technologies. Furthermore, it has been proved useful to a remarkable increase in published randomized controlled trials and, consequently, to an improved quality of available data (8).

It can represent an additional and potentially suitable tool for follow-up monitoring of patients especially during the pandemic lockdown, and through it, we were able to ensure continuity of specific treatments for the management of inflammatory pathologies by identifying urgent remote situations, such as an infectious complication or a serious onset of the disease that requires physical consultation (8, 9).

CHANGES TO PRACTICE DURING THE PANDEMIC

From March 11, 2020, all patients affected by rheumatic diseases and treated with biological disease-modifying drugs afferent to Rheumatology Unit of Policlinico S. Marco in Catania were contacted.

The synchronous telemedicine application is meant to offer a virtual alternative to the in-person rheumatologist's visit, and it requires a live interaction between health professionals and patients; this activity has been provided by telephone follow-up visits and by fax and e-mail usage in order to send reports to the patient. Technological improvements, combined with the high-speed internet and the massive spread of smartphones, enable the possibility to apply this framework and quickly deploy video teleconsultations from a patient's home.

Patients were called to evaluate the state of health and the presence of any adverse events; laboratory test reports, such as acute phase reactants (erythrocyte sedimentation rate and C-reactive protein), have been examined. All patients with symptoms of infection temporarily withdrew biological disease-modifying antirheumatic drugs (DMARDs) or traditional DMARDs at the time of symptoms onset. A nurse administered the clinimetric questionnaires assessment to evaluate the disease activity, the impact of rheumatic disease on the health status, and the presence of anxiety, depression, and fibromyalgia. In addition to disease activity and any adverse events, with particular regard to infectious events, the assessment of the psychological situation will be important. Indeed, COVID-19 has also a serious impact on mental health, and Huang and Zhao (10) demonstrated a significantly higher incidence of anxiety disorders and depressive symptoms (DSs) especially in younger people. Depression and anxiety are frequently associated with fibromyalgia (11), which is one of the numerous comorbidities that may accompany inflammatory rheumatic with possible interference with symptomatology, disease activity and overall management plan (12).

In particular, the following scales, described in **Table 1**, have been used:

The Assessment of SpondyloArthritis international Society Health Index to describe the total impairments and restrictions due to axial spondyloarthritis and Bath Ankylosing Spondylitis Disease Activity Index to measure patient-reported disease activity for patients with spondyloarthritis (13, 14).

For patients with rheumatoid arthritis (RA), the following evaluations have been used: the Rheumatoid Arthritis Impact of Disease, a patient-reported outcome measure evaluating the impact of RA on patient quality of life (15); the Clinical ARthritis Activity (PRO-CLARA), a short and easy self-administered index that combines three items on patient's physical function and self-administered tender joints count (TJC) and patient global assessment (PGA) into a single measure of disease activity (16). For patients with psoriatic arthritis, The Psoriatic Arthritis Impact of Disease questionnaire with 12 domains of health, each based on a 0- to 10-point numerical rating scale and with a different weight (17), has been used. There is not a clinimetric index to evaluate physical function for psoriatic arthritis; therefore, we used self-administered TJC such as PRO-CLARA for RA for the part related to joint count.

The presence of DSs has been assessed using the beck's depression inventory (BDI)-II, a 21-item self-report instrument that measures the severity, mild to severe, over the last 2 weeks with threshold of 14, which is used in several studies to examine the prevalence of DSs (18, 19).

The STAI, state–anxiety scale, which consists of 20 items with response options based on a self-reported 4-point Likert scale, has been used regarding anxiety disorder. The state-anxiety score ranges from a minimum of 20 to a maximum of 80. A low score indicates no or little anxiety while a higher score indicates a higher level of anxiety (20–22).

The Fibromyalgia Rapid Screening Tool questionnaire is a brief, self-administered questionnaire made of six yes/no

TABLE 1 | Clinimetric questionnaires assessment.

	Diagnosis	Description	References
The Assessment of SpondyloArthritis international Society Health Index (ASAS HI)	Spondyloarthritis	Questionnaire to describe the total impairments and restrictions due to axial spondyloarthritis (axSpA)	(13)
Bath Ankylosing spondylitis disease activity index (BASDAI)	Spondyloarthritis	Short and easy self-administered index to measure patient-reported disease activity	(14)
Rheumatoid Arthritis Impact of Disease (RAID)	Rheumatoid arthritis	Patient-reported outcome measure evaluating the impact of rheumatoid arthritis (RA) on patient quality of life	(15)
Clinical ARthritis Activity (PROCLARA)	Rheumatoid arthritis	Short and easy self-administered index that combines three items on patient's physical function and self-administered TJC and PGA into a single measure of disease activity	(16)
The Psoriatic arthritis impact of disease (PsAID)	Psoriatic arthritis,	Questionnaire with 12 domains of health, each based on a 0–10 numerical rating scale (NRS) and with a different weight	(17)
Beck's Depression Inventory (BDI-II)	Depressive symptoms	A 21- item self-report instrument that measures the severity, mild to severe, over the last 2 weeks with threshold of 14 which is used in several studies to examine the prevalence of DS	(18, 19)
Fibromyalgia Rapid Screening Tool	Fibromyalgia	Self-administered questionnaire made of six "yes/no" questions for detecting fibromyalgia	(23)
State-Trait Anxiety Inventory (STAI)	Anxiety disorder	Questionnaire consists of 20 items with response options based on a self-reported 4-point Likert scale has been used regarding anxiety disorder. The state anxiety score ranges from a minimum of 20 to a maximum of 80. A low score indicates no or little anxiety while a higher score indicates a higher level of anxiety	(20–22)
VAS pain	Pain	A numeric visual analog scale (VAS) to evaluate the intensity of the perceived pain	(24)

questions for detecting fibromyalgia that has demonstrated high sensitivity and specificity among patients with chronic diffuse pain conditions and has been used in this study (23).

The visual analog scale for the assessment of pain (24) has been used for measurement of pain perception. Comorbidities may have an important impact on the health status of our patients; therefore, we used the Charlson comorbidity index to evaluate this important aspect as well (25).

We are working on the correlation of the results obtained to have more information that can guide us to a correct clinical evaluation because questionnaires assess different aspects and could provide us an additional element in our diagnostic evaluation (flare disease or fibromyalgia) and affect the therapeutic choices.

DISCUSSION

As being in the Rheumatology Department, we have switched ∼80% of outpatient appointments to synchronous telemedicine. This has worked surprisingly well, and patients have been very understanding. Outpatient clinic face-to-face consultations are limited to urgent patients. Patient management through telemedicine has allowed us to carry out a remote assessment of the state of health and of the psychological implications that the changes related to the pandemic from COVID-19 have been determined in our patients without exposing them to an increased infectious risk. Regarding the day-hospital patients, intravenous treatment was postponed if patient condition allowed it; however, treatments were maintained during COVID-19 pandemic. Regarding rituximab treatment, we know that this therapy induces B-cell depletion, and it reduces the immunogenicity of several vaccines; similarly, the immunological memory following SARS-CoV-2 infection will probably be impaired by this biologic, making patients sensitive to a reinfection (26). In this case, there is not an unequivocal strategy to be suggested; instead, it is an individual strategy, considering that these drugs can often be lifesaving. The usage of subcutaneous administration could be suggested when the same mechanism of the drug is available, with a limited risk for the patients mainly in terms of possible loss of efficacy. Human contact in the care of patients and face-to-face questioning and physical examination are important for a careful analysis of the clinical situation, perhaps for acceptance of care and for ensuring good compliance as well (9). Most aspects of rheumatology practice have changed since the onset of the COVID-19 pandemic, and new modes of care delivery may reshape practices and help with workforce shortages and asymmetric distribution of providers; furthermore, our challenge will also be to get information about the effect of rheumatic disease therapies on dysregulated inflammatory responses that may be associated with the morbidity and mortality that are seen with COVID-19. Even though the evidence for a superior or equal effectiveness of telemedicine compared to the standard face-to-face approach was weakened preventing to draw definitive conclusions, we continue to work modifying our approach to try to ensure the necessary care while respecting safety, and optimistically, this tool will become an important part of management in rheumatic diseases.

AUTHOR CONTRIBUTIONS

All Authors contributed to the writing of the manuscript.

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Ready for Prime Time? Using Normalization Process Theory to Evaluate Implementation Success of Personal Health Records Designed for Decision Making

*Selena Davis**

Health Information Science, University Victoria, Victoria, BC, Canada

Personal health records designed for shared decision making (SDM) have the potential to engage patients and provide opportunities for positive health outcomes. Given the limited number of published interventions that become normal practice, this preimplementation evaluation of an integrated SDM personal health record system (e-PHR) was underpinned by Normalization Process Theory (NPT). The theory provides a framework to analyze cognitive and behavioral mechanisms known to influence implementation success. A mixed-methods investigation was utilized to explain the work required to implement e-PHR and its potential to integrate into practice. Patients, care providers, and electronic health record (EHR) and clinical leaders ($n = 27$) offered a rich explanation of the implementation work. Reliability tests of the NPT-based instrument negated the use of scores for two of the four mechanisms. Participants indicated that e-PHR made sense as explained by two qualitative themes: game-changing technology and sensibility of change. Participants appraised e-PHR as explained by two themes: reflecting on value and monitoring and adapting. The combined qualitative and quantitative results for the other two NPT mechanisms corroborated. Participants strongly agreed (score = 4.6/5) with processes requiring an investment in commitment, explained by two themes: sharing ownership of the work and enabling involvement. Weak agreement (score = 3.6/5) was observed with processes requiring an investment in effort, explained by one theme: uncovering the challenge of building collective action, and three subthemes: assessing fit, adapting to change together, and investing in the change. Finally, participants strongly agreed (score = 4.5/5) that e-PHR would positively affect engagement in self-management decision-making in two themes: care is efficient, and care is patient-centered. Overall, successful integration of e-PHR will only be attained when systemic effort is invested to enact it. Additional investigation is needed to explore the collective action gaps to inform priorities and approaches for future implementation success. This research has implications for patients, care providers, EHR vendors, and the healthcare system for improving the effectiveness and efficiency of patient-centric services. Findings confirm the usefulness of NPT for planning and understanding implementation success of PHRs.

Keywords: personal health records, shared decision making, self-management, patient-centric services, implementation science, normalization process theory, eHealth, mixed methods

Edited by:
Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Maria Vittoria Bulgheroni,
Ab.Acus, Italy
Åsa Cajander,
Uppsala University, Sweden

***Correspondence:**
Selena Davis
daviss@uvic.ca

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INTRODUCTION

Healthcare systems and clinician practices are actively seeking health information technologies (HITs) that engage patients in decision-making as part of health self-management (1). One patient-facing HIT is the personal health record (PHR). PHRs are electronic health records (EHRs) controlled, shared, and maintained by patients to support patient-centered care (2). For optimal engagement, PHRs offer patients:

(a) access to their health information, such as results, clinical notes, and self-management information such as standard forms, educational materials, and protocol information in a linked or embedded knowledge base;
(b) the ability to contribute patient-generated data to their health record, such as subjective experience data and objective data related to their condition over time;
(c) health management and decision support tools, such as disease-tracking tools, goal setting, decision aids, and evidence-based reminders and alerts; and
(d) the means to communicate with their care providers and community support groups using mechanisms such as secure messaging and video tools (3).

These PHR characteristics were also identified as components leading to improved health outcomes for patients in a systematic review ($n = 23$), which examined conditions potentially sensitive to the PHR (4). Patients' experiences with accessing their PHR are often positive and offer feelings of empowerment and engagement (5). Further, use of a PHR improves communications, partnership with care providers, and a sense of self-management (6). But PHRs have not seen widespread adoption or impact, often a result of lacking system functionalities (typically only simple messaging, viewing results, and appointment scheduling) or limiting architecture [architected as standalone or tethered to a specific provider EHR (7, 8)], as well as lack of provider acceptance (9). Designed for function and cohesive with the broader digital health ecosystem, PHRs present an opportunity for improvement in patient engagement in self-management and decision-making.

Shared decision making (SDM) between a patient and care provider is a collaborative process resulting in a treatment decision and care plan at a specific point in time that combines the best available evidence and patient values and preferences (10). The process of SDM is modeled, based on the work of several authors (11–13), to include four core elements: (a) awareness that a decision is needed, and choice exists—acknowledge; (b) receive and interpret options, including benefits and risks—consider; (c) explore preferences, values, and goals and incorporate them into the making of the decision—decide; and (d) record the decision and track outcomes—act. The fourth SDM element, act, adapts and extends the SDM model identified by Elwyn et al. (11), to make explicit the recording of the shared decision in the patient care plan with follow-up to ensure the treatment decision respects patient preferences and to track outcomes of the decision. SDM is neither about convincing the patient to follow a care provider's recommendation nor about leaving a patient to decide on her/his own (14). When patients are more informed and empowered and participate with their care providers in making treatment decisions, they have better health outcomes (15). SDM is fundamental to patient-centered care, increases patients' and providers' satisfaction, improves quality of life, and fosters a better patient–provider relationship (16), yet it has been difficult to implement into clinical practice (13). PHRs are a promising technology for overcoming barriers for integrating SDM (7, 17).

To successfully implement a PHR designed to enable SDM, a preimplementation evaluation is useful (18) since the literature provides little guidance on the complex process of integrating PHRs (19). For PHR implementation success, patients and providers must interact differently by reorienting treatment, management, and decisions around data transparency and patient access; providers must make use of patient-reported data and patient preferences in combination with medical evidence using a collaborative care team approach; and communication options must be enhanced using integrated HIT tools. The number of implemented sociotechnical interventions that become "normalized" is limited, i.e., fits in with the routine work of individuals and the context of practice and no longer requires additional effort (20). Normalization Process Theory (NPT) seeks to understand the cognitive and behavioral work people do, individually and collectively, to integrate a complex intervention in its social context (21). NPT holds the view that many interventions implemented in healthcare settings are subject to a complex interplay between features of the intervention itself, the actions of individuals involved in the process, and aspects of the physical and social environment in which the implementation activities are undertaken (21). There is a considerable and growing body of research that supports NPT as a useful theory for explaining processes of normalization of practices associated with complex health interventions (21–25). More recently, NPT has effectively been used to aid implementation planning (21). Its applicability to the different stages of system design life cycle and its valuable set of conceptual tools for the understanding of implementation as a dynamic process make it appealing.

For this research, NPT provides an analytic framework to explain the work of care providers and patients to integrate PHR technology designed to enable SDM (e-PHR) and to indicate the level of agreement of a successful future implementation. NPT provides four sets of mechanisms that characterize different kinds of "normalization work," and each requires particular kinds of contributions from individuals and organizations that promote or inhibit successful implementation; these are (a) coherence—processes driven by contributions of meaning; (b) cognitive participation—processes driven by contributions of commitment; (c) collective action—processes driven by contributions of effort; and (d) reflexive monitoring—processes driven by contributions in appraisal (21). The research objectives were to describe (i) the work that patients and providers do, individually and collectively, to integrate e-PHR; and (ii) the potential for e-PHR to integrate into clinical practice to engage patients in self-management decision-making. This work builds on a prior user-centered design study ($n = 22$) in which the PHR functionality required to support the four core elements of the

SDM process (e-PHR) was substantiated by patients and care providers (26).

MATERIALS AND METHODS

This mixed-methods descriptive study was conducted between January and April 2018 within community care and complementing community-level services in British Columbia, Canada. The three study groups were patients (young adults with type 1 diabetes, 18–24 years of age), healthcare providers (physicians, dietitians, and nurses), and organizational providers responsible for the design, development, implementation, or management of EHR systems (government HIT leaders/clinical directors). Recruitment strategies comprised posters, social media, direct e-mail of clinics from publicly available lists, and snowball recruitment. Purposeful and convenience sampling was used, and sample size within each study group was guided by the principle of saturation and determined when the research obtained and interpreted sufficient data to reasonably understand the phenomena. The study received ethical approval from University of Victoria (protocol no. BC17-058).

This mixed-methods investigation utilized a triangulation convergence study design, i.e., concurrently collected and equally weighted quantitative measurement instrument and practice-related outcomes survey data and qualitative semistructured individual interview data. Underpinned by NPT, the investigative approach offered a deeper level of understanding and explanation about the integration of e-PHR into clinical practice and gave a voice to the multiple participant study groups.

e-PHR

In the user-entered design study by Davis and MacKay (26), the resultant e-PHR encompassed four central PHR functionality containing 23 specific PHR functions for the enablement of SDM. According to the study (26), to enable the SDM elements *acknowledge* and *consider*, PHR functionality *receive decision-support* comprised functions such as "receive intelligent alerts," "receive personalized decision support resources," and "elicit preference in context of a treatment decision." To enable the SDM element *decide*, PHR functionality *access health information* and *communicate with others* comprised functions such as "review provider clinical notes and annotated data in provider EHR" and "participate in a virtual consultation with provider." To enable the SDM element act, PHR functionality *record health information* comprised functions such as "coauthor care plan."

e-PHR was described by participants in the prior study (26) as one that should be architected as an interconnected PHR; i.e., it gathers and autopopulates patient data from multiple health information systems and applications. **Figure 1** illustrates the ecosystem for e-PHR, contextualized from the perspective of a patient with diabetes and simplified in terms of integration with the overarching electronic healthcare information systems, including the connectivity of interfaces, devices, and applications required by patients to self-manage their health. This figure was provided to participants in this study as part of an online video prior to data collection.

Guiding Theoretical Framework

NPT provides a framework to analyze four process mechanisms and their related constructs known to influence implementation success (**Figure 2**). Coherence is the sense-making work that people do individually and collectively when they are faced with the problem of operationalizing e-PHR. Cognitive participation is the relational and commitment work that individuals in teams do as they anticipate roles and tasks to accomplish new ways of doing things with e-PHR. Collective action is the operational or effort-type work needed to enact e-PHR. Reflexive monitoring is the appraisal work that people do to assess and understand the ways that e-PHR affects them and others around them.

Data Collection

At the beginning of the participant's scheduled virtual meeting, the researcher recapped the study details, and consent was affirmed and audio recorded. Then, the participant received an e-mail with a PDF of the user-validated functional model for e-PHR (**Supplementary Material 1**) and a link to an online, 3-min video (https://youtu.be/mV2koq1KN58) that was created to provide participants with more details and context of e-PHR.

The quantitative data were gathered by both a measurement instrument and survey. The new and first quantitative measurement instrument of NPT, the Normalization MeAsure Development (NoMAD), was used (**Supplementary Material 2**) (27). The NoMAD comprises 20 NPT constructs, separated into groups representing the four NPT mechanisms (coherence, cognitive participation, collective action, and reflexive monitoring) with items rated on a 5-point Likert scale. The NoMAD was administered to describe the level of agreement of patients, care providers, and organizational leaders with statements of the four NPT mechanisms and their related constructs known to influence the integration of an intervention. For example, frequent "strongly agree" responses (Likert scores = 5) indicate the intervention "makes sense" to participants (coherence) or that specific aspects of effort (collective action) appear low, given the frequency of "strongly disagree" responses (Likert scores = 1). While NoMAD has been identified as a robust instrument for use in quantitative investigations (21), at the initiation of this study, full psychometric testing had not been completed, so basic psychometric evaluation was included as part of this study. Utilizing the same five-point Likert scale as the measurement instrument, a small fixed survey of practice-related outcomes (**Supplementary Material 3**) scored the level of agreement with potential outcomes such as engagement in self-management decision-making, easier to participate in SDM, and e-PHR system would normalize in clinical practice. Online self-management interventions have demonstrated increased patient engagement, an important factor in helping patients to manage their health (28). As such, this research was interested in the potential for engagement as an outcome. Both the instrument and survey were delivered online to participants via SimpleSurvey (29) and a link provided in an email.

Once the instrument and survey were submitted, the phone interview commenced for the collection of qualitative data. The semistructured interview conducted by the researcher (S.D.)

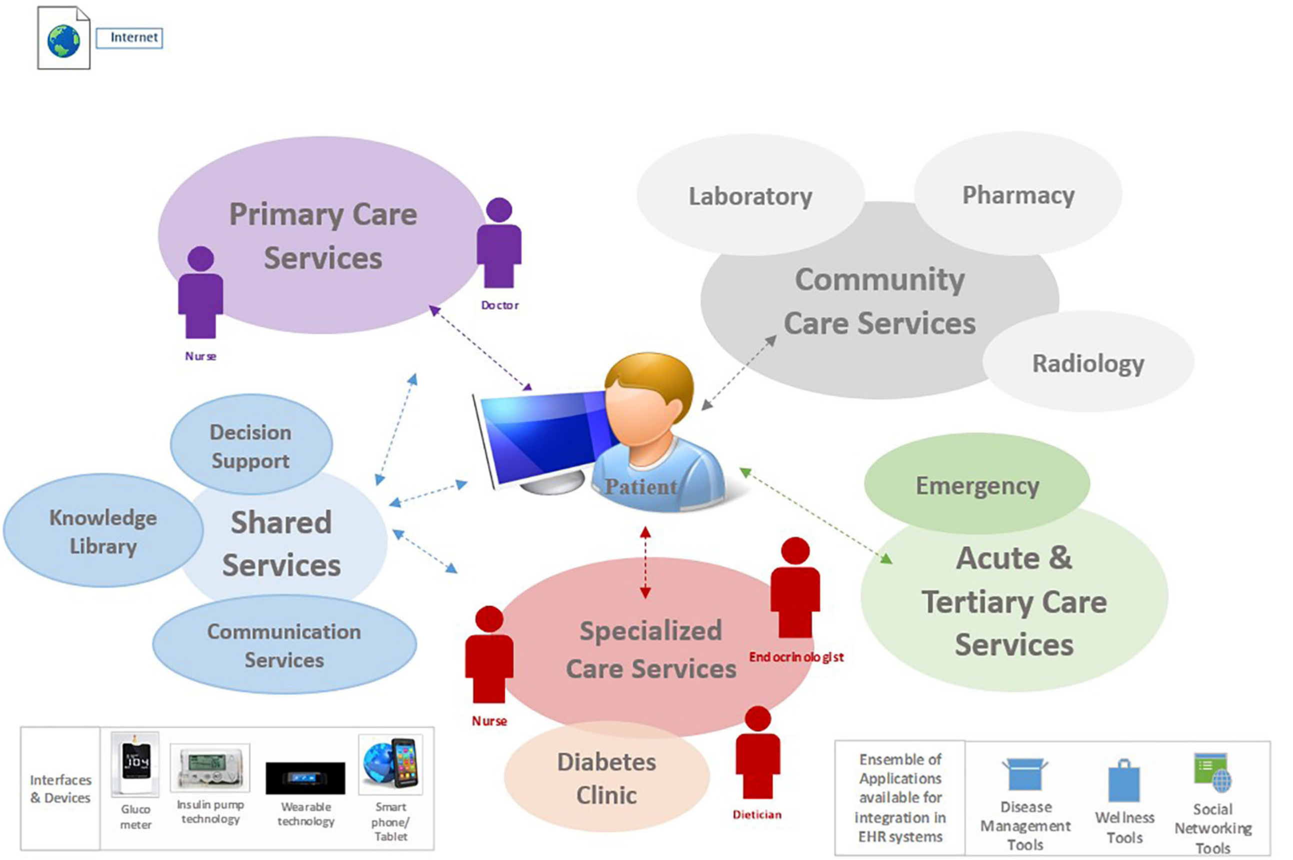

FIGURE 1 | e-PHR ecosystem.

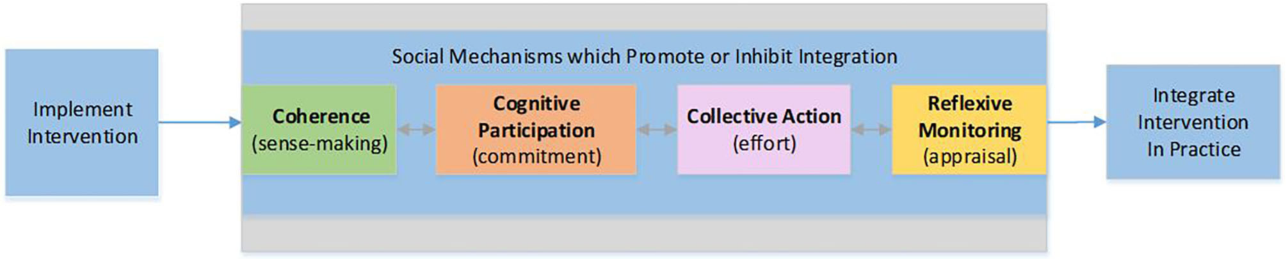

FIGURE 2 | Normalization Process Theory framework.

followed an interview guide (**Supplementary Material 4**) and was structured using the four process mechanisms of NPT to describe the work of integrating e-PHR into clinical practice (**Table 1**).

The concurrently gathered qualitative and quantitative data were collected to thematic saturation. Once six participants' data were collected within a study group, the data were analyzed concurrently with the collection of data from each additional participant within a study group so that thematic saturation could become known and as such recruitment ended.

Data Analysis

Demographic characteristics of the participants were described using Excel for simple descriptive statistics. NoMAD instrument and survey data were analyzed using R statistical software (30) for descriptive statistics including mean scores. Psychometric tests of the NoMAD instrument were conducted to examine the reliability and validity attributes of the instrument within the context of this study. Cronbach α testing was conducted on all four NPT mechanisms to measure the reliability or internal consistency of their constructs.

TABLE 1 | Interview questions aligned with NPT.

Interview question	NPT mechanism
How would you describe the e-PHR and is it distinct from your current practice?	Coherence
Does it have a clear purpose for patients and providers?	
Do you believe patients and providers will see the value and importance of e-PHR?	
Are the benefits likely to be valued by potential users?	
Do you believe it is right to engage in the use of the e-PHR?	Cognitive participation
Are the users likely to think it is a good idea?	
Will users be prepared to invest time, energy, and work into the use of the e-PHR?	
Do you think users can sustain involvement in the use of the system?	
Does e-PHR fit with existing skill sets and work practices?	Collective action
Will the system be supported and resourced?	
Do you think users will have confidence in the system?	
Will the e-PHR make people's work easier?	
What would you say about the likely effects on patients or healthcare providers and their work environment?	Reflexive monitoring
Are the effects likely to be perceived as advantageous for them?	
Will it be clear what effects the intervention has had once it has been in use for a while?	

TABLE 2 | Characteristics of study participants.

Characteristic		Patients	Care providers	Organizational providers
Age	Mean (years)	20.25	—	—
	Median (years)	20	—	—
Sex	Female	7	6	3
	Male	1	5	5
Geographic location	urban	5	6	7
	rural	3	5	1
Time in clinical practice (years)	1–4	—	2	—
	5–10	—	3	—
	11+	—	6	—
Working with EHR systems (years)	1–4	—	3	—
	5–10	—	5	3
	11+	—	3	5
Use of information and communications technologies	Advanced	6	2	5
	Average	2	9	3
	Basic	—	—	—
	Non-user	—	—	—

Interview data were transcribed and imported into Atlas.ti (31). Using coding as a heuristic discovery process (32), data were coded by the researcher (S.D.) for evidence of the constructs of NPT via a deductive qualitative approach. Concept coding was applied to the transcripts as the first cycle coding method. The second cycle coding method employed axial coding, essentially to identify dominant codes from the process of first cycle coding and to reorganize the data set such that the best representative codes were selected to form an emergent category. Lastly, comparing category to category and their related codes and data allowed themes to emerge. Throughout the complete analytic process, memo writing was used to capture the researcher's reflections on coding processes, code choices, any data that fell outside of the coding frame, and arising patterns in the data. Finally, emergent descriptive themes were identified, along with quotations of the participants that best illustrated the themes.

Consistent with the study design, the analyzed quantitative, and qualitative data were amalgamated to present results during the interpretation. That is, the analyzed data from the instrument, survey, and interviews were merged to a unified whole as a joint display framed by NPT for the purposes of complementarity in outcome interpretation and description.

RESULTS

Participant Demographics

Twenty-seven participants in British Columbia, Canada, participated, including patients ($n = 8$), care providers ($n = 11$), and organizational providers ($n = 8$). The median age of patients was 20 years. Of the care providers, four were endocrinologists, two were family practice physicians, two were dietitians, and three were nurses. Of the eight organizational leaders who participated, six were government HIT leaders including chief medical information officers, chief information officers, and directors of information management/information technology (IT), whereas the remaining two were clinical directors. All considered themselves average or advanced in use of ITs. Characteristics of the participants are summarized in **Table 2**.

Psychometrics of NPT-Based Measurement Instrument, NoMAD

Cronbach α test was used to measure the extent to which all constructs of an NPT mechanism measured the same concept. In this study, tests of internal consistency varied in terms of supporting the use of these items either as an overall measure of "normalization" (20 items, $\alpha = 0.60$) or as four NPT mechanism measures (ranging from $\alpha = 0.33$–0.80) (**Table 3**). Because of reliability issues identified in this study with the NoMAD instrument, the overall normalization score and the scores for two of the four NPT mechanisms, coherence and reflexive monitoring, were not used in further analysis as originally planned.

Normalization of e-PHR in Clinical Practice—An Integrated Summary

The integrated summary was arranged by NPT mechanism. The quantitative results offered descriptive statistics and indicated a direction of agreement with measures of

TABLE 3 | Reliability of NPT mechanisms.

	Coherence	Cognitive participation	Collective action	Reflexive monitoring	Overall normalization
Cronbach α	0.33	0.8	0.8	0.55	0.60

TABLE 4 | Combined qualitative and quantitative results for coherence by study group.

NPT	Descriptive themes	Exemplar quotes			Mean score* ± SD
		Org providers	Care providers	Patients	
Coherence	Converging views of meaning—a game-changing technology	"This is fundamental to where we need to go with healthcare. I see it as an enabling mechanism to put the ownership of a person's care more in their court, to shift the paradigm we have in our system from a didactic provider-dominated healthcare service to one that is truly person-centered"	"It challenges and pushes providers to be more patient-oriented and to have the conversation with patients about what is important to them vs. what's important to us as providers, which is often different"	"The shared decision making would kind of improve the relationship or make a deeper relationship between patients and their doctors. The technology is the conduit"	—
	Sensibility of change	"The important piece is, when a patient wishes to engage in this way and we have that option as a system to provide that [e-PHR] to them, there must be a shared understanding of what that means"	"Once we involve our patients, it is likely that we will have a better chance to have more compliant patients and better outcomes too, like less [disease] complications"	"So, I'll see the nurse and the dietitian and then my endocrinologist separately. I have to explain what's going on three different times before I can even start asking my questions. I think them having the whole story before I even go in would be really helpful"	

normalization. The qualitative results used descriptive themes to provide a rich explanation of the findings using the participants' voices.

Coherence: Meaning and Sense-Making Work of Integrating e-PHR

Qualitative results indicated that e-PHR made sense as explained by two themes for the coherence mechanism: a *game-changing technology* and *sensibility of change*. **Table 4** illustrates exemplar quotes by study group for each theme. Because of reliability issues identified in this study with the NoMAD instrument, the mean score for coherence was not used. To participants, e-PHR is a supportive approach to healthcare for patients and would formalize collaborative relationships, provide access to a comprehensive set of data, and offer timely and convenient communications. Participants made sense of e-PHR by noting its significant deviation from the current practice, requiring a shift in the culture of medicine and system policies, as well as a change in clinical workflow and business practices.

In general, while patients appeared less preoccupied with issues of this nature, care providers and organizational providers expressed openness to the required shifts in medical practice. In the words of OrgProvider1, "This is fundamental to where we need to go with healthcare. I see it as an enabling mechanism to put the ownership of a person's care more in their court, to shift the paradigm we have in our system from a didactic provider-dominated healthcare service to one that is truly patient-centered." Participants understood the benefits of e-PHR as being a supportive approach for patients, an improvement in care efficiency, and a conceivable, positive impact on patient outcomes. The latter was most simply described by CareProvider3 as "Once we involve our patients, it is likely that we will have a better chance to have more compliant patients and better outcomes too, like less disease complications." The ability for a care provider to have a more comprehensive set of patient health details prior to an encounter was seen overall by participants as very beneficial. Patient4 described it as "So, I'll see the nurse and the dietitian and then my endocrinologist separately. I have to explain what's going on three different times before I can even start asking my questions. I think them having the whole story before I even go in would be really helpful." Shared access to patient health information and treatment strategies for integrated planning purposes was summed up by CareProvider4 as "When we don't know the details of what the other care providers on our team are doing, it makes it hard to make a cohesive shared plan." Meaning was also linked to concerns of workload and workflow, and a limited shared understanding of purpose. CareProvider8 highlighted that "patients' time to engage with the system may not match the systems' time to engage with them."

Cognitive Participation: Commitment and Engagement Work of Integrating e-PHR

There was very strong agreement by all participants across all four items related to the investment of commitment (overall mean score out of 5 was 4.6 ± 0.45) (**Table 5**). Participants felt they would be engaged with processes that promote participation individually and together. Interestingly, organizational providers' mean scores indicated the strongest levels of agreement across all items of this mechanism, revealing their assessment that care providers, and patients are up for the relational work needed to build and sustain a new practice around e-PHR. This was explained qualitatively by two themes: *sharing ownership of the work* and *enabling involvement*. **Table 6** illustrates exemplar quotes by study group for each theme and mean score.

To participants, e-PHR is the right direction for healthcare. Commitment to e-PHR was demonstrated through a shared interest in the collaborative, relationship-based focus of care. Patient7 explained that e-PHR would be "strengthening the relationship between me and my healthcare provider. They have to be a little more involved in my life, and I have to be clearer in my communications with them." Participants expressed openness to new ways of working individually and together, as well as some fear of change and lack of systemic ownership of the change. Participants wanted to know that implementing e-PHR would have the right resources and supports in place to enable and sustain involvement. At the individual level, that involved upskilling such as education and training. At the clinic level, that required an examination of current processes for fit and the identification of additional resources and supports required to enable involvement. At the system level, the alignment of business drivers, such as the care provider funding model, was identified as fundamental. CareProvider7 highlighted, "In a fee-for-service environment, I am going to be relatively disinterested in this because I can't get paid for using it. In the value-based funding, I am going to be all over this because it allows me to maintain a high level of wellness in my population." This was further demonstrated by CareProvider6 as "If the higher ups support e-PHR, they must provide the protected time and the resources and the infrastructure that's needed. The biggest issue with our healthcare system is these kinds of things become available, and they are implemented without any thought to the additional resources or training or time that is necessary to do that well."

TABLE 5 | Cognitive participation and collective action scores by study group.

	N	Cognitive participation score* ± SD	Collective action score* ± SD
Patients	8	4.4 ± 0.52	3.9 ± 0.33
Care providers	11	4.5 ± 0.39	3.4 ± 0.58
Organizational providers	8	4.9 ± 0.19	3.2 ± 0.44
Overall	27	4.6 ± 0.45	3.6 ± 0.53

**1, strongly disagree; 5 = strongly agree.*

TABLE 6 | Combined qualitative and quantitative results for cognitive participation by study group.

NPT	Descriptive themes	Exemplar quotes			Mean score* ± SD
		Org providers	Care providers	Patients	
Cognitive participation	Sharing ownership of the work	"From a health system perspective, I have the least faith because our system doesn't do new initiatives very well. We don't put in the right supports. We don't put in the right governance. We don't put in the right funding. We have too many things that need to happen. There are too many conflicting priorities. There's politics which get in and redirect this to short term wins. This isn't a short-term thing"	"e-PHR is a great idea, but I'm less confident about how this could happen. Well I guess we would have to see how that would be, what kind of impacts it would be like, what the workflow is like, what kind of supports there are to understand it, introduce it and develop it"	"Helping diabetes management and strengthening the relationship between me and my healthcare provider. They have to be a little more involved in my life and I have to be clearer in my communications with them"	4.6 ± 0.45
	Enabling involvement	"If patients are feeling better supported and safer and their health is improving in a way that they notice, as opposed to indicators that don't really mean much to them, then I think the system will become self-perpetuating."	"If the higher ups support e-PHR, they must provide protected time and the resources and the infrastructure that's needed" "I don't understand why you would stick to something when there's better opportunities"	"Anything that makes you feel like you are more on top of [disease management] and more in control is going to keep being used" "If you are seeing the benefit, then you would want to sustain it"	

**1, strongly disagree; 5, strongly agree.*

Collective Action: Effort Work of Integrating e-PHR

Weak agreement (overall mean score out of 5 was 3.6 ± 0.53) was observed with collective action processes requiring an investment in effort (**Table 5**). With some exceptions for patient participants, who had the highest level of agreement across all items of this mechanism, participants exhibited uncertainty about the work that operationalizes e-PHR. Both ambivalence and disagreement were observed in mean scores of organizational providers around a number of normalization processes that influence the mechanism of collective action, including (a) ease of incorporating the system into existing work, (b) disrupting working relationships, (c) confidence in other people's ability to use the system, (d) having sufficient resources available, and (e) adequate management support. Healthcare providers likewise neither agreed nor disagreed, as observed by their mean scores, about the ease of incorporating the system into existing work and about having the confidence in others' ability to use it, but their level of agreement with the other promoting processes of this mechanism was more positive.

This implementation mechanism was best explained qualitatively by one theme: *uncovering the challenge of building collective action*, and three subthemes: *assessing fit*, *adapting to change together*, and *investing in the change*. **Table 7** illustrates exemplar quotes by study group for each theme and mean score. The effort to enact e-PHR would require an upskilling of care providers, a shared accountability among patient and care providers, and sufficient leadership and financial investment as part of the shift in the culture of medicine to patient-centered care. e-PHR exists in an environment of transparency and shared responsibility. OrgProvider2 explained that "We have more work to do across the system for sure around truly enacting a patient-centered approach to care. If the culture of care does not reflect the e-PHR, it won't be well-supported or used." Participants agreed that patient accountability will increase, and overall a realignment of the care team and sharing of the various tasks will be required, including the task of care planning. OrgProvider3 noted that "the design of e-PHR might drive the redesign of the teams that provide care. It will put more onus on any member

TABLE 7 | Combined qualitative and quantitative results for collective action by study group.

NPT	Descriptive themes	Descriptive subthemes	Exemplar quotes			Mean score* ± SD
			Org providers	Care providers	Patients	
Collective action	Uncovering the challenges of building collective action	Assessing fit	"We have more work to do across the system around truly enacting a person-centered approach to care. If the culture of care does not reflect the SDM via PHR, it won't be well supported or used" "I don't believe we've done a good job of really digging deep into what [is required] to change the culture of care, really create and develop the skill set around that"	"We will be uncovering people with poor skills on doing the engagement that should have been happening all along without the tool. The tool will expose gaps that in turn might precipitate more anxieties on the part of the providers, because they are going to be asked to do stuff that we took for granted they should be doing all along"	"For young people, we grew up with technology, so for us it is a second language." "I don't think it would be that much of a change in effort [for patients]; we don't get to not be thinking about [our disease]. So, I think the only difference with this new technology is that it would be shared"	3.6 ± 0.53
		Investing in the change	"e-PHR is likely to be sponsored in theory but not resourced to the extent it needs to be"	"Seeing benefits and return on investment from those conversations and the collaborative decision making with their patients will bring the support"	"If we introduce the concept [to patients of disease management] being in your hands, not just your doctors at an earlier age that would be beneficial"	
		Adapting to change together	"We need to clarify the road map and to establish some amount of centralized control, but we don't want to stifle creativity. That is the complexity and the art of public policy"	"Patients automatically assume that you are checking lab work for them daily. But I don't necessarily have the time to be going through and making sure their HbA_{1c} is in target. So, I think figuring out where is the ownership?"	"It would be relinquishing some of the accountability from the providers' side over to the patient which they have not typically been accustomed to… and the different practitioners and teams, it would be moving everybody up I think to a more parallel playing field around roles and responsibilities"	

**1, strongly disagree; 5, strongly agree.*

of the care team to establish the care plan in collaboration with the patient because ultimately it is putting more ownership back to the patient around their care plan." Participants deemed that measuring and demonstrating benefit will foster an ongoing investment. If population-level improvements are demonstrated, the system will resource e-PHR. CareProvider3 shared that "seeing benefits and return on investment from the collaborative decision-making with their patients will bring the support."

Participants expressed an ambiguity toward the ability to adapt to change together; i.e., e-PHR may not easily integrate into existing work without a disruption to current relationships and processes and some lack of trust and confidence in others' ability to carry out tasks required to enact e-PHR. Shifting roles toward partnership was explained by Patient2 as "it would be relinquishing some of the accountability from the providers' side over to the patient which they have not typically been accustomed to… and the different practitioners and teams, it would be moving everybody up I think to a more parallel playing field around roles and responsibilities." In adapting to the change together and to satisfy the practical process issues of integrating this new paradigm into clinical practice, participants identified the importance of a top-down strategy and policies with embedded practical experience from on-the-ground clinical practice, yet there is an uncertainty about how well they will merge. Participants argued that the time is ripe to really get it right, citing the opportunities for efficiencies in the care approach are well-worth the realignment of workflow and business practice, but there was a lack of clarity around what those new business rules might be. CareProvider7 shared "Patients automatically assume that you are checking lab work… daily. But I don't have the time… So, figuring out where is the ownership?" Participants expressed that expectations need to be established that are respectful of care providers' workload yet drive patient engagement. CareProvider6 stated, "one concern I have is the pace of information transfer today and the expectation of response… Would that be disengaging for a patient to reach out and then have nobody answer until Monday morning?"

Reflexive Monitoring: Appraisal Work of Integrating e-PHR

Participants appraised e-PHR as explained by two themes for reflexive monitoring: *reflecting on value* and *monitoring and adapting*. **Table 8** illustrates exemplar quotes by study group for each theme. Because of reliability issues identified in this study with the NoMAD instrument, the mean score for reflexive monitoring was not used. To participants, e-PHR would nurture engagement and collaboration by removing barriers to care and increasing care efficiency and effectiveness, but outcomes must be measured and benefits demonstrated. CareProvider11 assessed the shift in the care approach as valuable because "by engaging patients in their care this way and providing them with this kind of empowerment and increasing frequency of contact, that would translate into better outcomes." Patients shared how the timeliness of connections would improve their experience of care. Patient8 described it in the following manner, "Instead of it being one little issue that turns to a big issue, you can fix them with your doctor as they show up." Participants perceived improvement in the effectiveness of care—specifically, the enabling of collaboration with an ease to communications and a more comprehensive picture of the patient's health. Participants argued that the integration of the care team online with access to a more complete patient profile and various communication mechanisms supports the patient in the day-to-day management of health. Patient6 offered, "Communication would be better and therefore probably be less risks at home because you'd be able to share information about the problem

TABLE 8 | Combined qualitative and quantitative results for reflexive monitoring by study group.

NPT	Descriptive themes	Exemplar quotes			Mean score* ± SD
		Org providers	Care providers	Patients	
Reflexive monitoring	Reflecting on value	"A more respectful engagement in care. Being more of a partner to [healthcare] service, being more respectful of the values and beliefs and recipients of the care"	"By engaging patients in their care this way and providing them with this kind of empowerment and increasing frequency of contact, that would translate into better outcomes"	"Instead of it being one little issue that turns to a big issue, you can kind of fight all these little battles at once and fix them with your doctor as they show up"	—
	Monitoring and adapting	"The effects will only be evident if we are purposeful about bringing that forward and measuring it"	"Patients share some results and ask me what I should do. How does that get remunerated? Do I have to do a billing interaction every time I have a 10-s interaction with the portal? …Those kind of implementation details will make a big difference"	"Communication would be better and therefore probably be less risks at home because you'd be able to share information about the problem and then solve the problem faster"	

1, strongly disagree; 5, strongly agree.

and then solve the problem faster instead of being like 'oh well my appointment is in 2 months so I'm going to fix it then.'" Getting clear about the effects of e-PHR came with an imperative from participants to measure and demonstrate outcomes on an ongoing basis and to monitor workload and adapt clinical practice accordingly. OrgProvider7 explained that the effects will only be evident if "we are purposeful about bringing that forward and measuring it."

Bridging Theme of Integrating e-PHR

One qualitative theme resulted that spanned all NPT mechanisms. This theme, *Really get it right!—United views of system usability, intelligence, and connectedness*, may be indicative that all four cognitive and behavioral processes that influence the integration of e-PHR into clinical practice are impacted by aspects of its ultimate design, which remain elusive to participants in this early design/preimplementation phase of e-PHR. Because these repeating ideas could not be connected to any one NPT mechanism, it was described and added to the integrated results as a bridging theme. This theme captured the repeating idea of really getting this technological innovation correct in terms of a usable, intelligent, and mobile design within a standard-based, federated, technical infrastructure.

When describing what would keep people motivated to continue taking part, the topic of usability of e-PHR was associated with an alignment to other current, intuitive, and acceptable ways of working, as argued by CareProvider2, "I can't stress enough that the program has to be user friendly in order for it to be accepted easily. I think that user-friendly would be that intuitive piece. You know, if you pick up an iPhone, it's quite intuitive, but if you picked up a different model, you really have to struggle your way along." Designing e-PHR with patient mobile access in mind was expressed by participants throughout. Patient4 explained when speaking about what makes the effects of e-PHR seem beneficial: "If nothing else, while we are moving around [geographically], you know that you are at least still connected to people that care about your health." The importance of system intelligence for e-PHR as it relates to managing and presenting the data and information and adaptive decision support was also highlighted across all normalizing mechanisms. Patients often and easily alluded to their need for a simple yet comprehensive dashboard to manage their health. The overall management of data and information by the system in terms of a usable presentation style and search functionality without increasing workload was often identified by care and organizational providers. As one example, CareProvider3 described how the value of e-PHR is judged, "I would just hope that with all the latest technology that's available they would be able to have it organized in a way that's easily searchable. So, if you were looking for their kidney function, you wouldn't have to traipse across all of the files." The significance of an intelligent system for a computer-tailored approach to clinical decision-support was described by some care and organizational providers. CareProvider4 stated, "Knowing all the decision support intelligence stuff, I think it would really help a lot of patients' needs to not even have to reach out to a care provider if some of that information was more readily in their hands with some intelligent decision support behind it—alerts, reminders, those types of things." Finally, the notion of an integrated ecosystem of EHR systems cannot be underestimated as participants often and, across all normalization mechanisms, described its relevance and importance. As one example, when speaking about what makes the effects of e-PHR seem beneficial, OrgProvider4 shared, "We need a standard-based infrastructure that these things can plug into. This environment gives you a space where multiple vendors can create new products, start-ups that can plug in; they don't have to build the entire stack, they can just build what they are specializing in and interact with the rest of the system."

Practice-Related Outcomes of Integrating e-PHR

Participants strongly agreed that e-PHR would positively affect engagement in self-management decision-making and agreed that it would become a normal part of work. The potential practice-related outcomes generated two descriptive themes: care is efficient, and care is patient-centered. The mean scores for the practice-related outcomes by study group and overall were calculated (**Table 9**). **Table 10** illustrates exemplar quotes by study group for each theme and mean scores. The practice-related outcome of normalization obtained general agreement (mean score = 3.9/5); however, the organizational providers expressed more ambivalence to this potential outcome (mean score = 3.2/5) compared to care providers (mean score = 4.1/5) and patients (mean score = 4.0/5). This outcome was described by participants as only likely if the required shift in the culture of medicine toward patient-centered, team-based care occurs. As OrgProvider2 noted, "the care approach has to marry and reflect that same philosophy and culture. If those two things are in place, I believe it will positively impact engagement."

There was strong agreement by all participants that e-PHR would positively affect engagement in self-management decision-making (mean score = 4.5/5), with 14 strongly agreeing, 12 agreeing, and one participant neutral. Participants perceived an increased efficiency of care and everyone being more informed. The efficiency of care appeared to arise from a level of convenience that is both desired and perceived as available with e-PHR in terms of access to and the provision of care. As Patient8 described, "If we had this system at our disposal to use and vocalize some of the concerns we have, rather than just thinking of them, we'd actually be acting on them, so I think it would have positive effects on being engaged in your own care." In terms of convenient access to care, CareProvider9 shared, "It just makes it way easier for patients to access care… and they don't have to be in town. They can be in Vancouver. They can be in Montreal. They can be wherever they want to be and still stay connected to their clinic."

According to the overall mean scores, all participants perceived e-PHR would make it easier to participate in SDM (mean score = 4.6/5) and to support patients in managing their own care (mean score = 4.4/5). From the patient perspective, it appeared as though access to information would empower them to participate in decision-making as expressed by Patient7: "It makes you feel more involved, like you have more of a voice in your own health, as weird as that sounds." Participants described

TABLE 9 | Mean practice-related outcomes scores by study group.

Practice-related outcome	*N*	Patients mean score* ± SD	*N*	Care providers mean score* ± SD	*N*	Organizational providers mean score* ± SD	*N*	Overall mean score* ± SD
Positively impact engagement in self-management decision-making	8	4.4 ± 0.74	11	4.5 ± 0.52	8	4.6 ± 0.52	27	4.5 ± 0.58
Easier to participate in SDM	8	4.8 ± 0.46	11	4.4 ± 0.50	8	4.8 ± 0.46	27	4.6 ± 0.50
Become a normal part of my work	8	4.0 ± 0.53	11	4.1 ± 0.54	4 4	3.2 ± 0.50 Not relevant to my role	23	3.9 ± 0.60
Easier to support patients in self-management	8	4.4 ± 0.52	11	4.3 ± 0.65	8	4.8 ± 0.46	27	4.4 ± 0.58

1, strongly disagree; 5, strongly agree.

TABLE 10 | Combined qualitative and quantitative results for practice-related outcomes by study group.

Practice-related outcome	Survey mean score* ± SD	Descriptive themes	Exemplar quotes		
			Org providers	Care providers	Patients
Positively impact engagement in self-management decision making	4.5 ± 0.58	Care is efficient Care is person-centered	"The care approach has to marry and reflect that same philosophy and culture" "It feels to me that there is a cultural elitism thing there, which needs to go away. So, this kind of tool would help with that because it would drive the culture toward partnership" "The magnitude of impact on hard clinical outcomes is probably going to be low. I think if we don't focus on that and be a little more holistic in our health approach and think does this improve treatment satisfaction or does it reduce diabetes distress scores or quality of life score, I think it probably will be positive"	"We are actually able to directly contact [our patients] and have a conversation without them having to come into the clinic" "It gives information to the patient that they've never had… and shifts the relationship to more of a collaborative one" "it just makes it way easier for those patients to access care… and they don't have to be in town" "[patients] might go home and think, what kind of instructions did [my provider] give me again and if it was all in e-PHR, then I think would make it easier for patients and care providers too" "If we are truly doing person-centered care, around their beliefs and values, we might find that some of the things we know clinically a person should be doing or moving toward may not be the care plan for that individual"	"Rather than just thinking of [our concerns], we'd actually be acting on them" "It makes you feel more involved, like you have more of a voice in your own health, as weird as that sounds" "I think a lot of factors get left out such as stress levels and activity levels if you have been traveling, for example, or you changed your diet… if [care providers] could just see kind of what you see every day, with your activity changes and emotional changes, it might be a little easier to fine tune how to care for yourself if they had that extra information that usually gets lost"
Become a normal part of my work	3.9 ± 0.60				
Easier to participate in SDM	4.6 ± 0.50				
Easier to support patients in self-management	4.4 ± 0.58				
Reduce diabetes complications	3.6 ± 0.58				

1, strongly disagree, 5, strongly agree.

that having access to the "big picture" would allow patients to take more ownership of their own care and related decision-making. CareProvider7 noted that the ability to participate is because "it gives information to the patient that they've never had, which may empower them to engage more frequently and shifts the relationship of care provider and patient to more of a collaborative one." When it comes to having access to comprehensive information, such as a care plan, outside of the care encounter, CareProvider3 pointed out how helpful this would be: "[the patient] might go home and think, what kind of instructions did they give me again, and it would be all in e-PHR." Participants described the ability to support patients in their care as a result of treatment decisions being made that will more likely be followed because they are made with the patient, taking into account the whole person with a more comprehensive set of data. Patient1 shared how having a more complete understanding of the person would aid decisions and enable ensuing actions to be more accurate. She shared, "I think a lot of factors get left out such as stress levels and activity levels if you have been traveling, for example, or you changed your diet. A lot of those tiny factors have a really big effect on your managing your health, and I think those can definitely be missed in appointments when [care providers] are just looking at the [laboratory] numbers… if they could just see kind of what you see every day, with your activity changes and emotional changes, it might be a little easier to fine tune care if they had that extra information that usually gets lost."

Overall Interpretation for the Normalization of e-PHR

Overall, participants' cognitive and behavioral processes of sense-making, commitment, and appraisal to normalize e-PHR in practice to engage patients in self-management decision-making appeared encouraging. However, the collective action mechanism or implementation effort required to enact and sustain e-PHR was less positive, as indicated by the lower mean score and the description of the concepts of the theme and subthemes. The mean scores of the two NPT mechanisms, cognitive participation and collective action, and their qualitative themes corroborated each other. **Figure 3** illustrates the overall results in response to the research questions, using a joint display of mean NPT mechanisms scores and themes benefitting from the NPT framework and the mean scores and themes for the practice-related outcomes.

DISCUSSION

The discussion section examines (a) the psychometric tests of the NoMAD instrument in this study, (b) the implementation work of e-PHR and its potential to integrate into clinical practice in terms of the four NPT mechanisms, and (c) the potential practice-related outcomes.

NPT-Based Measurement Instrument, NoMAD

The NoMAD tool was chosen as it is the first quantitative measure based on NPT. In the test for reliability, both the cognitive participation and collective action mechanisms in this study had strong internal consistency, but the internal consistency of the coherence and reflexive monitoring mechanisms were weak. The overall measure of normalization had a Cronbach α of 0.60 and may be explainable by the poor reliability in two of the four NPT mechanisms. The small sample size may be a significant factor in this study. Modification of the NoMAD instrument and further primary studies examining its psychometric performance are needed before it can confidently be used as a reliable measurement instrument of NPT. Notably in this research, there was congruency between the NoMAD scores for cognitive participation and collective action and the qualitative data. This result strengthened the study and gave depth to the findings by providing a fuller understanding of these two normalization processes.

e-PHR: Implementation Success Evaluated

Coherence refers to peoples' understanding of an intervention and the sense-making work involved in establishing this understanding. Participants made sense of e-PHR by noting its deviation from the current practice. Participants concurred that the transparency and fluidity of data associated with e-PHR and the processes that e-PHR avails users differ significantly from the way care is carried out today. For patients, access to comprehensive and timely data and the responsibility and power for decision-making offer opportunities to effectively self-manage and communicate confidently with providers (33).

While e-PHR made sense to participants, its deviation from current practice will require numerous shifts at the individual, organizational, and system levels. In-line with Scholl et al. (34), these shifts include the following: align clinical workflow and payment models, foster a shared understanding, and create supportive legislation and policies. At the individual level, this relates to knowledge and skills, workflow within care team, perceived influence, change in patient–provider accountability, and loss of control. Miles and Asbridge (35) articulate valuable methods to move from the current didactic provider-dominated service through the rhetoric of patient-centered healthcare to implementation and outcomes, including mapping deficiencies and deficits and upskilling providers. The literature has described the value of shared accountability with interprofessional care teams in terms of clarity of roles, tasks, and goals (36), but with the emergence of the patient as partner in digital care, a new shared model of accountability is needed.

At the organizational and system level, shifts were conveyed as changes in the culture of medicine and changes in health system processes and policies. To enable a shared digital-health information ecosystem, changes in health-system policies require review in terms of provider incentive models and privacy legislation. There is a growing body of evidence about the potential effectiveness of provider incentive models that align payment with quality performance (37) and drive adoption of a shared digital-health information environment (38). Further, and in alignment with the work of Brennan et al. (39), this research illustrated the need for system-wide efforts to involve patients in the design of technological solutions such as PHRs, whereby patients will invest in meaning, commitment, and effort because the design is grounded in their needs and preferences.

Participants saw the sensibility of e-PHR through its expected benefits and how it affects the work of patients and care providers. Access, connectedness, and convenience were seen by participants as the most supportive aspects of e-PHR for patients. Linking access and ease and timeliness of communications to measured outcomes will favorably support ongoing sense-making work of e-PHR. Patients explained that with e-PHR use

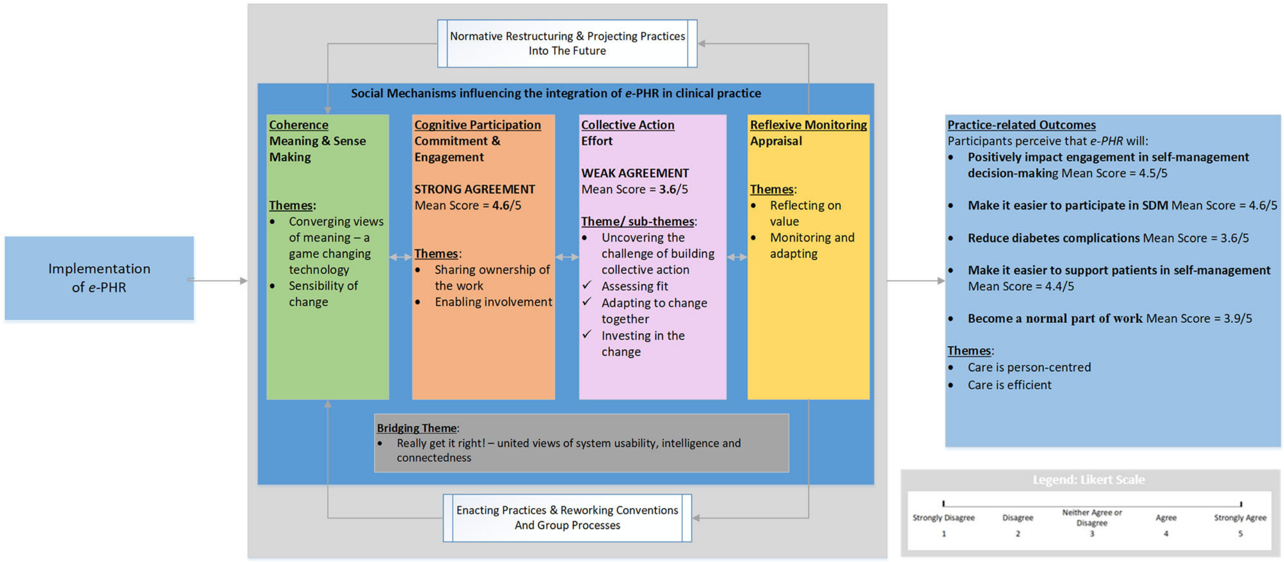

FIGURE 3 | Overall interpretation for the normalization of e-PHR.

they would feel more supported because decisions need to be made often and, for example, not only at a prescheduled 6-month follow-up appointment. In a study on designing a patient portal for patient-centered care, patients identified the importance of decision-making with their provider and wanted to be able to view the evolution of their health over time and to be notified when health changes were identified (40). Patients also described a likely improvement in their experience of care by increasing their confidence in their ability to self-manage. In fact, improved quality of healthcare through improved access to and sharing of information and improved ability of patients to manage their own healthcare were the identified patients' experiences in a study exploring their perceptions and experiences with PHR use (33). The authors (33) also conveyed that maximum benefits would be realized when PHRs contain a complete collection of relevant health information. Given the interconnected design of e-PHR, it is expected that optimal care quality will be attainable.

For care providers, the sensibility of e-PHR is overshadowed by concerns related to their ability to operationalize workflow and the anticipation of an increased workload. In a study relating new responsibilities with PHR use, Hill et al. (41) found intersecting concerns with PHR use on time demands and liability within already heavy workloads of care providers. The sheer volume and fluidity of data with e-PHR highlight issues of alert workload, a well-known problem identified by care providers that is still debated (42). Research on the topic of EHR alerts and patient safety has illustrated that patient safety is at risk with increased inappropriate firing of alerts, which has led to alert fatigue and the potential for ignoring important notifications (43). More investigations are needed regarding the benefits and impacts of e-PHR use to better understand, mitigate, and support changes to care processes and policies.

Organizational providers expressed ambiguity around the patients and care providers having a shared understanding of the purpose of e-PHR. This may be an emergent property of implementation. That is, over time, a coherent and shared understanding will likely develop as patients, care providers, and organizational leadership become more familiar with the practice. Still, in another implementation study using NPT (25), lack of agreement over the intervention's purpose was observed, and the authors indicated that clarifying its purpose at the outset would likely remove resistance by reducing the extra work caused by uncertainty. Thus, to successfully root e-PHR into practice, its purpose must be well-defined, common, and made to be intrinsic to healthcare. Additional work is required to foster this shared understanding as well as to manage the expectations of both patients and care providers around care services as they shift with the introduction of this game-changing technology.

Cognitive participation is the relational work that people do to engage and commit to a new intervention. Participants felt strongly that they would engage with processes that promote participation individually and together. This insight requires explicit attention of implementers such that strengthening of patients' and care providers' sense of their collective experience will translate to commitment and engagement in the practice of SDM via PHR.

While participants are committed to e-PHR, strategies are needed to address the collective resistance to change and the fear of non-systemic ownership of the change, as well as to manage patients' and care providers' expectations and allocate substantive resources and training. Thoughtful change management efforts, such as training and resources to support the change, will be imperative to maintain this openness to new ways of working and shift any fear and resistance. Training is one way of communicating what is involved and the possible benefits. Indeed, training led to high levels of involvement and commitment in one implementation study underpinned by NPT where this preparatory exercise led key people to drive the intervention forward and get others involved (22).

When describing shared ownership of the work, participants identified e-PHR as the right direction for healthcare with its increased levels of engagement, collaboration, and practice efficiencies. However, participants emphasized that the ownership is not only by patients and care providers, but also by organizations and the healthcare system. Active leadership has been identified as crucial to the implementation of new practices and especially effective when focused on the redesign of supportive policies and organizational structures (44). A common and significant concern identified by participants was that an inadequate level of system leadership and resources could hamper the success of e-PHR. Resources and funding are not new barriers to the implementation of EHRs. In fact, a systematic review of users' perspectives with EHR implementation indicated that 19 of its 52 studies considered the lack of funding as a barrier to implementation (45). A well-resourced financial outlay for sustainment was also described by participants in their appraisal work and effort required to enact e-PHR. Strategies and operational solutions to manage this barrier are paramount.

Collective action is the operational work that people do to enact an intervention. In general, the collective action aspects of the work required to enact e-PHR appear low and point to a set of inhibiting factors on which to focus future efforts. In other studies using NPT, this mechanism assisted in identifying the factors to optimize the intervention for testing in a larger-scale trial or for a subsequent full-scale implementation (46, 47). The effort to enact e-PHR will require an upskilling of care providers, the redesign of teams and processes, a well-resourced investment, and support to bolster a systemic willingness to adapt to change together.

Participants in this study exposed an underexamined issue related to care providers' skills (or lack of) to engage the patient in decision-making and care. A study on physician SDM skill acquisition confirmed that additional skills are needed and should be delivered through medical education (48) and continuing education programs (49). Canadians' vision for the creation of better health through digital solutions is to establish conditions for greater patient involvement in and increased transparency of decision-making (50). Enhancing care providers skills around the use of SDM and collaborating in teams with the patient as a partner in digital care will likely be invaluable to the collective action work of implementing e-PHR. Related is a study where the use of EHR was interpreted as a possible threat to professional autonomy of physicians (45). The need to support providers with the transition of their care practices to an environment of shared responsibility and transparency is imperative. If not addressed, it could have a significant negative impact on both the perceived usefulness of e-PHR and the willingness to invest effort into operationalizing it.

Most participants expressed doubt about the likelihood of a well-resourced implementation explaining that, while e-PHR was likely to be sponsored in theory, it was not likely to be resourced to the extent needed; historically, this has been the case with other healthcare interventions. A lack of IT infrastructure and resources that could adequately support an intervention were identified as impeding factors of collective action in other implementation studies (22, 25). Demonstrating incremental benefits is likely to drive effort, and it turn these advantages should drive investment.

Participants expressed ambiguity regarding their ability to adapt to change together; i.e., e-PHR may not easily integrate into current practice without a disruption to relationships and processes. Trust and collaborative partnerships for optimal care play an important role here, especially given the perceived relinquishing of control and accountability toward the patient. In a study to understand how patient privacy concerns affect their disclosure of health information, the authors (51) found the perception of high-quality care reduced the likelihood of withholding information and may be an effective strategy to foster patient–provider trust. Further investigations around trust and relationships between patients and care providers may uncover strategies for them to collectively adapt. Contrary to participants' concern of a disruption to relationships and processes, use of PHRs can strengthen patient–provider relationships (52).

In this study, the cognitive and behavioral processes of meaning, commitment, and engagement did not translate strongly to enacting collective implementation efforts. The lack of translation from one mechanism to another was consistent with finding of Burau et al. (44), where the authors found that participants identified a health promotion intervention as meaningful, yet it did not translate into an engaged, collective implementation effort. NPT developers have acknowledged that the dynamic and contingent activities of the four mechanisms and their production and reproduction evolve over time (53). Future research should pay closer attention to the complex interplay between the four NPT mechanisms; for example, how the intervention, the context, and the individuals determine how meaning and engagement are translated into enactment.

Reflexive monitoring refers to how people evaluate an intervention, the collection, and use of feedback and how the intervention changes over time. Given that this evaluation was carried out at the design and planning stage of e-PHR with no tangible solution for participants to assess, the value of this reflective process may not be relevant. The process of reflexive monitoring is likely better suited to implementation stages that are further along than planning. That said, participants in this study did appraise the value of e-PHR as having the potential to nurture engagement and collaboration by removing barriers to care and improving patient care experience.

Participants conveyed an imperative to measure and demonstrate outcomes on an ongoing basis and adapt at the system- and practice-level accordingly. Similar to results reported by Dickinson et al. (22), participants were interested in more formal evaluations of the intervention and how positive effects could be maintained beyond the defined implementation period. In another study by Yeung et al. (54), the reflexive monitoring mechanism offered constructive insights by care providers regarding implementation of a screening intervention; specifically, it found providing quarterly feedback reports gave providers an opportunity to reflect and appraise their work and identify changes within their control that could be made to their practices to facilitate screening. These insights are valuable and should be utilized in a future implementation of e-PHR.

Healthcare system decision makers need to take strategic and operational leadership on technological infrastructure to center the patient in care and engage them within an integrated EHR ecosystem using the patient-facing version, the PHR, which is where their health information for SDM lives.

e-PHR: Potential Practice-Related Outcomes

All participants perceived e-PHR as a technology to both engage the patient and make it easy for the patient to participate as a partner in their care and decision-making in a manner that is respectful of their care preferences. PHRs have been identified as tools to improve patient engagement (55–57), particularly in engagement related to self-management (58). Any future implementation of e-PHR should evaluate measures of patient engagement and SDM.

Weak agreement was observed among participants around whether e-PHR would become a normal part of their work. Organizational providers indicated the greatest uncertainty. This may signal a greater awareness on their part, relative to patients or care providers, of the breadth and depth of organizational- and system-level challenges required to integrate e-PHR into clinical practice. In a scoping review of 48 articles on organizational- and system-level characteristics that influence the implementation of SDM, Scholl et al. (34) categorized the influencing organizational characteristics as (a) leadership, (b) culture, (c) teams, (d) priorities, (e) workflows, and (f) resources, and the influencing system-level characteristics as (a) incentives, (b) policies, (c) culture, and (d) education and training. The authors (34) argue that tailoring strategies to address these influencing characteristics could improve implementation success. Given that many of these characteristics were identified in this study, a future implementation of e-PHR would be well-served by distinguishing which levels of organizational leadership should take action to address a specific influencing characteristic, for example, which leadership level should set related priorities and resources, support multidisciplinary patient–provider teams, and disseminate strategies to support patient and provider workflows. Further, the healthcare system and their organizations should be methodical and unified in their approach to create a culture that supports SDM via PHR.

Strengths and Limitations

The application of mixed-methods gave depth to the descriptive study with qualitative results corroborating with quantitative results using NPT measurement tool. Further, thematic saturation within study groups was achieved adding strength to our findings. Although a small sample size, the sample offered the research the desired maximum variance of multiple study populations in British Columbia with regard to several key characteristics, such as sex, geographic location, and number of years in clinical practice as shown in **Table 2**, to best understand the topic while reaching a reasonable saturation in the collection of data. In other descriptive studies with similar approaches, data saturation was reached within similar range of sample size (20, 25). While the use of a non-representative sample does not permit generalizability to other populations, the high "information power" (59) of the participants with the specific clinical condition of diabetes is in line with the vision for digital solutions of Canadian citizens with varying clinical conditions (50) and adds both credibility and transferability of the results and makes possible the drawing of valid conclusions.

In terms of the quantitative results from the NoMAD instrument, caution in interpretation of the results is necessary given the large number of statistical tests performed relative to the small sample size. A strength of this study was its mixed-methods approach. That is, the outcomes of the NoMAD instrument for two of the four NPT mechanisms were consistent with the qualitative data. In a recent mixed-methods study using NoMAD (24), the NoMAD instrument outcomes were consistent across all four NPT mechanisms with qualitative data, although no psychometric testing of the instrument was completed.

In terms of the qualitative data analysis, only one researcher coded the data. Every effort was made by the researcher to remain open to the possibility that data may fall outside of the NPT coding frame used in this research and therefore required further examination to determine if important concepts or ideas were being missed.

It is possible that study participants were particularly interested in technology (such as characteristics known to early adopters) or the advancement in diabetes care. Their views of e-PHR may not reflect the views of people with other health conditions or interest in the use of technology. Additional research across other clinical domains is needed.

Finally, this study was a preimplementation assessment, and as such, there was no tangible solution for participants to assess; rather, they did so theoretically. Additional feasibility and usability studies with a developed system would be valuable for results to be grounded in the participants' experience with use of e-PHR.

e-PHR: Implications for Successful Integration

This study identifies key aspects for future development, implementation success, and usage of e-PHR.

First, the need to consider user perspectives in the development and deployment of HITs has been established both in academic research forums and in public discussions. In this work, the cognitive and behavioral processes associated with e-PHR implementation success were examined from the perspectives of patients, care providers, and system-level leadership. User-involved approaches increase the likelihood of implementation success because they are aligned with the needs of the users (26). As such, the findings in this research indicate high practical relevance. For system developers, an advanced prototype may undergo usability testing to ensure that an implementation of the system does not fall short of expectations of its users. In line with this research approach, every effort should be made by developers and implementers to put in place processes for ongoing engagements with users throughout the implementation stages to both inform and educate them and be informed and guided by them.

With the integration of e-PHR into the digital health ecosystem, patients and care providers will have enabling processes, tools, and technologies in place for SDM and access to health information and communications that align with the ways of working today. These enablers create opportunities for more engaged patients and better health outcomes; nevertheless, care providers' workload, clinical team workflow, and medical–legal issues require further investigation. Further, system implementers and organizational leaders can apply the learnings from this preimplementation evaluation of e-PHR with a focus on boosting enablers and bridging the barriers for a successful future implementation.

For the healthcare system, examination of policies, incentives for care providers, and operational and strategic pathways to resource and advance the required technological infrastructure of connected systems are needed. As we move into an ecosystem of connected care, information sharing across private and public domains is required, and current policies and governance structures must align. Considerations will be needed to encourage system developers to reengineer their products (or new vendors to design products) to align with the functional requirements of SDM via PHR and identified standards and protocols for seamless information exchange. With a change in the way care providers are remunerated, the foundation will be laid for new ways to engage patients and support their care. This will require additional education and training for care providers and patients on SDM and around office efficiency within connected care systems.

Finally, the healthcare system and its organizations should be methodical and unified in their approach to shift a didactic provider-dominated medicine culture to align with a patient-centered philosophy that supports e-PHR and a quality improvement spirit, including mapping deficiencies and deficits, measuring outcomes with e-PHR use, and highlighting excellence.

Concluding Remarks

PHR technology designed to enable SDM and built on an interconnected architecture can offer a complete, shared, and balanced profile of the patient and provision of personalized decision support and communications tools. This preimplementation process evaluation, grounded in NPT, was extremely valuable for informing future implementation of e-PHR, including perceived benefits and barriers. The use of NPT in planning stages of implementation projects provides a real-world context in which to explore the work that will take place to integrate a new practice or technology and important data to redirect or stop planning if the likelihood of normalization is low (60).

The results of this study indicate that NPT offers an applicable framework in which to detail the processes known to influence successful integration of HITs into their complex sociotechnical healthcare environment. In detailing the use of NPT, it is, in and of itself, a valuable contribution to implementation science theory (60). In addition to the usefulness of NPT in the preimplementation stage, its use should be considered at all stages of the system design life cycle for e-PHR. For example, with an e-PHR prototype developed and deployed in small scale, the processes routinely operationalized in everyday work by care providers and patients could be evaluated for optimization prior to deploying in a larger scale.

The state of SDM in clinical practice is not a question of whether we should do it or not; rather, it is a question of successfully integrating the practice of SDM for patients and care providers within today's evolving EHR–PHR ecosystem and patient-centered care approach, and tomorrow's interconnected, mobile, and ubiquitous technology environment. Using the NPT framework, findings from this preimplementation process evaluation indicated participants invest in sense-making, commitment, and appraisal work of this PHR designed to enable SDM. However, integration of e-PHR into normal clinical practice is not quite ready for prime time and will only be attained when systemic effort is invested to enact it. Further research is needed to explore this gap to inform priorities and approaches for future implementation success.

DATA AVAILABILITY STATEMENT

All datasets generated for this study are included in the article/**Supplementary Material**.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Victoria Harmonized Human Research Ethics Board. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SD led the research and was responsible for the literature review, knowledge modeling, data collection and analysis, interpretation of the data, initial drafting of the manuscript, edits of the final manuscript, and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2020.575951/full#supplementary-material

Supplementary Material 1 | User-validated functional model for e-PHR.

Supplementary Material 2 | The NoMAD: a measurement instrument of NPT.

Supplementary Material 3 | Survey of practice-related outcomes.

Supplementary Material 4 | Semistructured interview guide.

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OPINION
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Does Patient Access to Clinical Notes Change Documentation?

Charlotte Blease[1]*, *John Torous*[2] *and Maria Hägglund*[1,3]

[1] Division of General Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, United States, [2] Department of Psychiatry, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, United States, [3] Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden

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Edited by:
Matthias Jaeger,
Psychiatrie Baselland, Switzerland

Reviewed by:
Martin Zinkler,
Kliniken Landkreis Heidenheim gGmbH, Germany
Susanne Jaeger,
ZfP Südwürttemberg, Germany

Correspondence:
Charlotte Blease
cblease@bidmc.harvard.edu

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Open, honest, and trustworthy communication is crucial to ensure the effective responses of citizens. Paralleling transparency in the arena of public health are new practice policies that are set to transform the transmission of information at the level of doctors and patients. While patients have legally been entitled to obtain copies of their records for many years, in March 2020 federal legislation in the United States (U.S.) mandated that health providers offer all patients rapid and secure online access to their clinical notes via patient portals ("open notes") (1). Similar developments are underway in the United Kingdom (U.K.) where in April 2020 it was announced that patients in NHS England will be granted online access, albeit prospectively, to their full general practitioners' notes (2). Worldwide, open notes have already been enacted in more than ten countries including Sweden, Estonia, and Norway (3).

A variety of surveys have been conducted into patients' and doctors' experiences of open notes but much less is understood about the objective changes in documentation that may arise as a result of patient access (4–7). We review current research into open notes including clinicians' reports on how they have modified their notes as a result of implementing the practice. Highlighting the potentially beneficial and harmful effects that different types of documentation changes might have on the therapeutic relationship and on patient outcomes, we argue that more research is needed to investigate objective changes in notes as a result of patient access.

PATIENTS' AND DOCTORS' EXPERIENCES OF OPEN NOTES

The overwhelming majority of patients who access their records online report positive experiences (5, 7, 8). Patients describe feeling more in control of their care, enhanced understanding of the rationale for treatments and referrals, better remembering their treatment plans, and doing a better job taking their medications (5, 7–9). Only a small proportion—in one U.S, survey of over 22,000 patients between 3 and 5%—report being very confused or more anxious by what they have read (5). We were not able to find any cases of patient harm caused by sharing notes or legal action taken because of something a patient read. In addition, patients also describe interpersonal benefits of access including feeling better about their clinician after reading their notes, enhanced levels of trust, and strengthened goal-alignment and perceptions of teamwork with providers (5, 10).

How do healthcare clinicians view the practice? While the majority of surveyed physicians consider open notes to be a good idea (5) there does appear to be some variation in attitudes both between medical specialties (2, 11–14) and countries (14, 15). Mental health clinicians, for example, including psychiatrists, in the U.S. and in Sweden appear to be more cautious [(11, 12), p. 2]. In a survey at a medical center in the U.S. Veterans Health Administration nearly one in two mental health clinicians (49% $n = 98$) reported that they would be "pleased" if the practice were discontinued. Some healthcare professionals report negative effects of note sharing including perceptions of heightened patient distress or worry from reading notes [(12), p. 2, (14, 15)]. Finally, while around one third of surveyed clinicians report spending more time writing notes (6, 11) most do not perceive an increase in patient contact or visit times [(5, 11, 12), p. 2, (14)] because of open notes.

SURVEY EVIDENCE OF DOCUMENTATION CHANGES

A major focus of current survey research is the influence of open notes on physicians' documentation practices. In multiple surveys, as a result of patient access to their notes, many clinicians report being more mindful of the words that they use (6, 11). For example, in a recent large-scale survey, the majority of primary care physicians describe adjusting their language to avoid being perceived as critical of patients with around half omitting terms such as "non-compliant," and "patient denies," or modifying how they document sensitive clinical, mental or social information (6). In addition, around a quarter (26%, $n = 61$) of U.S. primary care physicians report employing more partnering or encouraging language in their notes (6).

As a result of patient access, physicians also report changing their use of medical terminology, and the level of detail included in their notes. For example, in survey research in Sweden, one in five (22%, $n = 147$) mental health clinicians [(12), p. 2], and two in three (67%, $n = 43$) oncologists (15) admitted writing less candid notes. In the U.S., the majority (69%, $n = 108$) of mental health clinicians report writing fewer details (11), and a quarter (26%, $n = 63$) of primary care physicians report changing how they document differential diagnoses (6). In a major survey of US physicians from different medical specialities, 22% ($n = 168$) did consider their notes less valuable (6) because of open notes.

WHY DOCUMENTATION CHANGE MATTERS

Open notes may provide an opportunity to "extend the visit" providing patients more time to read and reflect on their doctors' recommendations away from the pressures and time-restrictions of face-to-face interactions. As a result of patient access, however, the tone and content of clinical notes and any changes to documentation may have the potential to influence the quality of care in both positive and negative ways.

By removing language that may be perceived as negative, or including reassuring or supportive wording, documentation changes may heighten patient perceptions of empathy and strengthen trust in clinicians, factors that are associated with improved patient outcomes, beneficial health behaviors, and increased patient satisfaction (16, 17). In addition, patient recall and understanding of information communicated during visits is often poor (18). Convenient electronic access to clinical notes and changes to documentation that improve the clarity of the notes—for example, using plain language to provide brief but understandable explanations for tests and treatments—may boost patient comprehension, recall, and adherence to medications and care plans.

Results of clinician surveys suggest, however, that there may be some risks to documentation practices of open notes. Knowledge of patient access may create a tension between writing understandable notes balanced against over-simplifying medical information and thereby devaluing the utility of documentation for health professionals. Indeed, medical records can be understood as a form of "cognitive scaffolding" helping to aid physician memory, and facilitate diagnostic reasoning. Well-intentioned strategies by physicians to avert worry or anxiety among patients by failing to list differential diagnoses may undermine these crucial functions of record-keeping. In Norway, healthcare professionals report keeping a "shadow record" to document information that they believe should be inaccessible to the patient, a work-around that may risk patient safety and security (19).

MEASURING DOCUMENTATION CHANGES

Although survey research provides valuable insights into physicians' perceptions about changes to documentation, these findings are dependent on self-report and it is not known how response biases affect results. Addressing these challenges, preliminary investigations have sought to analyse the possible objective changes to documentation.

Researchers have examined whether open notes might influence the socio-emotional tone of notes using the computer program the Linguistic Inquiry and Word Count ("LIWC") (13). The LIWC software has been used extensively in clinical psychology to assess patterns of language use and association with behavior (20). It can be used to track the use of pronouns (such as "we" which is associated with perceptions of partnership); the inclusion of cognitive words (for e.g., "because," "reason," "think"); and the use of positive and negative emotion words. Applying this program to investigate changes in clinical notes in oncology, investigators reported no significant modification of the linguistic character of documentation pre- and post-implementation of open notes (13). Although a promising method of assessing changes in collaborative language, this approach has important limitations. While the LIWC can quantify the use of affective and cognitive language, the validity of the method is challenged by contextualization problems; for example, it is unable to discern whether positive or negative emotion words pertain to the patient's history or the physicians' own descriptions.

In another recent study, investigators employed natural language processing (NLP) techniques to quantify the use of "n-grams" —that is, clusters of words—to explore changes pre- and post-implementation of open notes (21). Analyzing more than 100,000 notes written by 36 hematology/oncology clinicians, researchers found that, on average, there was no change in n-grams (21). While this method offers a fast method of text-mining at scale, it is unclear how to interpret these changes, or lack of thereof, at a semantic level. Newer research in deep learning for sentiment analysis offers the potential to look beyond clusters of words and attempt to understand the representation of sentences—though still an area of active research (22). Indeed, the utility of machine learning and NLP techniques in analyzing clinical notes is currently limited although evolving, and such methods cannot yet reliably decipher meaningful changes in documentation—for example, whether more or simpler explanations are offered for medical treatments; or whether clinicians offered more supportive care (23). The best analytical methods are only as good as the data that they are trained against and efforts toward improved classification of notes will require unique collaboration with both patients and clinicians offering insight into their meaning, intentions, and reactions.

A range of existing software packages, however, can be employed to compare the length and comprehensibility of notes before and after patient access. For example, computer programs that use validated metrics such as the Flesch–Kincaid reading scale can track the number of words per sentence, word length, and the number of syllables per word to obtain meaningful measures of readability. This may provide a useful route to compare differences in documentation pre- and post-open notes. To complement this approach and pending further advancements in NLP, qualitative research may also provide a valuable method to help assess objective changes in the socio-emotional tone and content of notes, and in how physicians list differential diagnoses. While its scale and speed is considerably restricted, traditional thematic analysis may help to provide deeper insights about potential documentation changes after patient access to notes.

BOX 1 | Key Messages

- Online access to clinical notes via patient portals ("open notes") is growing, and patients', and clinicians' experiences of the practice are generally positive.
- With the knowledge patients might read their clinical notes, some clinicians report changes to documentation practices including: removing language perceived as critical, adding collaborative or encouraging wording, and being less detailed in notes.
- Further research is needed to explore objective changes to documentation as a result of open notes including how clinicians might optimize this communication tool to benefit patients and health professionals.

BOX 2 | Key questions and findings

What is already known about this topic?

- ➢ Worldwide, increasing numbers of patients can access their clinical notes via online patient portals ("open notes").
- ➢ In extensive surveys patients describe benefits of open notes. Many report that the practice encourages engagement, recall and understanding of care plans, and strengthens patient-clinician relations.
- ➢ While there is some variation between medical specialties and between countries, after implementing open notes most clinicians are also positive about the practice.
- ➢ With the knowledge that patients might read their clinical notes, clinicians do report adjusting their documentation practices including: avoiding language perceived to be critical of patients, being less detailed in notes, and changing how they document differential diagnose

What are the new findings?

- ➢ Limited research has been conducted into assessing objective changes to the content and tone of clinical notes as a result of patient access.
- ➢ Documentation changes may be positive, enhancing patient understanding and providing reassurance and support. However, some changes may interfere with clinical reasoning.
- ➢ Further research is needed to develop objective measures of documentation change and to explore how clinicians might optimize clinical notes to improve patients' experiences and outcomes.
- ➢ As the practice of open notes continues to grow, clinicians may need training in how to preserve the traditional functions of medical documentation while maximizing the potential new benefits of this communication tool.

CONCLUSIONS AND RECOMMENDATIONS

Patients have a right to access their medical information (see **Boxes 1**, **2**). Open notes are increasingly common, and will continue to grow. As more care continues to be delivered via telemedicine because of COVID, access to notes may help patients better adjust to this new care delivery format (24, 25). While innovation brings about new benefits it also invites unforeseen challenges. Most patients report feeling empowered by online access to their clinical notes but further research is needed to investigate how the practice might influence documentation practices, and the consequences for patients and other health professionals.

In the meantime, we recommend that supportive, empathic, and encouraging wording in clinical notes may help to strengthen patient-doctor relationships (26, 27). Such language may have the potential to improve treatment adherence, health engagement, and outcomes for patients. We also recommend that open notes might be optimized to communicate in clear and understandable language the reasons and rationales for tests and treatments. In contrast, we strongly oppose changes that may undermine clinical reasoning, including omitting of key medical information and differential diagnoses. Notwithstanding, modifications in medical documentation may be feasible while maintaining the original function of notes as an accurate and detailed aide memoir for physicians. For example, it may be possible to list differential diagnoses in ways that are fully transparent and honest (and therefore of utility among health professionals) but also reassuring for patients. Other strategies—such as automatic annotation of notes via tooltips—might help to facilitate patient understanding of medical terminology without burdening clinician workflow (28).

As with all new technologies, changes in work practice can be more challenging to implement than the technology itself. In a recent survey, only a quarter of dermatopathologists reported that if their notes were accessible they would need specialized training in how to communicate with patients (14). Going further, we suggest that in the new era of open notes, it is imperative that all clinicians are trained in how to preserve the traditional functions of medical notes, and in maximizing the potential new benefits of this communication tool. Preliminary evidence from web-based clinician training programs suggests that this is achievable (29). Tracking changes in clinical documentation will be key to assess the impact of clinician training, and to evaluate how modifications to clinical notes influence patients' experiences and clinical outcomes.

Finally, by offering patients online access to their clinical notes, the documentation may be more correctly viewed as co-owned by patients and clinicians. Looking ahead, however, it is conceivable that this balance will shift with patients taking even greater control, and potentially becoming the outright owners of their clinical records (30). Indeed, developments are already underway for patients to co-generate medical documentation by setting pre-visit agendas, and providing feedback on their care (25, 31). Interactive notes—so-called "OurNotes"—could offer several important benefits to the quality of documentation, and as a result, patient care. This innovation allows patients to report on their concerns, and describe their health status since their last visit. In addition, co-produced notes offer a more direct opportunity for patients to point out factual inaccuracies in documentation, and to document subjective effects, and side-effects of treatments. Such advancements in clinical documentation may help to close the feedback loop on care (32).

AUTHOR'S NOTE

CB, Ph.D., (guarantor) is an interdisciplinary researcher and philosopher of medicine based at OpenNotes, Beth Israel Deaconess Medical Center who investigates the ethical considerations of sharing clinical notes with patients. JT, M.D.MBI., is an assistant professor and psychiatrist and Director of Digital Psychiatry at Beth Israel Deaconess Medical Center. His research focus on digital mental health and clinical work in augmenting care with smartphone interventions. MH, Ph.D., is an associate professor in health informatics and senior lecturer in implementation science at Uppsala University, Sweden, and a Keane OpenNotes scholar at Beth Israel Deaconess Medical Centre. MH is a member of the Swedish research network DOME that studies the implementation and use of open notes in Sweden, and she chairs a European Working Group on Citizen Health Data.

AUTHOR CONTRIBUTIONS

CB, MH, and JT conceived manuscript and revised drafts. CB wrote first draft. All authors contributed to the article and approved the submitted version.

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Evaluation of the Skeleton Avatar Technique for Assessment of Mobility and Balance Among Older Adults

Sofia Backåberg[1,2], Amanda Hellström[1], Cecilia Fagerström[1,3], Anders Halling[4], Alisa Lincke[5], Welf Löwe[5] and Mirjam Ekstedt[1,6]*

[1] Department of Health and Caring Sciences, Faculty of Health and Life Sciences, Linnaeus University, Kalmar, Sweden, [2] Sports Technology Research Lab, Faculty of Kinesiology, University of Calgary, Calgary, AB, Canada, [3] The Research Section, Region Kalmar County, Kalmar, Sweden, [4] Department of Clinical Sciences, Center for Primary Health Care Research, Lund University, Malmö, Sweden, [5] Department of Computer Science and Media Technology, Faculty of Technology, Linnaeus University, Växjö, Sweden, [6] Department of Learning, Informatics, Management and Ethics, Karolinska Institutet, Stockholm, Sweden

Background: Mobility and balance is essential for older adults' well-being and independence and the ability to maintain physically active. Early identification of functional impairment may enable early risk-of-fall assessments and preventive measures. There is a need to find new solutions to assess functional ability in easy, efficient, and accurate ways, which can be clinically used frequently and repetitively. Therefore, we need to understand how functional tests and expert assessments (EAs) correlate with new techniques.

Objective: To explore whether the skeleton avatar technique (SAT) can predict the results of functional tests (FTs) of mobility and balance: Timed Up and Go (TUG), the 30-s chair stand test (30sCST), the 4-stage balance test (4SBT), and EA scoring of movement quality.

Methods: Fifty-four older adults (+65 years) were recruited through pensioners' associations. The test procedure contained three standardized FTs: TUG, 30sCST, and 4SBT. The test performances were recorded using a three-dimensional SAT camera. EA scoring was performed based on the video recordings of the 30sCST. Functional ability scores were aggregated from balance and mobility scores. Probability theory-based statistical analyses were used on the data to aggregate sets of individual variables into scores, with correlation analysis used to assess the dependency between variables and between scores. Machine learning techniques were used to assess the appropriateness of easily observable variables/scores as predictors of the other variables included.

Results: The results indicate that SAT data of the fourth 4SBT stage could be used to predict the aggregated results of all stages of 4SBT (with 7.82% mean absolute error), the results of the 30sCST (11.0%), the TUG test (8.03%), and the EA of the sit-to-stand movement (8.79%). There is a moderate (significant) correlation between the 30sCST and the 4SBT (0.31, $p = 0.03$), but not between the EA and the 30sCST.

Conclusion: SAT can predict the results of the 4SBT, the 30sCST (moderate accuracy), and the TUG test and might add important qualitative information to the assessment of movement performance in active older adults. SAT might in the future provide the means for a simple, easy, and accessible assessment of functional ability among older adults.

Keywords: performance analysis, mobility, older adults, functional tests, balance

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Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Mengxuan Ma,
University of Missouri, United States
Eling D. de Bruin,
Karolinska Institutet (KI), Sweden
Jordi Bernad,
University of Zaragoza, Spain

****Correspondence:***
Sofia Backåberg
sofia.backaberg@lnu.se

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INTRODUCTION

Maintaining mobility and physical activities of daily living among older adults has significant impact on quality of life, prolonging independent living, decreasing risk of falls, and reducing sedentary behavior (Rejeski et al., 2015; Aunger et al., 2018; Talarska et al., 2018). In the coming years, the proportion of people 65 years or older will increase dramatically, which implies a global challenge in several aspects (World Health Organization, 2015). This will require investments in promoting healthy aging and fundamental shifts in how we think about aging. The functional ability (i.e., mobility and balance) of older adults in everyday life is often limited by processes related to aging, such as gradual loss of muscle mass by 0.5–1% per year, as well as concomitant diseases. Levels of physical activity decrease with age (Lara et al., 2015; Stierlin et al., 2015), which has serious implications for the burden of chronic disease and mortality (Lee et al., 2012). Maintaining mobility despite disease can be crucial for being able to continue living at home, manage everyday life, and interact with the surrounding society. Strength, balance, and flexibility exercises are among the most effective strategies to counteract age-related decline of functional capacity and prevent falls among older adults (Paterson and Warburton, 2010; Dipietro et al., 2019). Physical activity is a modifiable behavior that contributes substantially to maintaining functional capacity and health (Lee et al., 2012). Thus, measures to prevent physical impairment and fall-related injuries for older adults are particularly important, with balance and mobility being essential aspects (Dipietro et al., 2019). Through regular assessment of functional ability, interventions could be initiated early, which might prevent mobility loss, improve quality of life, and prolong independent living among older adults. In community care, however, everyday rehabilitation and preventive work are not always prioritized alongside domestic care, and there is reason to believe that current functional tests (FTs) and similar assessment methods are insufficient.

Today, a range of tests and assessments of mobility and balance are available. Commonly, assessments of physical disability include performance-based (performance-oriented mobility assessment) and self-reported assessments (activities of daily living) (Cress et al., 1995). However, these are seldom routinely used, due to cost, the growing aging population, and the fact that an assessor, often a health professional, is needed to perform the tests. The consequences may be that physical activity and function of older adults become less visible and that early interventions are not being performed. For some diagnostic groups with chronic diseases, these tests can be exhausting or too challenging to carry out. The 30-s chair stand test (30sCST) is an example of this. The tests are commonly measured in time, counts, or distance. In the absence of expert assessments (EAs), crucial information about the qualitative aspects of the movement performance, such as compensatory movement patterns, may be neglected, which may lead to inadequate health interventions and inadequate use of resources.

The advent of commodity three-dimensional (3D) sensor technology, e.g., the Kinect camera, has enabled efficient automated assessment of human movement. The Kinect camera technology is promising in detecting the risk of falls among older adults (Ejupi et al., 2015) assessing aspects of balance and postural control (Clark et al., 2015) and has been beneficial for the classification of the different stages of Parkinson disease related to freezing of gait (Dranca et al., 2018). Further research is needed to explore how the technique can be used to determine functional ability among older adults.

As the method still requires the use of the Kinect camera in a laboratory or having it installed at home, it excludes many people, especially those who have mobility difficulties (Ejupi et al., 2015). Also, our research was conducted using version 2 of the Kinect camera, which has been discontinued. However, the new version called Azure Kinect Development Kit has been released in 2019[1]; it is easier to use. There are also alternative low-cost 3D camera systems, such as Orbbec's Astra Mini[2] and Intel's Real Sense[3] These alternatives were tested against the Kinect version 2 and showed comparable tracking abilities (Hagelbäck et al., 2019b). Moreover, two-dimensional (2D) tracking software, such as PoseNet[4], and the pose detection of Google's ML Kit[5] exemplify another promising technology development. This type of software can be integrated in commodity mobile phones enabling skeleton avatar technique (SAT) to be both widespread and handy. Our own ongoing research maps the 2D SAT data of these software systems to 3D SAT data with high accuracy. In summary, the study presented here shows the predictive potential of SAT among older adults. On top of this feasibility study and based on the latest SAT development, there is a high potential of this technology facing a wider adoption in elderly care and even among elderly people.

Machine learning approaches map recorded movement instances to expert scores providing an automated assessment of the movements (Dressler et al., 2019a; Hagelbäck et al., 2019a). The so-called *skeleton avatar technique* (Dressler et al., 2019b) refers to the pipeline of hardware, software, and artificial intelligence components that records human movements with a 3D sensor, estimates the position of joints in each frame of the movement recording, and maps this information to a movement quality score.

Also, existing measures of mobility and balance among community-dwelling older adults have several limitations due to incompleteness, ceiling effects, and limited sensitivity to change and responsiveness (Lundin-Olsson, 2010; Pardasaney et al., 2012, 2013). Furthermore, there is a lack of a common language among different professional groups regarding the assessment of balance and mobility, which can, for example,

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Abbreviations: 30sCST, 30-s chair stand test; 4SBT, 4-stage balance test; CNN, convolutional neural network; EA, expert assessment; FT, functional test; MAE, mean absolute error; RNN, recurrent neural network; SA, self-assessment; SAT, skeleton avatar technology; TUG, Timed Up and Go.

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[1] https://azure.microsoft.com/en-us/services/kinect-dk

[2] https://orbbec3d.com/astra-mini-series

[3] https://www.intel.com/content/www/us/en/architecture-and-technology/realsense-overview.html.

[4] https://github.com/tensorflow/tfjs-models/tree/master/posenet

[5] https://developers.google.com/ml-kit/vision/pose-detection

hinder transitions between different care levels. Such difficulties when assessing mobility may reduce diagnostic sensitivity and the ability to capture improvements resulting from initiated interventions. Currently, a combination of several measures has to be used to encompass all aspects of functional ability (Berg and Norman, 1996; Dite and Temple, 2002). Thus, it is of significant importance to develop simple, inexpensive, and accurate assessment tools that are suited to the older adult's situation and can be used at a large scale in community care. As the first step in this development, the objective of this pilot study was to investigate the correlations between three FTs of mobility and balance [Timed Up and Go (TUG), 30sCST, 4-stage balance test (4SBT)], EAs, and the SAT.

MATERIALS AND METHODS

Study Design and Participants

This pilot study applied a cross-sectional design and was performed in purposely arranged and separate rooms at four different locations in the south of Sweden. Community-dwelling older adults (>65 years) were recruited via four pensioners' associations through emails/phone calls. In total, 54 older adults (38 females and 16 males) signed up for this study. All participants included in the study signed an informed consent form approved by the Swedish Ethical Review Authority (Dnr: 2019-02553).

Data Collection

Participants first completed a questionnaire with demographic information about their gender, age, weight, height, diagnosis, and symptoms, as well as a self-assessment (SA) of mobility and balance status (see Appendix 1 in the **Supplementary Material**). Twenty participants reported one or several medical diagnoses, with nine people reporting heart diseases, eight hypertension, four diabetes, and three reporting thyroid disease. Next, participants were instructed to perform three standardized FTs, the TUG, 30sCST, and 4SBT, which measure balance and mobility (Podsiadlo and Richardson, 1991; Rossiter-Fornoff et al., 1995; Jones et al., 1999). The FTs were performed in a controlled environment and supervised by a physiotherapist. Each test was recorded frontally with a Kinect sensor camera (Microsoft), with an infrared depth sensor of 512 × 424 pixels and an RGB camera resolution, 1,920 × 1,080 pixels. Its software development kit (SDK v2.0) computes 25 body joints (of which 13 were effectively used as discussed below), at a frequency of 30 Hz. The Kinect sensor camera was placed horizontally (no tilt angle) in 50-cm height. The participants were asked to stand in front of the camera before each test, so that the SAT could detect the person's full body (Dressler et al., 2019a; Hagelbäck et al., 2019a) in order to assess functional ability (mobility and balance). SAT data are 3D skeleton avatar sequences of the movements of the person performing FT.

Assessments

We assessed *functional ability* as an aggregate of *balance* and *mobility*, using three assessment approaches: an SA questionnaire, FTs, and an EA score of movement quality. However, SA is subjective, and the relatively large margin of error when self-assessing physical activity levels is a well-known problem (Thyregod and Bodtger, 2016). SA should therefore be used together with other assessments. The FTs used in this study (TUG, 30sCST, and 4SBT) are standardized and objectively measured in time and require standardized settings and the involvement of a trained person during performance.

Expert Assessment

An experienced physiotherapist performed the EA of the sit-to-stand movement in this study, using a newly developed instrument for structured movement analysis of person transfer and mobility in physical activities of daily living (Backåberg et al., 2020). The instrument has been developed by an expert group of experienced physiotherapists, an occupational therapist, a researcher, and instructors within the field of safe person transfer and has been tested for face validity by a group of clinical physiotherapists. The instrument contains detailed descriptions of everyday life movements, focusing on the quality of the critical components of the movement performance. Performance is rated 0 = in accordance with the description, 1 = small deviation from the description, or 2 = large deviation from the description.

Mobility

Three mobility-related questions from the SA questionnaire and two standardized FTs (TUG and 30sCST) were used to measure the mobility of the participants. The mobility-related questions focused on sedentary behavior and levels of physical activity in daily life: time spent sitting or lying down during a day (scores 0–7, a higher score indicates a more sedentary lifestyle), time spent in physical activity during a week (scores 0–7, a higher score indicates more physical activity), and time spent exercising during a week (scores 0–7, a higher score indicates more exercise) (see Appendix 1 in the **Supplementary Material** and **Table 1**).

In the TUG test, the participants were asked to perform a sequence of movements: sitting in a chair with armrests, standing up, walking 3 m, turning around, going back, and sitting down again. The time needed to complete the test was measured. The TUG test has been shown to predict an elderly person's ability to walk independently (Podsiadlo and Richardson, 1991), and a score ≥14 s is associated with a higher risk of falls (Shumway-Cook et al., 2000). There is a categorization based on the time needed to perform the movement sequence, where ≤10 s is considered normal/no problems in mobility, 11–20 s = independence in movement, 21–29 s = large variation in functional ability, and more than 30 s = dependent/in need of assistance. The higher the score, the more difficulties. The test has shown good reliability and validity among healthy older adults (Podsiadlo and Richardson, 1991; Shumway-Cook et al., 2000). Previously reported psychometric properties of the TUG show high interrater reliability among community-dwelling older adults [Intraclass correlation coefficient (ICC) = 0.98] (Shumway-Cook et al., 2000), whereas another study show that the test–retest reliability was moderate among older persons (Rockwood et al., 2000) The TUG has a high sensitivity (87%) and specificity (87%) and is able to identify elderly persons who are prone to fall. The discriminate analysis suggests that older adults

TABLE 1 | Demographic, self-assessment, and functional test data of participants (*n* = 54, missing 0–1.9%).

Variable	Men *n* = 16	Women *n* = 38	All *n* = 54
Age in years, mean (*SD*)	75.6 (3.2)	73.7 (4.7)	74.3 (4.4)
BMI, mean (*SD*)	26.2 (4.5)	25.9 (5.4)	26.0 (5.1)
Mobility			
Sitting and lying, hours/day, *n* (%)			
Never	0	0	0
1–3 h	4 (25.0)	3 (8.1)	7 (13.2)
4–6 h	9 (56.3)	22 (59.5)	31 (58.5)
7–9 h	1 (6.3)	8 (21.6)	9 (17.0)
10–12 h	1 (6.3)	4 (10.8)	5 (9.4)
13–15 h	1 (6.3)	0	1 (1.9)
Most all day	0	0	0
Physical activity, min/week, *n* (%)			
>300 min	8 (50)	20 (54.1)	28 (52.8)
150–299 min	5 (31.3)	7 (18.9)	12 (22.6)
90–149 min	1 (6.3)	5 (13.5)	6 (11.3)
60–89 min	0	1 (2.7)	1 (1.9)
30–59 min	0	3 (8.1)	3 (5.7)
<30 min	2 (12.5)	1 (2.7)	3 (5.7)
No time	0	0	0
Strenuous activity, min/week, *n* (%)			
>300 min	0	2 (5.4)	2 (3.8)
150–299 min	4 (25.0)	6 (16.2)	10 (18.9)
90–149 min	4 (25.0)	9 (24.3)	13 (24.5)
60–89 min	2 (12.5)	8 (21.6)	10 (18.9)
30–59 min	2 (12.5)	6 (16.2)	8 (15.1)
<30 min	3 (18.8)	3 (8.1)	6 (11.3)
No time	1 (6.3)	3 (8.1)	4 (7.5)
TUG test, *n* (%)			
No problems	14 (87.5)	36 (94.7)	50 (92.6)
Independence in movement	2 (12.5)	2 (5.3)	4 (7.4)
Large variation in functional ability	0	0	0
Dependent	0	0	0
30sCST, *n* (%)			
Below normal	3 (18.8)	6 (15.8)	9 (16.7)
Normal	9 (56.3)	15 (39.5)	24 (44.4)
Above normal	4 (25.0)	17 (44.7)	21 (38.9)
Balance			
Experienced difficulties with balance last 12 month, *n* (%)			
No difficulties	10 (62.5)	22 (59.5)	32 (60.4)
Difficulties	6 (37.5)	15 (40.5)	21 (39.6)
Number of falls last 12 months, *n* (%)			
No falls	12 (75.0)	30 (81.1)	42 (79.2)
One	1 (6.3)	6 (16.2)	7 (13.2)
Two	2 (12.5)	1 (2.7)	3 (5.7)
Three	0	0	0
More than three	1 (6.3)	0	1 (1.9)
4SBT, *n* (%)			
Stage 1 feet side by side 10 s	16 (100)	38 (100)	54 (100)
Stage 2 instep touches toe 10 s	16 (100)	37 (100)	53 (100)
Stage 3 tandem stand 10 s	12 (75.0)	28 (75.7)	40 (75.5)
Stage 4 one foot stand right 10 s	8 (50.0)	16 (43.2)	24 (44.4)
Stage 4 one foot stand left 10 s	8 (50.0)	18 (48.6)	26 (48.1)

who take longer than 14 s to complete the TUG have an increased risk of falls (Rockwood et al., 2000; Shumway-Cook et al., 2000).

In the 30sCST test, the participants were asked to rise from a chair repeatedly within 30 s. The test is used to assess the mobility and strength by timing the maximum number of stands from a chair in 30 s. The stand is performed with arms crossed over the chest and feet parallel. A score for the expected number of sit-to-stands, adjusted for age and gender, is provided. The number of stands is then categorized in three groups: *below normal*, *normal*, or *above normal*. The higher the score, the better the mobility. The test has good validity and reliability in measuring lower body strength in the elderly (Jones et al., 1999). Test–retest intraclass correlations of the 30sCST are high in both men (0.84) and women (0.92), indicating good stability of the measure. Moderate correlations between the test and leg-press performance suggest that 30sCST is a reasonably reliable and valid indicator of lower body strength in generally active, community-dwelling elderly. Construct validity is supported by the test's ability to detect differences between various age and physical activity level groups (Jones et al., 1999).

Balance

Two balance-related questions in the SA questionnaire [if the person had experienced difficulties with their balance within the last 12 months (yes = 1, no = 0) and number of falls the last 12 months (score 0–5, the higher the score, the more falls)], together with one of the FTs (4SBT), were used to measure the balance of the participants.

The 4SBT is used to assess static balance (Rossiter-Fornoff et al., 1995). The participants are instructed to stand in four different positions that are progressively harder to maintain. First, the person is instructed to stand with their feet side-by-side. The next position is to place the instep of one foot, so it is touching the big toe of the other foot. The third position is a tandem stand, i.e., to put one foot in front of the other, heel touching toe. Lastly, the person tries to stand on one foot. How long each position is held is measured in seconds; the hold should preferably exceed 10 s without the person moving his/her feet or needing support. The inability to maintain a tandem stand for 10 s has been associated with an increased risk of having a fall (Gardner et al., 2001). Test–retest of the 4SBT shows moderate correlation (0.66) in community-dwelling elderly. The test is also correlated to other measurements for balance in the same population (Rossiter-Fornoff et al., 1995).

Data Preprocessing

In the data preprocessing step, we applied the following filters and transformations to the FT results: (a) removing columns that had zero variance (all participants performed the exercise equally); (b) normalizing the test results using the (complementary) cumulative (sample) distribution function; (c) aggregating the four individual balance test results (two individual mobility test results, respectively) to a common balance (mobility) score using the joint cumulative (sample) distribution of the individual balance (mobility) scores. For each subject, the data transformations (b) and (c) computed a score expressing the probability of a performance worse than the subject's performance. The same transformation was applied to the SA and EA results.

The normalization (b) and aggregation (c) steps deserve some explanations and motivations: The cumulative distribution function (CDF) of a variable X is the probability that X will take a value less than or equal to x, i.e., $\mathrm{CDF}_X(x) = \mathrm{P}(X \leq x)$. It requires that X is measured at least on an ordinal scale, i.e., "less than" ($\leq$) is defined on X. For instance, balance test times induce an order; gender does not.

The distribution of X is, in general, unknown and can only be approximated numerically by observing a (representative, sufficiently large) sample X of the population X. Then, the empirical (or sample) cumulative distribution function (ECDF) is a good approximation of CDF. $\mathrm{ECDF}_X(x)$ can be calculated as the relative frequency of observations in the sample X that are less than or equal to x, i.e., $\mathrm{ECDF}_X(x) = |\{x|x\epsilon X, x{<}x\}|/|X|$ with $|\cdot|$ the size of a set.

The number of participants in the described study is relatively small and may be biased. Hence, we cannot claim that we assessed a representative sample X of the population X in any of the FTs. Consequently, ECDF_X may not yet be a good approximation of CDF_X. However, our study shows the predictability of the (empirical) scores from SAT data. It is plausible that this predictability continues to hold for scores based on larger samples, as well. Then, our deep learning model would predict the normalized score based on SAT data, and ECDF^{-1} of this score, the actual variable values.

What is considered a sample set that is sufficiently large depends on the number of distinguishable variable values; we would like to observe each possible value at least once in the sample. This number is finite for discrete value domains, e.g., the number of squats that are possible within 30 s for 30sCST (0… <100), but also for physically continuous value domains due to discretization of the measurement method and the digital representation, e.g., the balance time in 10th of a second for each 4SBT stage (0… 100). However, in the latter case, this number might become large, in general, e.g., when we would assess the balance time in microseconds (0… 10,000). Then, sufficiently large would become prohibitively large and expensive for practical studies. Consequently, for any reasonably practical sample size, ECDF would not be an injective but a *step* function, and its inverse ECDF^{-1} would provide the predicted *interval* of the variable values. This could either be accepted or avoided by using smoothing PDF/CDF estimations[6].

In the present study, we did not apply any mitigation and accept the too small sample as a limitation: although our study shows the predictability of the empirical scores from SAT data, it is not the capable of predicting the actual value of a test.

(E)CDF nicely generalizes to multivariate distributions allowing to integrate different variables into one score. For instance, the results from all stages of the 4SBT (five variables, say $X_1, X_2, X_3, X_{4\mathrm{r}}, X_{4\mathrm{l}}$) can be integrated into a balance score using the *joint* CDF. Again, each variable needs to be measured at least on an ordinal scale. For our purpose of scoring, it also needs to be known whether large or small values are desirable. For instance, for each variable X_1, X_2, X_3, $X_{4\mathrm{r}}$, $X_{4\mathrm{l}}$, larger balance times (up to 10 s) are desirable. If small values are desirable, we use the complementary CDF defined as $\mathrm{CCDF}_X(x) = P(X \geq x)$. As a consequence, regardless of whether large or small variable values are desirable, larger scores are always better than smaller, and 1 (resp. 0) is the best (resp. worst) possible score. The empirical complementary CDF is computed analogously to ECDF, i.e., $\mathrm{ECCDF}_\mathsf{X}(x) = |\{\mathsf{x} \mid \mathsf{x}\epsilon X, x \geq x\}|/|X|$. Without loss of generality, we continue our discussion based on the (E)CDF and do not explicitly mention the variables requiring (E)CCDF scoring.

Unfortunately, the inverse of a joint CDF is not unique. In general, CDF^{-1} maps a score s to a *set* of vectors $\{v_1 \ldots v_\mathrm{n}\}$, each vector with positions for each variable. More precisely, $\{v_1 \ldots v_\mathrm{n}\} = \mathrm{CDF}^{-1}(s)$ *iff* $s = \mathrm{CDF}(v_1), \ldots, s = \mathrm{CDF}(v_\mathrm{n})$. The vectors $\{v_1 \ldots v_\mathrm{n}\}$ are not comparable; i.e., for any two of them, say v and v', it is neither $v \leq v'$ nor $v \leq v'$. However, the set of vectors can be abstracted to value intervals of lower and upper values for each of the variables. For instance, for a concrete aggregated balance score, it can be stated that each of $X_1, X_2, X_3, X_{4\mathrm{r}}, X_{4\mathrm{l}}$ is within a concrete value interval.

Yet again, for representative, sufficiently large samples of the population, the joint ECDF approximates the joint CDF. Our deep learning model would predict the normalized joint ECDF score based on SAT data, and ECDF^{-1} of this score, the corresponding variable value intervals.

In summary, the normalized scores $s(v)$ of any measured/observed value v computed step (b) can be interpreted as the (sample) probability of finding a worse or equal value in the (sample) population. What "worse" means depends on the interpretation of the respective test. For example, lower values of physical activity (in minutes/week) are worse, whereas higher values of sitting and lying down (hours/day) are worse. To compensate for the different interpretations of values, we used the cumulative (sample) distribution function if high values were encouraged for a test, whereas we used the complementary

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[6] For instance, the Parzen–Rosenblatt window method, https://en.wikipedia.org/wiki/Kernel_density_estimation.

cumulative (sample) distribution function if low values were encouraged. As a result, all scores were normalized to between 0 and 1, and high scores were always better than low scores. For details of the normalization method, we refer to Ulan et al. (2019).

The SAT recorded movement sequences of the subjects' 3D joint positions. The Kinect camera used identified 25 such joints. Because of the low reliability of the other joints, we used only the following 13: head, left/right shoulder, left/right elbow, left/right wrist, left/right hip, left/right knee, and left/right ankle.

Each recorded movement is a sequence of frames. A frame is a record of features. It describes the body posture at a specific point in time during the recorded movement. A feature is called direct if it is directly measured by the 3D camera and indirect if it is computed from direct features or other indirect features. The direct features include the x, y, and z coordinates of 13 skeleton joints. Indirect features include the angles between different limbs and angles between limbs and the axes of the 3D coordinate system.

We conducted each machine learning experiment twice, once with the standardized features and once with the raw (direct and indirect) features.

We tested both the uncut sequences, including some frames where subjects were getting into position before starting the movement, and the sequences cut to encompass only the actual movement from start to finish. For the TUG tests, we always cut at the turning point.

In accordance with a standard technique in machine learning, we used data augmentation to artificially increase the number of training and test sequences. In general, data augmentation increases the amount of training data, e.g., by adding slightly modified copies of existing data, which reduces overfitting when training a model (Shorten and Khoshgoftaar, 2019). Specifically, we stretched each frame in the x and y directions by the same constant factors around 1, and we rotated each frame around the y axis by the same constant angle around 0 degrees. Cascading these transformations led to an increase of the number of sequences for machine learning by a factor of about 1,000.

Statistical Analysis

SPSS 26.0 (IBM Corp., Armonk, NY, USA) was used for descriptive statistics. Pearson correlation analysis was conducted using MATLAB version R2020a (Massachusetts, USA)[7]. Significance was set at $p < 0.05$. Pearson correlation coefficient r was used to determine the dependencies between three assessment approaches for mobility and balance. The correlation results were interpreted as low ($r < 0.30$), moderate ($0.30 \leq r < 0.60$), or high ($r \geq 0.60$).

Machine Learning/Deep Learning

In general, machine learning uses predictors (features) $X = [X_1, \ldots, X_p]$ to *predict* or *infer* a response (output) Y. It assumes a functional relationship, $Y = f(X_1, \ldots, X_p) + e$, with e being an irreducible random error and f representing the systematic information that X provides about Y. Statistical/machine learning tries to estimate functions f minimizing the *reducible* error. More precisely, to predict $Y = f(X_1, \ldots, X_p) + e$, machine learning calculates an estimator function $Y' = F(X_1, \ldots, X_p)$ and uses Y' as a predictor of Y.

If the estimator function F is accurate; i.e., the error between the actual response Y and its predictor is always small, machine learning can answer questions such as what is the expected value y of Y given the values $x = [x_1, \ldots, x_p]$ for the predictors $X = [X_1, \ldots, X_p]$. Moreover, if the estimator function F is sufficiently simple, machine learning can also give answers to questions such as the following: Which predictors are associated with the response? What is the relationship between the response and each predictor? Can the relationship between the response and each predictor be adequately summarized using a known type of function, e.g., linear? Unfortunately, there is a trade-off between prediction accuracy and estimator interpretability. For further details, we refer to machine learning textbooks such as James et al. (2013).

There are different ways of formalizing the reducible error. We selected the mean absolute error (MAE) for both learning F and assessing its accuracy on the training and test data, respectively. MAE is defined as the arithmetic mean of the absolute difference $|y - y'|$ for each actual response $y \in Y$ and its corresponding predictor value $y' \in Y'$ in the training and test data, respectively.

In our experiments, we use *deep learning* approaches that are known to trade off interpretability against accuracy. Here, deep learning approximates a function mapping sequences of 3D joint positions (preprocessed as described earlier) to the different SA, FT, and EA scores. The input shape depends on the number of indirect features and the number of frames in the shortest sequence; both varied in the different setups. As the responses, i.e., the different scores, are normalized to 0–1, the *MAE* is also between 0 (no error) and 1 (theoretical maximum). We interpreted the machine learning results, i.e., the accuracy of the trained predictor, as good (MAE $<$10%), moderate (10% $\leq$ *MAE* $<$20%), or bad (*MAE* $\geq$20%).

Our experiments applied standard neural network technology (Goodfellow et al., 2016) implemented in Python 3 using the Tensorflow framework (Abadi et al., 2015).

Architecture

We tested three principally different neural network architectures with roughly the same number of parameters to learn.

1. A dense network with three dense layers of 128, 64, and 32 neurons, respectively, all activated with a rectified linear unit (ReLU), and an output layer with a single output (the score) activated with a sigmoid activation function.
2. A convolutional neural network (CNN) with three one-dimensional (1D) convolutional layers with a depth of 128, 64, and 32 neurons, respectively, and all followed by a 1D maximum pooling layer of size two and activated with an ReLU, followed by an output layer, as in 1.
3. A recurrent neural network (RNN) with three long short-term memory layers of 32 neurons each, followed by an output layer, as in 1.

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[7] The Mathworks Inc., Natick, Massachusetts: MATLAB version 9.8.0.1323502 (R2020a).

In all architectures, we used either dropout, with a rate of 0.5 in the first layer, or kernel and activation regularization (L2 norm, penalty of 0.001) of the first two layers.

Training

We randomly split the original sequences into about 90% training data and 10% test data. We did not mix the augmented sequences. All transformed training (test) data sequences remained in the training (test) data set. We did not separate test and validation data.

For training, we used the MAE as the loss function. We trained the networks with a minibatch size of 128 data points for 500 epochs. We used early stopping if the validation loss (MAE) did not decrease for the latest 50 epochs. The whole machine learning process is summarized in **Figure 1**.

We used the Tensorflow default weight initialization (Glorot uniform initializer) for all layers. It draws samples from a uniform distribution within $[-limit, limit]$, $limit = \sqrt{(6 / (in\ degree + out\ degree))}$, and *in* (*out*) *degree* the number of predecessors (successors) of a neuron.

We used "Adam" as the gradient-based weight optimization strategy for the dense and the convolutional networks, and "RMSprop" for the RNNs. Both approaches are implemented in Tensorflow, and we applied the provided default hyperparameters (learning rate, etc.).

In general, we avoided fine-tuning of hyperparameters. The explicitly set training parameters were initially chosen by experience and then only minimally adapted after a visual inspection of the learning history in some few initial tests (as reported). For most hyperparameters, we chose the default settings of the Tensorflow framework. The rationale behind this approach was that the goal of the present study was to principally show the predictive power of SAT data for FT scores. The small sample size alone prohibited aiming for optimal prediction models or minimal training times. This will become future work when large and representative samples are available.

Machine learning approximates a predictor function mapping predictor values (here, SAT frame sequences) to response values (here, the different normalized values, e.g., the time in seconds that a subject was able to stand on one leg). The results reported are the MAEs of the predictor functions applied on the test data using cross-validation. In detail, we

1. added features to the SAT frame sequences, such as angles between adjacent limbs, or skipped this step;
2. cut the SAT frame sequences to encompass the period between start and stop of the actual exercise, or skipped cutting;
3. augmented the resulting SAT frame sequences;
4. standardized the SAT frame sequence data, or skipped standardization;
5. normalize the observed values, cf. preprocessing (b);
6. aggregated these values to a score, cf. preprocessing (c);
7. copied the scores such that each SAT frame sequence transformed in Rejeski et al. (2015) got the same score as its original;
8. performed 10-fold cross-validation that iterated 10 times through the deep learning (step 9); and
9. performed deep learning on each fold.

The cross-validation step 8 randomly split the preprocessed predictor and response data into 10-fold. Cross-validation was iterated 10 times through the deep learning step 9, each time choosing a new fold as the test data and using the remaining folds as the training data. The overall result is the average over the 10 computed MAEs from each iteration. In each iteration, step 9 learns an estimator function *F* for the training data, mapping the contained predictor to response data. Its MAE is then computed on the test data.

Because of the high computational effort, cross-validation was only performed on promising combinations of preprocessed data and neural network model. Predicting FT and EA scores from balance SAT data using the CNN and the RNN based models gave promising results, i.e., good accuracy for predicting two of three FTs (4SBT, 30sCST) and the EA and moderate accuracy for the

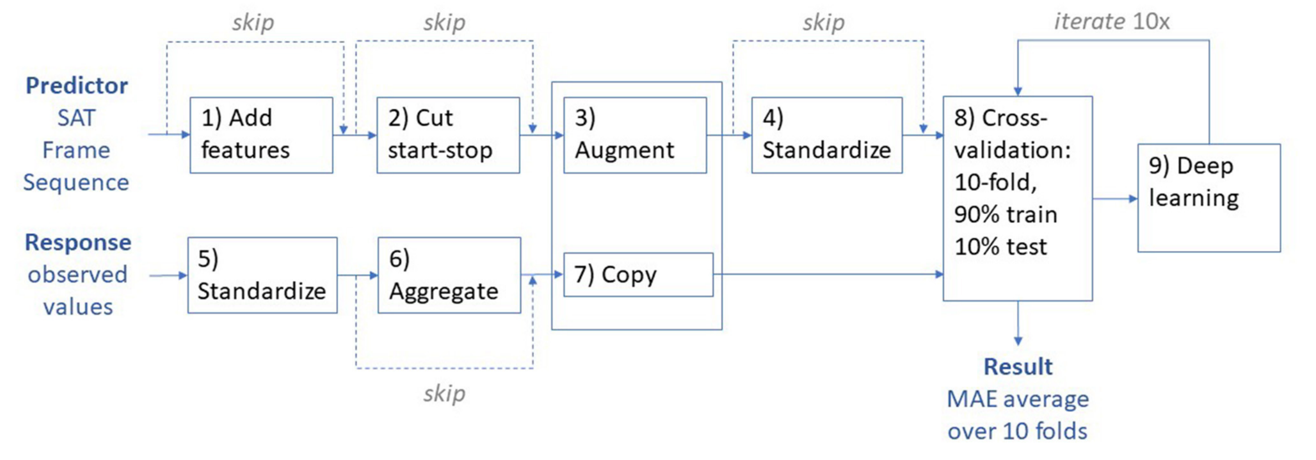

FIGURE 1 | Summary of the machine learning process.

third FT (TUG), as we will document in the following section. Therefore, we cross-validated these predictor models.

RESULTS

Summary of Collected Data

Table 1 presents a summary of the collected data for the FTs (TUG, 30sCST, 4SBT) and the SA questionnaire. Most participants performed well or very well on the tests. Twenty-eight persons (52.8%) carried out leisure-time physical activities for more than 5 h/week. All but four persons (7.5%) stated that they performed moderate to high levels of physical activities every week. Six persons (11.3%) reported that they spent 10–15 h sitting or lying down every day. Approximately half of the sample (52.8%) had an exercise program that they followed. How many times a week they performed the program varied, as did the length of the programs. Of those who followed an exercise program, 65.5% had a program that was 30 min or longer. Participants were also asked if they considered themselves physically active; 71.7% did. Eleven persons (20.8%) reported having had a fall one or several times during the last 12 months. Twenty-one persons (39.6%) stated that they had experienced difficulties with their balance within the last year (**Table 1**).

All study participants managed the TUG test within 20 s, indicating independent walking. According to the 30sCST, 45 persons (84.9%) in the present study had muscle strength as anticipated or better given their gender and age. All study participants managed the first stage of the 4SBT, i.e., standing for 10 s with feet side-by-side. The third stage of the 4SBT, i.e., the "tandem stand," standing with one foot in front of the other, showed that 13 persons (24.5%) in the sample might be at risk of having a fall.

Correlation of Mobility and Balance Assessments Between FTs, SA, and EA

There was a moderate (significant) correlation between the 30sCT and the TUG test, and between the third stage of the 4SBT (4SBT3), i.e., the tandem stand position, and the fourth and final stage of the 4SBT (4SBT4), i.e., the one-foot standing position, on the right or left foot, respectively. No significant correlation was found between the second stage of the 4SBT (4SBT2), i.e., one foot placed with the toes at the insole of the other foot, and the other stages of the 4SBT, the TUG test, or the 30sCST. There was a high (significant) correlation between right and left foot for the 4SBT4 (**Table 2**). There was a moderate (significant) correlation between the functional balance test scores (FT balance), i.e., the 4SBT, and the SA scores that related to mobility (SA mobility) (**Table 3**). No significant correlation was seen between the 30sCST and EA.

Prediction of FT and EA Results Using the SAT

The SAT data–based neural network models were well able to predict the aggregated functional balance test score, the 30sCST, and the EA of the sit-to-stand movement. However, the models could predict the result of the TUG test only with moderate accuracy (**Table 4**).

TABLE 2 | Correlation coefficients of mobility and balance characteristics in FTs.

r (*p*)	**TUG**	**30sCST**	**4SBT2**	**4SBT3**	**4SBT4, right**
30sCST	**0.55 (0.001)**				
4SBT2	0.09 (0.536)	−0.04 (0.773)			
4SBT3	−0.03 (0.847)	0.18 (0.207)	−0.08 (0.576)		
4SBT4 right	0.22 (0.122)	0.25 (0.081)	0.12 (0.407)	**0.34 (0.018)**	
4SBT4 left	**0.36 (0.011)**	**0.31 (0.029)**	0.14 (0.318)	**0.40 (0.004)**	**0.67 (0.000)**

Bold font mean p < 0.05; TUG, Timed Up and Go; 30sCST, 30-s chair stand test; 4SBT2, second stage of the 4SBT, i.e., 10-s one foot placed with the toes at the insole of the other foot; 4SBT3, third stage of the 4SBT, i.e., 10-s tandem stand position; 4SBT4, fourth stage of the 4SBT, i.e., 10-s one-foot stand.

TABLE 3 | Correlation coefficients of aggregated mobility and balance scores in SA and FTs.

r (*p*)	**SA balance**	**SA mobility**	**FT balance**
SA mobility	0.2 (0.167)		
FT balance	0.18 (0.217)	**0.40 (0.005)**	
FT mobility	0.22 (0.134)	−0.05 (0.755)	0.19 (0.198)

Bold font mean p < 0.05. SA, self-assessment; FT, functional test.

Moreover, based on the SAT data of the fourth and final stage of the 4SBT (4SBT4), i.e., 10 s, one-foot stand, the neural network models could well-predict the performance in the 30sCST and the EA of the sit-to-stand movement. They were able to predict the TUG test result only with moderate accuracy (**Table 5**).

To secure the results, we conducted 10-fold cross-validation on the predictions based on the SAT data of the 4SBT. We restricted the cross-validation to the CNN and RNN model variants. Cross-validation confirmed that SAT 4SBT4–based RNN models could predict the performance in the functional balance tests and the EA of the sit-to-stand movement. The RNN models consistently outperformed the CNN models. The RNN models were even able to predict the TUG test result with high accuracy. However, they could predict the 30sCST test result only with moderate accuracy (**Table 6**).

DISCUSSION

The results of this study indicate that the SAT-based data of the 10-s one-foot stand balance test (4SBT4) could be used to predict the results of all functional balance tests (MAE 7.82% cross-validated), the TUG test (MAE 8.03% cross-validated), and

TABLE 4 | MAEs for predicting FT results and EA scores using the corresponding SAT data.

	SAT 4SBT4 → FT balance	SAT 30sCST → FT 30sCST	SAT TUG → FT TUG	SAT 30sCST → EA sit-to-stand
MAE in %	2.31%	7.40%	16.22%	5.89%
Model/data	RNN/uncut, not norm., direct features	CNN/cut, normalized, direct features	CNN/uncut, normalized, all features	RNN/cut, normalized, all features

SAT, skeleton avatar technique; FT, functional test; 4SBT4, fourth stage of the 4SBT, i.e., 10-s one-foot stand; 30sCST, 30-s chair stand test; TUG, Timed Up and Go; EA, expert assessment; MAE, mean absolute error; RNN, recurrent neural network; CNN, convolutional neural network.

TABLE 5 | MAEs for predicting FT and EA scores using SAT balance data.

	SAT 4SBT4 → FT 30sCST	SAT 4SBT4 → FT TUG	SAT 4SBT4 → EA sit-to-stand
MAE in %	7.02%	18.21%	6.86%
Model/data	RNN/uncut, normalized, all features	CNN/uncut, normalized, all features	CNN/uncut, not norm., all features

SAT, skeleton avatar technique; FT, functional test; 4SBT4, fourth stage of the 4SBT, i.e., 10-s one-foot stand; 30sCST, 30-s chair stand test; TUG, Timed Up and Go; EA, expert assessment; MAE, mean absolute error; RNN, recurrent neural network; CNN, convolutional neural network.

the EA results of the sit-to-stand movement (MAE 8.79% cross-validated). They might be used to predict the results of the 30sCST (11.0% cross-validated). This first attempt to validate the SAT in relation to commonly used FTs in healthy and physically active older adults provides support to proceed with a larger sample of people with a varying degree of functional ability before the SAT can be used as an alternative method for assessing mobility and balance.

This study is the first step to outline the possibilities of using the SAT to obtain detailed, objective, and reliable information from simple and accessible functional assessment of balance and mobility. Muscular and functional asymmetries have been shown to represent a risk factor for falls among older adults, and a current review study outlined that symmetricity in gait was correlated with better functional performance among older adults. Interventions to improve symmetry in movement patterns are therefore important (Guadagnin et al., 2019). Assessment of the qualitative aspects of movement performance, i.e., symmetricity, as mentioned above, how the movement is initiated, how force is used to accomplish the movement, and how the movement is coordinated, requires a trained expert, e.g., a physiotherapist. Such assessment could be expensive and time-consuming and is therefore often overlooked. The qualitative aspects in the assessment of movement performance can be crucial, especially among older adults, because of their increasing need to use their physical resources optimally. This may, for example, play an important role in the ability to perform physical activities in daily life and could provide valuable information about the risk of falls. These aspects seem to be missing in the studied standardized functional assessment tests (TUG, 30sCST, and 4SBT), which has been confirmed in previous studies (Inkster and Eng, 2004; Manckoundia et al., 2006). Including these aspects in the assessment of functional ability and in interventions targeting older adults is therefore important, as it may increase physical confidence, competence, and motivation for a safe, independent, and physically active life and reduce the risk of falls. The results from this pilot study indicate that the SAT has the potential to facilitate and supplement the clinically used FTs and may be a future solution to add qualitative perspectives to the assessment of functional ability.

Thirteen joints of the body were selected in the SAT analysis. Although the selected joints cover a large amount of the body segments, it is important to acknowledge that important movement segments (such as detailed movements of the feet or the neck) might still be missing in the overall analysis, which may be essential for the understanding of the whole movement performance. However, the SAT has the ability to add detailed information about relationships between multiple body segments in complex movement patterns, which is not possible to detect with the human eye. This information might be valuable in the clinical setting, i.e., for physiotherapists in movement assessment and evaluation. However, further development of SAT is needed to include all body segments. More research is furthermore needed to outline how the SAT can predict other kinds of movements, person transfers, and FTs and if the SAT can be used based only on a 2D video, which would imply greater accessibility for people to use the technique without expensive equipment and expert assistance. As we move into a period of increased population aging, everyday rehabilitation and preventive work in community care will not always be prioritized alongside domestic care. Thus, older adults may benefit from easy assessments of functional ability that can be used with the help of a nursing assistant or family caretaker in their own home. Furthermore, the SAT may create a greater possibility to detect physical impairment at an early stage, which is crucial in fall prevention and for the preservation of physical independence in aging.

Adults who have developed a lifelong understanding of the role of physical activity in healthy aging, who know about body movement skills and methods of improvement, may be more likely to sustain engagement in physical activity as an integral and meaningful part of their lifestyle in older age (Jones et al., 2018). Highly active persons of older age tend to use their resourcefulness to support their physical activity, which in turn contributes to their view of themselves as active. Barriers to being physically active in older age are all influenced by how older adults view themselves and how they are cognizant

TABLE 6 | Cross-validated MAEs for predicting FT and EA scores using SAT balance data; only recurrent neural networks (RNN).

	SAT 4SBT → FT balance	SAT 4SBT → FT 30sCST	SAT 4SBT → FT TUG	SAT 4SBT → EA sit-to-stand
MAE in %	7.82%	11.0%	8.03%	8.79%
Data	Uncut, not normalized, all features	Uncut, not normalized, all features	Uncut, not normalized, all features	Uncut, not normalized, all features

SAT, skeleton avatar technique; FT, functional test; 4SBT4, fourth stage of the 4SBT, i.e., 10-s one-foot stand; 30sCST, 30-s chair stand test; TUG, Timed Up and Go, EA, expert assessment; MAE, mean absolute error.

of and understand the social and physical environment and opportunities surrounding them (Jones et al., 2018). Although there is now strong evidence that regular physical activity is key to preserving physical function and mobility, which can delay the onset of major disability among older adults (Pahor et al., 2014; Dipietro et al., 2019), the majority of older adults do not achieve the recommended goals of physical activity (World Health Organization, 2015). Attitudes toward physical activity, lack of social support, feelings of being too old, and having few opportunities for physical activity in the surroundings are common barriers (Büla et al., 2011). There is vast opportunity for improvement in how to enhance physical literacy among older adults, which includes the motivation, confidence, and physical competence to achieve a physically active life (International Physical Literacy Association, 2015; Jones et al., 2018). In these efforts, the SAT may play an important role in facilitating assessments, providing feedback on movement performance, and improving physical competence, which in turn may contribute to the motivation and confidence to support and maintain physical activity throughout life.

In this study, EAs of the qualitative aspects of the movement performance were made only of the sit-to-stand movement. The duration of the sit-to-stand or stand-to-sit postural transition is commonly used for assessing function and strength of the lower extremities and can distinguish between older adults at low and high risk of falls. The sit-to-stand transition represents a complex motion that involves torques and forces on multiple joints (the trunk, hips, and knees), as well as requiring energy. However, it is argued that its duration is not sufficient to describe physical impairment in older adults (Inkster and Eng, 2004; Manckoundia et al., 2006). A model for optimality of the sit-to-stand movement has been developed that seems to be useful in detecting mobility changes (Madhushri et al., 2017). A fast sit-to-stand posture transition involves larger torques and greater wear on the body than a slow transition (Kerr et al., 1997). For each individual body constitution, there are movements/actions that provide optimal posture transition time. Physically fit persons are spontaneously very close to the optimal transition time, whereas older adults normally deteriorate in muscle strength and need to spend their resources wisely. Such persons might benefit from qualitative assessment of movement performance and functional ability, followed by tailored programs for exercise and mobility-oriented physical activity, to reach their optimal transition time. The results from the current study show that EAs of the sit-to-stand movement (Backåberg et al., 2020) did not correlate well with the 30sCST, but could be predicted by the SAT. The reason for this is unknown, but it may indicate that there is a complex movement pattern that is not easily assessed and that there might be a non-linear association between EA and the sit-to-stand movement. The clinical assessments of functional ability may possibly be substituted by the SAT in future tools.

STRENGTH AND LIMITATIONS

A strength of the article is the effort to develop a novel approach of assessing physical functioning in older adults, such as early identification of functional ability using modern technology. Another strength for the development of SAT in the early stage as we are was the low internal dropouts and that the whole sample had the strength and ability to perform all the different tests included. However, some limitations are needed to pay attention to. This pilot study is based on a small sample ($n = 54$), which increases the risk of type II error. Another design limitation in this study is that no causal relationships between the variables can be identified with this set up. Although the participants were community-dwelling older adults (>65 years), they were recruited through a limited number of pensioners' associations, which might imply that this group included rather healthy, physically active, and dedicated older adults. Thus, the results of the SAT can primarily be generalized to this population of primarily healthy individuals and not fully represent the older population as a whole. The small and homogenous sample (with regard to mobility and physically active) was beneficial for the current developmental phase, but might have affected the results of the tests, as most participants performed very well on the tests, with small variations. This might have impacted on the SAT's ability to predict the results of the functional mobility tests (30sCST, TUG). The same applies to the functional balance tests (4SBT) and the EA of movement quality (EA).

To compensate for the relatively small sample size, we tested the significance in the correlation analysis. For the neural network learning experiments, we applied aggressive data augmentation and cross-validation, as detailed in *Data Preprocessing*. Still, more experiments with a larger sample are needed to confirm the results.

As use of the SAT in assessing older adults' mobility and balance is relatively new, more research is needed. In the next step, participants with more functional limitation variations should be included, to further evaluate the tests used. More sensitive tests would also be recommended.

The 3D technology was quite bulky and would need to become handier before any use in the caretaking practice can be recommended. Current activities aim at using 2D SAT-based mobile phone recordings. While the resulting skeleton avatar sequences contain even less information than the corresponding 3D-based sequences, they may contain enough information about the different FTs to yield relevant results.

The employed deep learning networks are hard to interpret for humans. The results merely show that the SAT sequences can provide systematic information about the FTs. To gain relevant insights into the dependency between the SAT sequences and the outcome of tests, other machine learning models should be used, features should be manually selected and deselected, and the prediction results of the different models should be compared.

CONCLUSION

Both in science and in clinical practice, there is a need to reduce the use of tests of functional ability that are difficult for patients to perform independently and replace with valid, simple, and accessible tools. In this study, we attempt to understand and verify what it is that we measure with FTs and how they correlate with new techniques. This study shows that the SAT may be a tool that is able to detect qualitative aspects in the assessment of movement performance, which seem to be missing in commonly used standardized functional assessment tests of mobility and balance (30sCST, TUG, and 4SBT). SAT was also shown to be able to a high extent predict the results of the 4SBT, TUG, and EAs of the sit-to-stand movement and, with some restrictions, the results of the 30sCST. However, this is the first attempt to use SAT as a functional assessment tool, and it needs to be investigated further, for example, how sensitive the SAT is to identify changes in physical activity levels and predict other aspects of functional ability. Research is also needed to investigate if SAT can identify changes in self-efficacy in movement performance, as well as securing the prediction of the 30sCST test in the older population.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Swedish Ethical Review Authority (Dnr: 2019-02553). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AHe, CF, AHa, WL, and ME contributed to the conception and design of the research plan. AHe, SB, and WL were responsible for the acquisition of data. AHe, AL, and CF conducted the statistical analysis of the self-assessments, the functional tests, and the expert assessment. WL designed, implemented, and conducted the deep learning experiments. SB drafted the manuscript and completed the expert assessment. All authors contributed with writing different parts and provided a critical review of both intermediary and final drafts of the manuscript and approved the final draft prior to journal submission. All authors accept accountability for the parts of the work they have done.

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SUPPLEMENTARY MATERIAL

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Conflict of Interest: WL is a co-founder of AIMO (https://aimo-fit.com/), which developed the SAT software used in this study.

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Stakeholder Recommendations to Increase the Accessibility of Online Health Information for Adults Experiencing Concussion Symptoms

M. Denise Beaton[1,2]*, *Gabrielle Hadly*[1,3] *and Shelina Babul*[1,4]

[1] British Columbia Injury Research and Prevention Unit, British Columbia Children's Hospital Research Institute, Vancouver, BC, Canada, [2] British Columbia Centre for Disease Control, Population and Public Health, Provincial Health Services Authority, Vancouver, BC, Canada, [3] School of Population and Public Health, University of British Columbia, Vancouver, BC, Canada, [4] Department of Paediatrics, University of British Columbia, Vancouver, BC, Canada

Background: Concussion is a global public health problem. In Canada, concussion is among the top five reasons for workplace time-loss. Concussion results in physical, cognitive, and/or emotional symptoms that temporarily worsen with physical and mental exertion, such as viewing electronic screens. The Internet is the primary source of consumer health information. Studies on the end-user needs of adults with brain injuries in regards to digital health technologies largely focus on informational content. There is little to no research on the accessibility of screen-based informational websites and smartphone applications among this population.

Objective: The aim of this research was to involve stakeholders in the design of a comprehensive educational resource to guide concussion recognition, recovery, and return-to-work, called the Concussion Awareness Training Tool for Workers and Workplaces (CATT WW). In order to ensure both relevant content and appropriate delivery of the information to the target groups, participants were asked whether adaptations could increase the accessibility of online health information for the general adult population experiencing concussion symptoms.

Methods: Data have been generated through semi-structured in-depth interviews and focus groups with participants from across British Columbia (BC): workers from various industries who were in the concussion recovery process or had returned to work ($n = 31$); and healthcare or workplace professionals who support concussion diagnosis, recovery, and return-to-work ($n = 16$). Data were analyzed using NVivo 12. Before commencing data collection, ethical permission was granted by the University of British Columbia Research Ethics Board (H18-00604), and approval was received from WorkSafeBC Research Services.

Results: Participants ($n = 47$) recommended twenty adaptations or supplements to electronic screen-based digital health technologies.

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Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Aniko Bartfai,
Karolinska Institutet (KI), Sweden
Ingvar Krakau,
Karolinska Institute (KI), Sweden

***Correspondence:**
M. Denise Beaton
m.denise.beaton@gmail.com
orcid.org/0000-0002-4106-2414

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Conclusion: Given the high prevalence of concussion among the working adult population, the symptom exacerbation commonly caused by prolonged use of electronic screens, and the demand for online educational resources, these findings can guide clinicians, researchers, technology developers, employers, and occupational health and safety committees to further support adults in concussion recovery and return-to-work.

Keywords: concussion, mild traumatic brain injuries, accessibility, online resources, digital health, technology

INTRODUCTION

Concussion, a term often used interchangeably with mild traumatic brain injury, represents 70–90% of all traumatic brain injuries and reportedly affects 100–600 people per 100,000 annually, depending on the definition criteria used (1, 2). In Ontario, Canada, recent analysis of linked data found an average annual incidence of 1,153 per 100,000 (3). These numbers are likely an underestimate of the true burden of concussion, given the lack of consistent reporting standards, misdiagnoses, and the inability to account for individuals who do not seek treatment (4, 5). The World Health Organization Neurotrauma Task Force defines mild traumatic brain injury as a blow or jolt to the head resulting in an acute disruption of brain function, manifested by a brief loss of consciousness (<30 min), confusion, or posttraumatic amnesia (<24 h) not accounted for by factors such as psychological trauma or alcohol/drug intoxication (6). A concussion can result in a variety of physical, cognitive, and emotional symptoms such as headache, blurry or double vision, anxiety, irritability, slowed reaction times, balance issues, and insomnia (7).

Most adults with a concussion recover within 1–3 months (8, 9). Expert consensus statements advise rest for 24–48 h, followed by gradually resuming normal activities in a step-wise approach, guided by the symptom exacerbation threshold (7, 10). Post-concussion syndrome, wherein symptoms persist past the standard recovery period, is estimated to occur in ∼15–30% of individuals, with prevalence rates varying significantly depending on timing, measurement, and classification method used (11, 12). Any individual is susceptible to a concussion; however, the majority of research focuses on sport-related concussions, children and youth, and military populations, resulting in a dearth of resources to guide concussion recovery and return-to-work for the average adult (13, 14).

An online survey commissioned by the Public Health Agency of Canada found that 97% of respondents believed concussion was an important health problem, with 51% of respondents indicating that they knew where to seek information on concussion. However, 54% of respondents did not know how to respond to a potential concussion, and 60% reported being unable to recognize the symptoms of concussion (15). Given that concussion awareness often precludes diagnosis, and that the management of concussion recovery relies upon self-report of symptoms, increasing education and awareness among the general public is crucial. The primary method of accessing health information is online, with 94% of Canadian households and 87% of American households connected to the Internet (16–18). In 2013, the British Columbia (BC) Injury Research and Prevention Unit, in partnership with BC Children's Hospital Foundation, Child Health BC and the BC Ministry of Health, developed the Concussion Awareness Training Tool (CATT), an accredited online continuing education course for medical professionals. The course was then redeveloped in 2018, in partnership with the Public Health Agency of Canada via Parachute Canada, a national nonprofit dedicated to reducing preventable injuries. Redevelopments included updating and incorporating new and emerging evidence, as well as translating all modules to French. Since its debut in 2013, CATT has developed a series of free-of-charge online educational modules and resources for other audiences including parents, players, coaches, and school professionals. A module specific to intimate partner violence has now been included and one specific to high performance athletes is scheduled to launch in early 2021. The content in all modules is evidence-based and aligns with the 2017 recommendations from the consensus statement on concussion in sport and new and emerging evidence. The site is frequently updated to accurately reflect the rapid pace of evolving concussion research and related best practice (4).

Due to high demand and current international gaps in addressing non-sport related concussion among adults, CATT for Workers and Workplaces (CATT W&W) launched June 2019. CATT W&W provides easy access to current best practices for concussion recognition, diagnosis, treatment, and management tailored for workers and their families, workplaces including employers, members of safety associations, unions, and joint occupational health and safety committees. This is the first CATT resource addressing adults who are experiencing concussion symptoms as a key audience, and ensuring the accessibility of this information is critical. Digital health information is necessary in supporting individuals to make knowledgeable decisions about their care. The third most common Internet activity is searching for health information (19). Health information is abundant online, and sifting through resources increases demands on the user's memory (20). It is common for health information to be unsatisfying when it fails to consider individual needs (21). Through involving stakeholders in the design of the CATT W&W resource, the information compiled—and the methods of presenting that information—will be of greater relevance. The overall objective of this study was to create an innovative educational product that meets the needs of the end-users and increases concussion knowledge and awareness. The study intends to identify potential adaptations or supplements which can increase accessibility of digital health technologies.

METHODS

Study Design

Among other aspects of the broader CATT W&W study on facilitators and barriers for recovery and return-to-work, the present study aims to identify adaptations and supplements to increase accessibility of online health information for the general adult population experiencing concussion symptoms. Qualitative research methods were used in order to generate knowledge grounded in human experience (22). We used interviews and focus groups to engage workers who had sustained a concussion and were in the recovery process or had returned to work, and workplace or healthcare professionals who support concussion recovery and return-to-work. The resulting data were assessed through qualitative inductive thematic analysis. Inductive thematic analysis allows for theoretical insights to be generated from data, as opposed to deductive research wherein theoretical hypotheses are tested via data collection (23). The ontology of this study fits within the social constructivist paradigm, recognizing that health does not exist separately from the person experiencing it (24).

Recruitment

Participants were purposively selected with the following criterions for inclusion: Workers to be between 19 and 64 years of age, and to have sustained a concussion, either at the workplace or outside of work, and to be in the recovery process or to have recovered and returned to work; Healthcare and workplace professionals were required to be a member of a joint occupational health and safety committee, a workers' union, a WorkSafeBC (the provincial workers' compensation board) professional, or a healthcare professional who is involved in any/all stages of diagnosis, treatment, and management of concussions with the general adult population.

We chose to invite the participation of workers from diverse industries with high rates of concussion, in order to obtain rich and relevant data. Invitations to participate were sent via email to over 100 British Columbian occupational health and safety committees, unions, and organizations within industries with high rates of time-loss concussion claims: service sector; transportation and warehousing; trades; public sector; primary resources; construction; and manufacturing (25). Invitations to participate were disseminated via email among WorkSafeBC staff, and recruitment posters were displayed in common areas on bulletin boards in WorkSafeBC offices. Invitations to participate were disseminated via email among concussion clinics and healthcare professional associations. The invitation to participate letter and poster instructed interested parties to email or phone the researchers. Upon contact, potential participants were sent a consent form to review, and provided with the opportunity to ask questions regarding the study. Participants were offered the opportunity to take part in a one-on-one interview, or a focus group with other participants from the same industry.

Participant Characteristics

Forty-six participants represented all health authority regions of BC, with approximately two thirds of workers residing in an urban location and one third in a rural location. One participant was from Ontario, and was forwarded invitation to participate from a contact in BC. The primary languages for workers were English ($n = 30$) and Senegalese ($n = 1$). The majority of workers experienced immediate symptom onset following the concussion-causing event ($n = 30$) while one experienced delayed symptom onset. The location of the most recent concussion-causing event was either at work ($n = 14$) or outside of work ($n = 17$), however, several participants in the latter category were commuting to or from work at the time of the concussion-causing event.

Ten female and six male healthcare and workplace professionals participated in the study. Occupations of workplace professionals were WorkSafeBC case managers ($n = 2$) and workers union advocate ($n = 1$). All healthcare professionals were employed at concussion clinics in the following occupations: occupational therapist ($n = 5$); kinesiologist ($n = 2$); psychologist ($n = 1$); physician ($n = 1$); neuropsychologist ($n = 1$); physiotherapist ($n = 1$); clinical counselor ($n = 1$); and office manager ($n = 1$).

Data Collection

Data were collected from spring 2018—winter 2019 in Vancouver, BC. Sixteen participants chose to form three focus groups consisting of: three participants (workers; arts, entertainment, and recreation), three participants (workers; arts, entertainment, and recreation), and 10 participants (healthcare professionals; concussion clinic). The remaining 31 participants preferred one-on-one interviews (three healthcare professionals; three workplace professionals; 25 workers) (**Tables 1**, **2**). Workers of those interviews, 13 were in-person, held at the BC Injury Research and Prevention Unit offices, and 18 were held by telephone for geographical reasons.

In acknowledgement of their time, all participants received a $10 CAD honorarium in the form of a gift card to a coffee shop of their choice. Participants interviewed via telephone received an e-gift card. One participant requested that the researcher give their $10 CAD honorarium to a random person experiencing homelessness. While a noble gesture, this request was outside the parameters of the study and would not conform to the requisite paper trail of a purchase receipt and a confirmation of gift card form signed by the participant. With the participant's approval, the researcher instead donated the $10 CAD honorarium to a non-profit which serves Vancouver's youth population experiencing homelessness.

Two semi-structured question templates with key questions and discussion prompts were used. The question template for workers contained a brief section with sociodemographic questions (gender, age, primary language, current occupation, length of time in current occupational role), followed by a section on the experience of concussion including the mechanism of injury and diagnosis. The next section pertained to the experience of recovery and return-to-work. The final section referred to resources which provided information or support, ranging from resources used, and resources required but non-existent. The penultimate question was what participants wished workers and workplaces in their industry knew about concussion; this

TABLE 1 | Workers sample characteristics ($n = 31$).

Category	Grouping	n
Sex	Male	9
	Female	22
Age	25–35	10
	36–45	4
	46–55	13
	56–60	4
Industry	Health Care	15
	Arts, Entertainment and Recreation	7
	K-12 Education	2
	Scientific / Technical Services	3
	Construction	1
	Transportation and Warehousing	1
	Administrative and Support	1
	Security	1
Length of Time in Occupation	1–5 Years	5
	6–10 Years	7
	11–15 Years	10
	16–20 Years	3
	21+ Years	6

TABLE 2 | Workers sample injury characteristics ($n = 31$).

Category	Grouping	n
Number of Concussions	1	15
	2	4
	3	7
	4	1
	5+	4
Mechanism of Injury*	Slip, Trip, or Fall	9
	Struck By/Against	15
	Car Crash/Collision	7
Level of Pre-Injury Concussion Knowledge**	A Lot	3
	Moderate Amount	6
	A Little	10
	None	11
Immediate Action After Injury*	Sought Medical Care	13
	Rested	4
	Resumed Activities	14
Family Support During Recovery*	Yes	19
	No	4
	Mixed	8

**Most recent concussion; **Pre-injury concussion knowledge prior to first concussion.*

provided an opportunity for participants to summarize their message, their reason for partaking in this research, and for the researcher to member-check their responses to increase accuracy. The final question was whether there was a question the researcher should have asked, but did not. In response, the first worker participant interviewed proposed, "*how can online resources accommodate people currently experiencing concussion symptoms*?" This question was then added to the interview guides for all subsequent interviews and focus groups. At the conclusion of the interviews and focus groups with workers, participants were encouraged to email or call the researcher if they later remembered something they wished to say, and were offered a copy of the question guide. Six participants experiencing memory loss wrote follow-up emails to expound upon their responses in the interview or focus group, and these communications were included in the data analysis.

The question template for workplace and healthcare professionals was briefer than the question template for workers. Sociodemographic questions were restricted to gender and occupation, while background questions were the length of time in their current role, and how they are involved in supporting workers who sustain concussions. The workplace and healthcare professionals question template focused on resources—resources used in their work, gaps in resources for workers and families, the optimal delivery of resources, the added question of how online resources can be presented to accommodate people experiencing concussion symptoms—and once again ended with, "*Is there any question that I [the researcher] should have asked, but didn't*?" Throughout the interview and focus groups, the researcher member-checked, summarized what was discussed and asked if anything was missed. The interviews and focus groups for all participants ranged from 14 to 150 min long, and the average length was 45 min. The digital audio-recordings of interviews and focus groups were professionally transcribed.

Data Analysis

Transcripts were cleaned of identifying information and the text was read through while listening to the audio to ensure accuracy. Raw data were archived with dates to provide an audit trail and a means of confirming our data analysis and interpretations for adequacy. An Excel spreadsheet was used to log all raw data, and to detail the progress in collecting and converting raw data to text that was subsequently analyzed by two independent researchers using NVivo 12, a qualitative analysis software. Step-by-step inductive thematic analysis was conducted in an iterative process, occurring concurrently with data collection. This allowed for newly emerging questions, such as digitally presenting information without provoking symptoms, to be explored. After familiarizing themselves with these data thoroughly, the researchers organized these data into a series of codes, described by Chapman, Hadfield and Chapman as "short statements that capture the meaning of the phrase, [. . .] used to index the data and group together phrases with similar ideas or meaning" (2015, p. 203). The codes were then combined into themes, which were reviewed and compared for comprehensive coverage of the data, and checked against new raw data, until saturation—wherein no new themes emerge—was reached.

The advantages of thematic analysis were its usefulness to synthesize large amounts of information, examining the perspectives of diverse research participants, cataloging the similarities and differences, generating insight while producing a well-organized final report (26). The limitations of thematic analysis typically include the potential for researchers to let unconscious bias influence the results. In an effort to reduce implicit bias, researchers reflected on their own relationship with concussion; MDB conducted the interviews and subsequent analysis and had never experienced a concussion, and GH, who also conducted the analysis, had sustained several sport-related concussions. To demonstrate validity and minimize bias, researchers wrote memos justifying selection or rejection of particular phrases and codes, and met frequently for inter-rater comparisons and discussion.

Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki (27). Before commencing data collection, ethical permission was granted by the University of British Columbia Research Ethics Board (H18-00604), and approval was received from WorkSafeBC Research Services. The participants' privacy was guaranteed by confidentiality throughout the entire study. Prior to the interview or focus group, each participant received a copy of the consent form via email with ample time to review. In the interview or focus group, participants were once again given the opportunity to examine the consent form and ask questions regarding the study. After being informed of the study aim, of their rights, and that participation was voluntary in all aspects, each participant provided their written consent, either in-person, via email, or fax. Each interview or focus group began only after the researcher reminded the participant(s) of the audio-recording. All names and places mentioned by participants have been changed to ensure anonymity; participants were given the opportunity to choose their own alias, or to have one assigned to them at random.

RESULTS

Overview

Participants ($n = 47$) made recommendations for twenty different adaptations or supplements to digital health technologies in order to better provide online health information without provoking concussion symptoms, summarized in **Table 3**.

These recommendations address not only physical, cognitive, and emotional symptoms, but also opportunities to further increase education and awareness.

TABLE 3 | Recommendations for adaptations or supplements to digital health technologies.

Recommendation	*n*
Provide audio options	17
Ensure easy navigation	16
Reduce visual stimulation	14
Ensure options to enlarge text	13
Provide color filter options	12
Use simple language	10
Accessible print options	9
Healthcare professional dissemination of printed materials	6
Feature personal stories of concussion recovery	6
Provide videos	5
Provide print resources on workplace location	4
Feature industry specific personal stories	4
Ensure a simple way to email information	3
Provide telehealth options	3
Develop mobile application	3
Utilize search term optimization	2
Prompted microbreaks	2
Geolocation targeted mobile ads	2
Auditory elements in low tones	1
Color coding	1

Recommendations to Address Physical Symptoms

Participants reported that simply looking at an electronic screen can provoke headaches and/or nausea, while others attested that their vision was blurry, or they experienced sensitivity to light. Ensuring the availability of auditory options to convey health information was recommended by seventeen participants.

> "*It would be the best for me personally, I guess, is kind of an audio option. But then also having something so you could kind of go back to it. But, yeah, I think in the beginning it was more like audio is sort of my best—the best way that I could get any information.*" ["Grace," age 32, accountant, 1 concussion, on long-term disability leave].
>
> "*The other thing I think specific to the population with brain injury is really about how you access that information. Because online is obviously the easiest and most accessible, but ironically the most difficult probably for people who have just had a concussion. I certainly couldn't engage on a screen for quite a long time. So I don't know, having different options like having an audio version or, yeah, some combination of, like, do you want to read it on a piece of paper, do you want to listen to it online or—not online, but do you want to just listen to it. Or do you want to watch the videos, so that maybe people throughout their concussion could have different ways of accessing it depending on what works best for them in the moment. Yeah, something like multimodal.*" ["Sarah," age 33, occupational therapist, 1 concussion, full return to work].

Furthermore, several participants suggested that the auditory option be separated into sections by topic, so that those experiencing memory issues can choose to listen to specific sections (e.g., how to manage symptoms). Participants had suggestions on how to improve the visual components as well. Providing easy navigation was recommended by 16 participants.

> "*I know as an educator, I can't quite remember, but something like if it's more than two or three clicks, it's too much.*" ["Deanna," age 48, clinical nurse educator, 1 concussion, long-term disability leave].
>
> "*But the less sort of— the least amount of click-on this, click-on this, register this, click-on this, user password, no password, is to burden someone. On my brain anyway. That's what I really found. [Cause I think people, women in particular around my age, aren't really great at the computer anyway. And then when you have to dig really deep into—before you get to the starting page like it should open to a website or something and give a good little table of contents*]". ["Amy," 59, speech language pathologist, 1 concussion, full return to work].

Fourteen participants suggested reducing visual stimulation on the website, which included subdued colors (e.g., navy instead of black), avoiding fast moving videos, and having a minimal amount of information presented per page.

> "*Not flashy stuff. Something that's flashing across the, I mean, any—I found, you know, when I first sustained it I could—less than a minute I could spend on a site—like on the computer, 30 seconds maybe till I really felt symptoms. Well, I felt symptoms all the time but—till they felt even worse.*" ["Victoria," age 54, registered nurse, 1 concussion, full return to work].

Thirteen participants recommended providing options to enlarge text size, with the caveat that it should not increase the need to scroll on the page.

> "*But even now my vision isn't great, so being able to enlarge it. I have a—like on my computer I can do that but then you lose part of the page. You lose part of the text so then you—you can't—it's hard—you have to slide the whole thing back and forth to make it big enough, but then I can't see the whole page, the whole width of the text. Which is not good when you have, like, nausea.*" ["Mayra," age 45, teacher, 2 concussions, partial return to work].
>
> "*Clear, larger font. There were some fonts even that I use at work that I realized I was looking at them and all of a sudden it was just all blurry.*" ["Charlotte," age 50, registered pharmacy technician, 2 concussions, full return to work].

Twelve participants recommended the provision of color filter options, so end users could adjust the screen to their preferences. Nine participants recommended ensuring an easily visible option to print resources, or to provide print resources mailed to the end-user following entry of an address.

> "*Reading the screen, obviously, is hard and being able to read something on paper is great. But probably just the first week or two that would be the most important.*" ["Raymond," 34, stunt performer, 3 concussions, full return to work with adaptations].

One participant provided advice regarding the type of auditory elements:

> "*If there is going to be any type of sound, that it's a very low calming sound, nothing sharp.*" ["Charlotte," age 50, registered pharmacy technician, 2 concussions, full return to work].

Recommendations to Address Cognitive Symptoms

Participants experienced a loss of concentration and memory while recovering from their concussion and provided recommendations of potential adaptations to address these cognitive symptoms. Ten participants recommended using simple language.

> "*Like keeping it very simple for the language. Easy to understand.*" ["Justine," age 26, communications advisor, 1 concussion, full return to work].

Furthermore, five participants recommended providing educational videos to sustain interest, and present content in a memorable way.

> "*I'm finding for people who have an actual concussion, reading, challenging. So maybe videos. Like, here's a video tutorial on concussions and what you can expect. As opposed to, here's a 200-slide PowerPoint with very detailed small font and lots of graphics that'll give me a headache. And I'll get through three or four slides, yeah. Not going to happen for a person with a head injury.*" ["Bruce," workers' union advocate].
>
> "*People watch TEDx or inspirational videos or will listen to things. So if it was engage—like, it'd have to maybe be for those ones that are, tend to be more passive, if it was really engaging, that they would then want to, and it would also help their memory if it was something that was more exciting.*" ["Penelope," occupational therapist].

Two participants suggested prompted microbreaks, so that end users with concussion symptoms can rest.

> "*I think it's a lot of the public in general, but sometimes people think that they can just push through it* [experiencing symptoms] *and they'll feel better. They'll push through it and it'll be okay. And so that's when the breaks become important.*" ["Janelle," kinesiologist].

One participant suggested that information sheets and sections of the website be color coded, to denote which resources are for which audience, eliminating the mental strain of searching for relevant information.

Recommendations to Address Emotional Symptoms

Participants stated that the experience of emotional symptoms, such as anxiety, depression, and mood swings, was unexpected. Physical and cognitive symptoms are well reported in media reports of professional athletes sustaining and recovering from a concussion. The emotional symptoms that can occur during concussion and post-concussion syndrome recovery were previously unknown to participants and their families, and they reported receiving little information or support to cope. Participants suggested two things that could help manage emotional symptoms: six participants recommended featuring personal stories of individuals recovering from emotional symptoms of concussion and post-concussion syndrome, to help normalize and destigmatize such experiences, and three participants in rural locations recommended the provision of telehealth options to connect with mental health experts that they otherwise would not have access to.

> "*There was a couple of times where I was, like, is this really in my head, or am I really experiencing this? And even now somewhere along the way I have to do a real good check-in with myself saying, you know, am I really making this more than it should be? Like, I'm not quite understanding—I shouldn't be feeling like this anymore. So it was that second guessing on my part. So definitely a section in there for people to refer to, to say, actually yeah, those people experienced something similar. So a bit of a reference to*

> *say, actually no, it's not in my head. Because then you go down a different path of oh, I'm losing it.*" ["Charlotte," age 50, registered pharmacy technician, 2 concussions, full return to work].
>
> "*I mean, it would be nice to have access to someone who's an expert in it. I was reluctant to go to like a—we have a chiropractor in town that calls himself an expert in concussions. And I didn't feel comfortable with that. And there were no other experts unless I left town to go to. And it would be nice to have telehealth support from an expert in the field so you're getting the best up to date information at the time. Cause I think that the physicians, one, they don't have time and, two, they don't— they may not all be up to speed on the current recommendations. It's not super helpful. And just—and having to go in and see them, just for no—other than, you know, they helped me get back to work, it just felt like a real effort and with no—nothing. I got nothing out of it other than get my note for work. [...] rather than trying to Google and find, you know, anecdotal stuff that—and then you think, well, it's just, you know, is this just for this person or—yeah.*" ["Victoria," age 54, registered nurse, 1 concussion, full return to work].

Recommendations to Increase Education and Awareness

Over half of participants did not immediately seek medical help following their most recent concussion-causing event, and the majority of those that did pursue immediate care were guided by their experience of previous concussion(s). Participants made five recommendations to harness the potential of digital health information resources to increase concussion education and awareness. Six participants suggested supplying print resources featuring the CATT W&W website address to healthcare providers so that adults diagnosed with concussion will receive timely information.

> "*So again, you'd want the physicians to be able to give those resources to their patient when they come in. It'd be ideal if somehow the medical association was included. Like, hey, by the way, we're developing this tool. If you ever get a patient who has a head injury that's work related or not, here's the tool and the resources are being developed. Please refer your patient to that site. Really important. [Cause otherwise the patient walks out of their 8-min consultation with the average physician and goes, what do I do now? My specialist I'll see in 3, 4, 5, 6 months. I can look online. I can Google it, and I'll be overwhelmed by all the information. I don't know what's legit, what's not, what's current, what's not. I think one portal, one doorway. Here's where you go if you've had a head injury and then go from there]*". ["Bruce," workers' union advocate].

Four participants recommended the provision of print resources on location in industries where occupations do not involve computer use and/or reporting of a concussion may be stigmatized.

> "*Yeah, just—I think if the information is easy to get, then people will be more likely to pick it up. Even if somebody's a little bit paranoid they still think, oh, people are going to think I'm a wuss but at the same time my head's really starting to bother me. The brochure's right there, I'll just stuff it in my bag when nobody's looking. And then they'll go home and read it.*" ["Adrian," age 50, professional wrestler/stunt performer, 5+ concussions, full return to work].
>
> "*Even if you give out, like, a pamphlet that won't hurt either, right. They could read on their own time and get them to be aware of it.*" ["Carlos," age 43, construction worker, 3 concussions, on unpaid leave].

Four participants recommended that personal stories of concussion recovery, return-to-work, and prevention be separated by industry in order to be more relatable.

> "*And I think even it would be important to have it from various walks of life, right, have a healthcare person. [Cause healthcare speaks to healthcare. That would be their peer, right. Construction, for example, I mean, we have some pretty serious injuries that come out of construction. Just let's have a wide range of people who have different occupations and different age groups too. Because I think then people can—it's more relatable if they feel like it could be captive in their own voice. I think that they—you probably are going to capture a bigger audience that way]*". ["Dolores," case manager, WorkSafeBC].

Three participants suggested a button on the website which made it easy to email information to a family member or colleague. Three participants suggested developing a mobile app, or ensuring that websites are mobile friendly. Two participants recommended using geolocation capabilities to target informational mobile ads for specific industries, e.g., for the film industry, at the site of major studios.

> "*So potentially we could do something around somebody walks onto a lot and an ad pops up and, you know, it's just a little prompt about concussion or about injury prevention.*" ["Raymond," 34, stunt performer, 3 concussions, full return to work with adaptations].

Two participants suggested that search term optimization be broadened to promote concussion health information websites among the results following Internet users searching associated terms such as, "whiplash," "car crash," as well as common concussion symptoms.

> "*It would be wonderful if you could—if anybody Googled "headaches" if it could come up. I guess maybe if I had Googled, like, headaches and was able to link what I was feeling and seeing—might have instigated me to go to the doctor maybe quicker. Rather than waiting. It's, like, no, this is not right, this isn't just whiplash. There's no relation to the neck what you're experiencing.*" ["Carol," 59, scheduler, 2 concussions, partial return to work].

The workplace and healthcare professionals who participated in the study provided recommendations based on an agglomeration of experience supporting adults with concussion, and felt frustrated that they lacked quality resources to recommend to patients or clients. Participants who had sustained concussion(s) felt distress due to insufficient information. This often delayed their choice to seek diagnosis, resulted in delayed recovery and return-to-work, and greatly impacted their care decisions as well as their physical, mental, and social well-being.

Principal Findings

The present study is a component of broader research on the experiences of concussion diagnosis, recovery, and return-to-work among the general adult population. These findings informed the creation of the CATT W&W e-learning course and related resources. Aligned with the current research literature, the initial aim of the CATT W&W study pertained solely to the needs of end-users for informational content and ensuring the credibility of that health information. Throughout the course of the study, participants emphasized the requirement for the presentation of online health information to be adapted or supplemented in order to increase accessibility for adults experiencing concussion symptoms. Participants made 20 recommendations to address physical symptoms (auditory options; easy navigation; fewer visually stimulating elements; enlarged text; color filter options; easily receiving printed resources at home, through self-printing or mail; and pleasant auditory sounds), cognitive symptoms (use of simple language; educational videos; prompted microbreaks; color coded information), emotional symptoms (personal stories; telehealth options), and to increase concussion education and awareness (print resources provided to healthcare providers; print resources for specific industries; industry specific personal stories; easy email options to disseminate information; mobile apps; utilizing geolocation to target ads; and search term optimization).

The categories these recommendations fall in are permeable and reflect the intended context of the participants' suggestions. Providing an easily visible option to print resources at home, or providing print resources mailed to the end-user following entry of an address, was suggested by nine participants as a solution to physical symptoms exacerbated by screen time. The same suggestion could be made to address cognitive symptoms, as a physical copy of the Return-to-Work Strategy, for example, could provide a reminder of the stepwise approach to recovery for those experiencing memory loss after they have left the online website. Or, it could fall under increasing education and awareness, as the same resource could be posted in the workplace or home of the individual recovering from a concussion, where it would be viewed by colleagues or family and friends, providing a visible reminder for an invisible injury. Occasionally, participants' recommendations contradicted one another; to address emotional symptoms, several participants suggested providing personal stories, as they would take comfort in knowing they were not unique in their experience. Other participants felt overwhelmed with the amount of anecdotal evidence found online. They would prefer access to expert opinion via telemedicine, to receive tailored advice. Given that no two concussions are alike, it is not surprising that recommendations varied, and reveals the need for a broad array of adaptations and supplements to increase the accessibility of online health technologies and support concussion recovery.

Including all twenty of these recommendations into the development of CATT W&W was beyond the initial scope of the project, however, certain suggestions aligned with online public health information best practice previously adhered to by CATT (simple language, easy navigation, pleasant auditory sounds, educational, and engaging videos). For the provision of print resources to specific industries and healthcare providers, all CATT print resources are available for order at low, cost-recovery prices. Other recommendations were easily incorporated *ad hoc*, such as providing print and auditory options. All modules of the CATT W&W e-learning course are available for download either as plain text, or as audio files. The 20 recommendations reveal a gap between participants' needs and what the healthcare system provided, and can guide the provision of future accessible concussion digital health information for the general adult population.

Comparison With Previous Work

This is the first study to date which considers potential adaptations and supplements to increase the accessibility of online health information in support of concussion recovery and return-to-work. Managing concussion requires consistent symptom monitoring which informs adaptations to the pace of activity resumption. Until recently, expert consensus statements recommended that concussion recovery necessitated complete rest until total symptom resolution. Individuals recovering from a concussion were advised to avoid physical activity that elevated their heart rate, tasks which increased the cognitive load (e.g., work or school), and exposure to sensory stimuli (light, noise, screens). A growing body of recent evidence suggests that resuming usual activities after 24–48 h of rest may lead to a faster recovery provided the individual does not exacerbate symptoms (8). Given that medical health professionals are not uniformly aware of the updated recommendations for concussion recovery, online health information plays a critical role in informing care.

A concern among medical professionals and workers' compensation boards is discerning "true" concussions from scenarios where an individual is "intentionally fabricating or exaggerating symptoms to achieve an external goal (e.g., malingering) or otherwise fabricating or exaggerating symptoms (i.e., feigning and dissimulating) to obtain attention from medical professionals or to avoid work, school, military service, or other responsibilities" [(28), pg. 96]. Malingerers may seek online health information to bolster their performance of symptoms, though studies have found that those who malinger can be identified by intentional poor performance on cognition tests, with those with mild TBI often exhibiting poorer effort and worse cognitive performance than those with moderate or severe TBI (29). New methods are being developed to discriminate fake from true brain injury, such as using latency of left frontal neural responses during old/new memory recognition (30). Regardless of the minority of malingering individuals, providing adaptations to increase the accessibility of online public health information benefits those experiencing concussion symptoms, as well as Internet users with varying visual, mobility, hearing, and intellectual disabilities (31).

Research on the potential of harnessing technology for concussion care includes virtual reality gaming as an assessment and/or neurorehabilitation tool (32, 33); eye tracking technology for concussion assessment among sports medicine clinicians (34); mobile applications (35); wearable technology, such as helmets and mouthguards, to aid in the detection of sports-related concussion (36); blood-based biomarkers (37); fluid biomarkers and genetic testing (38) and more. While the healthcare and workplace professionals interviewed within the present research acknowledged the burgeoning field of technological research and development in regards to concussion care, they stressed the need for low-tech solutions. Namely, evidence-supported, accessible resources which they can use to support workers with concussion in their recovery and return-to-work. Inappropriate communication which is limited to a brief exchange within a doctor's office, an emergency department, or a phone call with a workers' compensation board case manager, may result in poor understanding and difficulty to recall the discharge care or return-to-work plan (39).

In the early phases of recovery from concussion, research suggests that individuals may experience difficulty satisfying the basic psychological needs of autonomy, competence and relatedness, and early interventions offered should be attentive to the potential emotional symptoms which can arise (40). Chang et al. (41) found that work-related mild traumatic brain injury often resulted in long term consequences, including challenges in daily activities and return-to-work. Workers experiencing mild traumatic brain injury are 3.5 times more likely than the general unemployed population to remain unemployed one year later (42). Workers in positions of precarious employment, such as part-time, temporary, short or fixed-term contract, self-employed or seasonal work comprise 30–32% of the Canadian workforce. The lack of security, low control over work processes, as well as social and economic vulnerability experienced by precariously employed workers is compounded by illness or injury (43). Though the challenges are clear, the opportunity exists for organizations and researchers to champion a public health and prevention approach to safeguard employees' health (44).

Limitations and Future Directions

Findings from the present study are instructive for clinicians, researchers, technology developers, employers, and occupational health and safety committees to recognize the barriers and facilitators for individuals with concussion symptoms in accessing online health information. Given the recent shift toward working and studying from home, these findings could also inform organizational strategies to enable individuals recovering from concussion and post-concussion symptoms in accessing resources online. Strengths of the study include soliciting the perspectives of workers who sustained a concussion and returned to work or were in the recovery process from a wide array of industries, as well as the healthcare and workplace professionals who support these processes. The recruitment methods resulted in a sample which is predominantly English-speaking, securely employed, middle-aged, and female, which may negatively impact the transferability of results. These findings could provide a fuller picture by including the perspectives of the family members and colleagues of individuals recovering from concussion, as well as a more representative sample of the general population, including precariously employed workers, self-employed workers, older workers (aged 65 years and above), young workers (aged 25 years and below), and recent immigrant populations.

However, while the results cannot be generalized to everyone experiencing concussion recovery and return-to-work, they can be used in developing adaptations and supplements to the presentation of online health information for concussion, given the similarity of responses. Researchers may wish to explore a longitudinal investigation of the adaptations and supplements required by individuals recovering from a concussion at the various stages of recovery to ascertain which are most beneficial at certain time points. Research is also needed as to the uptake of health information to increase concussion awareness and education by various industries. Within our results, there appears to be a relationship between traditionally masculine occupations and the stigmatization of concussion symptoms, particularly in regards to emotional symptoms, as well as the disparate requirements of rural and urban populations; more research is needed to investigate the influence of these variables on experiences of concussion recovery and return-to-work.

CONCLUSIONS

Participants shared the adaptations and supplements which may have enabled them to receive the right online health information at the right time, further supporting concussion recovery and return-to-work. The diagnosis, evaluation, management, and determination of recovery from concussion relies largely on clinical assessment. Currently there is no sole instrument sufficient to assess concussion in isolation, and research supports comprehensive, multidomain assessment approaches to concussion, and a multi-disciplinary approach to care for post-concussion symptoms (45). Research suggests that a one-size-fits-all method of concussion care is ineffective (46). Every concussion is unique, but the way in which the general adult population seeks health information is not. Searching for online health information is one of the foremost uses of the Internet, and may preclude the decision for an individual to seek medical care. Harnessing the potential of online health information to increase education and awareness about concussion requires an array of adaptations and supplements to accommodate not only symptoms, but also the nature of the work being returned to, and the context in which the individual is recovering.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because informed consent was not obtained from participants to facilitate data sharing and scholarly reuse; therefore, these qualitative data cannot be legally and ethically shared. Requests to access the datasets should be directed to M. Denise Beaton, denise.beaton@bccdc.ca.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by The University of British Columbia Research Ethics

Board. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SB was the Principal Investigator and encouraged MDB to carry out the research and supervised the analysis and findings of this work. MDB wrote the manuscript with input from SB and GH. GH analyzed the data, and worked with MDB to establish inter-rater reliability. All authors reviewed the manuscript and provided final approval. All authors contributed to the article and approved the submitted version.

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BRIEF RESEARCH REPORT
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Patient Satisfaction With Medications for Opioid Use Disorder Treatment via Telemedicine: Brief Literature Review and Development of a New Assessment

Thomas O. Cole[1], *Darlene Robinson*[1], *Andrea Kelley-Freeman*[2], *Devang Gandhi*[1], *Aaron D. Greenblatt*[1], *Eric Weintraub*[1] *and Annabelle M. Belcher*[1]*

[1] Division of Addiction Research and Treatment, Department of Psychiatry, University of Maryland School of Medicine, Baltimore, MD, United States, [2] Life's Energy Wellness Center, Inc., 8737 Brooks Drive, Easton, MD, United States

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Edited by:
Maria Hägglund,
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***Correspondence:**
Annabelle M. Belcher
abelcher@som.umaryland.edu

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Telemedicine is increasingly being used to treat patients with opioid use disorder (OUD). It has particular value in rural areas of the United States impacted by the opioid crisis as these areas have a shortage of trained addiction medicine providers. Patient satisfaction significantly impacts positive clinical outcomes in OUD treatment and thus is of great clinical interest. Yet little is known regarding patient satisfaction with the increasingly important platform of telemedicine-delivered medications for opioid use disorder (tMOUD). The goal of this review is to provide a summary of the existing literature regarding patient satisfaction with tMOUD. We also submit a novel survey based on an existing framework designed to assess tMOUD satisfaction, and present pilot data ($N = 14$) acquired from patients engaged in rural tMOUD care. Telemedicine provides a feasible method for delivering MOUD in rural areas, and our survey provides a useful assessment to measure patient satisfaction with tMOUD. In light of the pressing need for innovative and technology-driven solutions to the opioid epidemic (especially in light of the COVID-19 pandemic), future research should focus on the development and refinement of tools to assess the important implementation goal of patient satisfaction.

Keywords: patient satisfaction, telemedicine, opioid use disorder, medication assisted treatment, rural, telebehavioral health, buprenorphine

INTRODUCTION

The United States is facing an opioid crisis that has little precedent. Once a problem constrained primarily to urban areas, the past two decades have witnessed a significant geographic shift, with rural communities experiencing increases both in non-medical opioid use and in the number of opioid overdose deaths. Rural areas of the United States have been disproportionately impacted by this crisis, with higher reported rates of non-medical opioid use and overdose compared to urban areas (1, 2). From a treatment capacity perspective, rural areas often lack providers who have met the training and registration requirements to prescribe buprenorphine for treatment of opioid use disorder (OUD). This results in a lack of access to medications for opioid use disorder (MOUD), rendering these communities poorly equipped to treat individuals with OUD (3–5).

The Centers for Medicare and Medicaid Services (CMS) is the Federal agency responsible for administering payments for medical services to seniors and low-income individuals in the United States. CMS defines telemedicine as two-way, real time interactive communication between patients and physicians or practitioners at a distant site for the purpose of improving patients' health (6). Telemedicine offers a viable solution to increase access to MOUD given its potential to fill gaps in provider access. The utility and value of telemedicine has been heightened by the emergence of COVID-19, as the need for remote, contactless methods of health care delivery is now crucial. Patient satisfaction is an important factor in the assurance of validation and acceptance of this emerging care medium. This variable is especially critical in the treatment of OUD, as previous reports have shown that satisfaction has a direct impact on treatment outcomes (7–10).

Although patient satisfaction has been accorded a great deal of attention in the frame of telehealth- and telemedicine-based care modalities, the literature is almost non-existent for telemedicine-delivered MOUD (tMOUD). The goal of this review is to summarize this literature and to present pilot data for a survey that we have created to assess patient satisfaction with tMOUD.

LITERATURE REVIEW

The Rural OUD Problem

The past two decades have witnessed an explosive opioid crisis in the United States. With the highest rates of opioid prescribing (11), as well as the highest per capita opioid-related death rates, rural areas of the country have been hardest hit by the crisis (12). The rural OUD problem is further exacerbated by a lack of available treatment options. Although behavioral and psychosocial treatment approaches for OUD occupy a rightful space and offer benefits for many people (13), treatment with medications that have action at opioid receptors is the most evidence-based method of treatment for OUD (14–16). But numerous barriers preclude access to MOUD in rural areas, the most significant of which is the lack of specialized providers able to prescribe MOUD (17). Rural OUD treatment seekers must often travel long distances and times— a burden that adds to the challenge of accessing and retaining individuals in care (12, 18, 19).

Socio-cultural factors are also believed to play a role in the disparities between rural and urban communities. Several factors have been identified that explain the disproportionate use of opioids in rural areas, many of which revolve around the fact that rural denizens tend to be employed with labor intensive work—work which poses an increased risk of occupational injury and a cultural acceptance of opioid use to manage pain (20, 21). Rural areas also tend to be comprised of older populations, who often have a greater frequency of chronic pain and thus, higher rates of opioid prescribing (21). Additionally, a lack of economic opportunity and closer-knit social and family networks that facilitate the distribution of opioids has compounded the prevalence of OUD in rural areas (21, 22). Regardless of the causes, there is a critical need to close the OUD treatment gap in rural areas of the United States, for which telemedicine shows promise.

Telemedicine for the Treatment of OUD

Telemedicine platforms have been utilized in the delivery of psychiatric care that incorporates psychiatric evaluations, therapy sessions, patient education, and medication management. Evaluations of telemedicine include several outcome measures; among these are feasibility, validity, reliability, satisfaction, cost, and clinical outcomes. Previous research has shown that telemedicine is effective in delivering treatment for mental health disorders, such as PTSD, depression, and ADHD (23), findings which paved the way for telemedicine expansion to OUD treatment. Telemedicine is being used increasingly for the treatment of OUD, and has recently been raised to national awareness in light of new federal and state regulations governing MOUD treatment during the COVID-19 pandemic (24). Along with others, our group has shown that treating OUD via telemedicine produces clinical outcomes (specifically, retention and illicit substance use) that are not significantly different from face-to-face interactions (25–27).

The University of Maryland School of Medicine Division of Addiction Research and Treatment (DART) has been at the forefront of delivering MOUD via telemedicine to rural areas of Maryland's eastern-shore and western Appalachian communities. Since August 2015, DART has partnered with intensive outpatient programs (IOP) as well as behavioral treatment programs in outlying, rural areas of the state (Caroline, Talbot and Dorchester Counties on the eastern-shore, and rural areas of Garrett and Washington Counties in western Maryland) to provide tMOUD for opioid-dependent patients. These counties have been significantly impacted by the opioid epidemic, with trends that show little sign of reversing. To illustrate, although the State of Maryland's opioid overdose rate decreased between 2018 and 2019, each of these counties saw either an increase or a relative flat line in the number of opioid overdose deaths (28). To date, our clinicians have treated over 450 patients with the combination of telemedicine and remote buprenorphine prescription, with planned expansions of our services to reach incarcerated populations (29).

Telemedicine-based treatment for OUD can take many forms, but briefly, patients are screened by trained substance use disorder (SUD) counselors at a partnering program. Patients who satisfy criteria for a diagnosis of OUD and who consent to treatment with telemedicine are referred to a telemedicine provider (either an addiction medicine physician or a federally waivered clinician). Throughout the course of treatment, patient encounters occur *via* a HIPAA-compliant synchronized live video-feed (25, 26).

The COVID-19 pandemic has changed the environment of how MOUD treatment is structured. Pre-COVID, in compliance with the Ryan Haight Online Pharmacy Protection Act of 2008, Drug Enforcement Agency (DEA) regulations required that an in-person medical evaluation be conducted by a prescribing clinician for the initial screening of patients (30). Shortly following federal emergency declarations in March 2020, as with other agencies (SAMHSA and the Centers for Medicare

& Medicaid Services [CMS]), the DEA eased regulations to facilitate OUD treatment access compatible with public health recommendations for social distancing. The most relevant changes for MOUD treatment included the elimination of the in-person health and physical examination for buprenorphine induction and the allowance (and coverage) of virtual (phone or video) counseling services (31, 32). Although these changes are in effect only for the duration of the public health emergency, these modifications have commanded attention to telemedicine, further heightening the need for data on patient acceptance of this mode of healthcare.

SUD and Patient Satisfaction

Patient satisfaction has been assessed in SUD-treated populations, and is associated with several important treatment outcomes, including reduction in substance use and greater retention, compliance, and patient engagement. In one of the earliest studies assessing patient satisfaction with SUD treatment, Carlson & Gabriel (33) found that among those starting an outpatient or residential SUD program, service use, satisfaction with access and satisfaction with treatment effectiveness was significantly associated with 1-year abstinence. Hser et al. (10) found that among those starting a drug-free outpatient or residential treatment program, patient satisfaction and service utilization had a positive relationship with treatment completion or longer treatment retention. Consistent with these findings, Kelly et al. (9) found a positive association between patient satisfaction and treatment retention. Specifically, methadone patients who were more satisfied with their treatment program and counselor were more likely to remain in treatment and were less likely to have self-reported cocaine and heroin use, positive urine toxicology results for cocaine and heroin, and involvement in illegal activity (9). In a systematic review of the literature exploring the link between patient satisfaction and treatment outcomes, Barbosa et al. (8) concluded that although there is broad support for an association between patient satisfaction and treatment compliance, adherence, and persistence, there is a pressing need for additional research. Lastly, Hawkins et al. (7) evaluated the acceptance and satisfaction of a Care Management Model (CMM) among a SUD treatment patient population and found that "trust" within patient-provider relationships was a contributing factor in patient engagement with CMM services. Collectively, these findings highlight the importance of focusing attention on patient satisfaction, as a variable that may have profound impact on several aspects of treatment outcomes.

Patient Satisfaction With Telemedicine

Although it is clear that satisfaction is an important factor in clinical outcomes for SUDs and OUD, little work has been done to evaluate patient satisfaction within the context of tMOUD. In a review of telemedicine-delivered treatment interventions for SUDs, Lin et al. (34) highlighted the finding that no article specifically examined patient satisfaction with MOUD, nor administered a patient satisfaction survey (26, 27, 35). The remaining articles included in that systematic review examined tobacco cessation and psychotherapy for alcohol use disorder and OUD. Eight out of the ten remaining articles administered satisfaction surveys, however, these surveys pertained to satisfaction with counseling services and experiences. Our own search for a literature on patient satisfaction with tMOUD underscored this gap; to our knowledge, no report has evaluated patient satisfaction with the emerging clinical medium of telemedicine with MOUD for the treatment of OUD.

Below, we report on the development and proof of concept implementation of a novel patient satisfaction survey specific to tMOUD. We based our survey on characteristics of previously published patient satisfaction surveys, utilizing the following thematic categories to frame the patient's subjective experience: (i) *communication; (ii) privacy; (iii) patient perceptions; and (iv) technology utilization.* These categories represent areas on which to assess general satisfaction, and have been implemented in other arenas of research, including the delivery of general mental health services, telemedicine for alcohol use disorder, and telemedicine consultations for mental health disorders (36–42). In addition to those four thematic categories, our survey also includes a thematic category to capture *(v) treatment access,* pertinent to understanding patient satisfaction with the availability of care.

DEVELOPMENT OF A NEW SURVEY FOR PATIENT SATISFACTION WITH TELEMEDICINE WITH MOUD

Patient Satisfaction Survey for Telemedicine With MOUD

Our telemedicine with MOUD patient satisfaction assessment is a 16-item survey with questions organized according to five thematic categories designed to evaluate satisfaction. See **Appendix-1** for full instrument questions.

Using thematic categories interpreted from previous published literature (36–42), we created a survey that assessed satisfaction with: *(i) communication; (ii) privacy; (iii) patient perceptions; (iv) technology utilization; and (v) treatment access*. We describe each of these briefly. The first category, that of *communication* (Questions 1, 5, 6, 7, and 15) relates to the exchange of information between the patient and telemedicine doctor. This category captures aspects of the therapeutic relationship and patient participation in care decisions–important aspects of the therapeutic encounter. *Privacy* (Question 4) is relevant to the extent to which participants felt that their communication with the telemedicine doctor was confidential (i.e., no other patients or staff members could hear their conversation with the telemedicine doctor). *Patient perception* (Questions 8–11, 14) relates to a patient's acceptance of the telemedicine medium, validation of care, likability of the telemedicine doctor, and willingness to be seen again by the telemedicine doctor. The fourth thematic category, *technology utilization* (Questions 2 and 3), is used to capture satisfaction with the patients' ability to hear and see the telemedicine doctor. The final category, *treatment access* (Questions 12, 13, and 16), was included to understand barriers to treatment as it relates to the time it took to obtain a tMOUD appointment, as well as the likeliness that the patient would have sought MOUD treatment had telemedicine not been available to them.

Setting

Life's Energy Wellness Center, Inc. (LEWC Inc.), with three locations on Maryland's Eastern Shore, was utilized for the study setting to pilot this satisfaction instrument. The LEWC clinic is registered as a DEA clinic meeting criterion to prescribe MOUD via telehealth without requiring a face-to-face encounter. LEWC Inc. offers a variety of counseling services including individual, group, and family counseling as well as counseling for individuals suffering from SUDs. Although mental health and counseling services are available for clients, the towns in which LEWC Inc. operates have a paucity of DEA-waivered providers. The telemedicine partnership with DART addresses this need, providing much-needed MOUD to LEWC Inc. patients.

Participant Selection

Using a convenience sampling method, new clients enrolling into LEWC Inc.'s IOP program ($N = 14$) were asked to voluntarily complete the telemedicine satisfaction survey immediately after completing an initial consultation with a DART telemedicine provider. LEWC Inc. staff members approached each new intake and determined interest in participation by asking "*Would you mind filling out a 5-min survey on your telemedicine experience? This is anonymous and will only be used for program quality assurance.*" Patients were assured that their involvement in the research survey would not interfere with the normal routine of clinical care received at the treatment center. Willing participants were given a touch screen tablet with an online survey link. Patients under 18 years of age and those already receiving treatment in the facility with telemedicine services were not invited to participate in the survey.

Study Design

Our anonymous survey was administered via touchscreen tablet and data were electronically recorded into a REDCap database (43). The scoring system utilized Likert scales with responses ranging from 0 to 4, with numbers corresponding to responses of "strongly disagree" (a score of 0) to "strongly agree" (a score of 4). Because this was a limited pilot and proof-of-concept study, we limited data collection to occur only within 1 month, from September to October 2019.

Results

We did not collect any personally identifying information from subjects who participated in our survey. Furthermore, as this study was conducted remotely as an anonymous, quality improvement (QI) program of evaluation, there were no direct interactions between the researchers and participants in the survey. Thus, this project was administratively reviewed by the University of Maryland, Baltimore Human Research Protections Office and was determined to not constitute research with human subjects. To characterize our patient sample we report demographics of all patients receiving tMOUD at the partnering site at which we collected survey data ($N = 65$; **Table 1**). Briefly, LEWC Inc.'s tMOUD patient population is predominantly White (76.9%) and predominantly male (56.9%). The mean age of patients enrolled in our tMOUD program is 35.6 years old (range = 19–66). tMOUD patients were more likely to have public insurance coverage (93.8%) and be prescribed buprenorphine (80%) as compared to naltrexone (20%). See **Table 1** for full LEWC Inc. DART tMOUD program demographic data.

TABLE 1 | Demographics of patients receiving treatment at LEWC Inc. enrolled in the Telemedicine with MOUD partnership with the University of Maryland School of Medicine.

Baseline Characteristic ($N = 65$)	***N***	**%**
Age at intake (years)		
Mean (±S.E.M.)	35.6 (±1.24)	
Range	19–66	
Gender		
Male	37	56.9
Female	28	43.1
Race		
White	50	76.9
Black	9	13.8
Other	4	6.2
Missing	2	3.1
Insurance Coverage		
Medicaid	61	93.8
Private	2	3.1
Self-Pay	2	3.1
Medication Type		
Buprenorphine	52	80
Naltrexone	13	20

A total of 14 new intake participants were approached, all of whom agreed to complete the tMOUD patient satisfaction survey. The preliminary findings showed an overall positive experience with tMOUD. Results of specific thematic categories are discussed below.

(i) *Communication*

> 100% of respondents agreed or strongly agreed with the following statements:
> I could talk comfortably with the telemedicine doctor on the screen.
> It was easy to talk with the telemedicine doctor over the screen.
> I could talk about my problems easily.
> I understood the recommendations and know what the telemedicine doctor wants me to do.
> I felt like I was part of decisions made related to my screen care.

(ii) *Privacy*

> 64% of respondents disagreed with the statement "I was worried about others hearing me."

(iii) *Patient Perceptions*

93% of respondents agreed or strongly agreed with the statement "I feel OK about the doctor's advice."

86% of respondents agreed or strongly agreed with the statement "I think other people would like the telemedicine doctor on the screen."

100% of respondents agreed or strongly agreed with the statement "I am willing to go back to this telemedicine doctor on the screen."

93% of respondents agreed or strongly agreed "I think that getting help over the screen was as good as getting help in person."

100% of respondents agreed or strongly agreed with the statement "I feel the amount of time spent during my telemedicine doctor visit was appropriate for my treatment needs."

(iv) *Technology Utilization*

100% of respondents agreed or strongly agreed with the following statements:

I could see the telemedicine doctor on the screen really well.

I could hear the telemedicine doctor on the screen really well.

(v) *Treatment Access*

36% of respondents agreed or strongly agreed with the statement "I would not have received opioid treatment were it not for telemedicine doctor", while 29% reported a neutral response to this question, and 21% respondents disagreed or strongly disagreed.

71% of respondents agreed or strongly agreed with the statement "The number of days waiting to see the telemedicine doctor for medication was reasonable."

79% of respondents agreed or strongly agreed with the statement "Following my initial assessment, I am satisfied with the amount of time it took for me to have an appointment with the telemedicine doctor."

Discussion

Telemedicine as a medium to deliver OUD treatment services is a feasible option for addressing the lack of access to MOUD in rural areas. Moreover, telemedicine is uniquely capable of addressing other barriers to accessing mental healthcare unrelated to geographic proximity to providers, such as stigma (the shame of addiction may preclude treatment) and anxiety surrounding an in-person encounter with a live doctor. These barriers aside, telemedicine has evolved with an increasingly technologically-inclined society. Indeed, when given the option, patients may even *prefer* telemedicine over routine in-person encounters with substance use disorder providers, as a recent report by Slightam et al. (44) suggests. This patient satisfaction survey serves as an important measure and provides guidance in assessing the satisfaction of patients regarding the quality of care provided via telemedicine. These pilot data show favorable satisfaction and acceptance by patients receiving tMOUD. Larger studies should further assess satisfaction to improve the way in which services are provided and delivered to patients.

It is important to note that these data were collected prior to the COVID-19 pandemic, and prior to the SAMHSA and DEA regulation changes to MOUD treatment. Along with others (45, 46), we (47) have argued against a full return to the pre-COVID *status quo* of restrictive, stigmatizing OUD treatment regulations. Further, we strongly encourage researchers to take advantage of the natural experiment availed by the pandemic to assess how a less restrictive environment might affect treatment outcomes (47). Part of these research efforts should include patient perspectives, as patient satisfaction will ultimately determine uptake and implementation of telemedicine in an OUD treatment practice.

A major limitation of our study is its small sample size. Although we were encouraged by the high rate of engagement (of the 14 patients approached, all 14 agreed to take part in the survey), the administration of the survey was dependent on LEWC Inc. staff involvement and time. Intake consultations can be cumbersome to both staff and patients, and clinical treatment needs would have taken precedence over completion of a voluntary survey.

Another limitation is that our assessment queried patient satisfaction at only one time, immediately following the initial telemedicine evaluation. Because this study aimed to determine whether the tMOUD platform was an acceptable medium for rural patients receiving MOUD, and was conducted as a QI project, we did not conduct follow-up assessments with patients to explore their satisfaction over the course of their treatment. Future research efforts will aim to assess satisfaction at multiple time points across treatment trajectory, particularly important considering that satisfaction may change over time, which may impact treatment engagement and retention.

A third limitation is that these pilot data utilized a convenience sampling method and did not include any randomization or control groups. Provider variation may impact the patient experience. As a proof-of-concept evaluation, we did not control for the number of telemedicine providers, nor did we balance the telemedicine encounters across our clinicians—one factor among several that could greatly impact patient satisfaction.

Finally, it is worth noting that although this instrument was derived using an existing body of literature that based global patient satisfaction with telemedicine on five themes, our particular instrument was not subjected to the rigorous psychometric testing that would be necessary for field adoption. The select rural population in which this survey was conducted is situated in one eastern county of the state of Maryland; other rural areas of Maryland may have different experiences. Prior to its implementation, this survey would need to undergo tests of reliability, validation and generalizability. Future studies will address these limitations.

Future Directions

As a growing number of rural communities and correctional institutions recognize the value in providing OUD treatment via telemedicine, evaluations of satisfaction will be needed as telemedicine programs are developed and expanded. A greater understanding of patient satisfaction with tMOUD will also help to inform the integration of mobile phone or app-based platforms, which may help to mitigate transportation barriers in rural areas. Assessing satisfaction in treatment over time is important given the high rates of dropout for rural MOUD patients who are prescribed buprenorphine (48).

Additionally, provider satisfaction should continue to be assessed to ensure clinicians' validation of evolving telemedicine mediums. Future studies should conduct psychometric evaluations of this instrument to ensure consistency, validity and generalizability to be able to conduct the necessary refinements that would allow for longitudinal studies of patient satisfaction. Finally, research efforts will assess whether this instrument may have prospective predictive value for treatment engagement or retention.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Review Board, University of Maryland, Baltimore. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

All authors contributed to the conception of this paper. AB developed the patient satisfaction survey. TC and DR conducted the literature search. TC wrote the first draft of the manuscript. All authors provided critical feedback, revisions to the manuscript, and approved the submitted version.

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SUPPLEMENTARY MATERIAL

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ORIGINAL RESEARCH
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Satisfied or Frustrated? A Qualitative Analysis of Need Satisfying and Need Frustrating Experiences of Engaging With Digital Health Technology in Chronic Care

Carolina Wannheden[1]*, **Terese Stenfors**[1], **Andreas Stenling**[2,3] and **Ulrica von Thiele Schwarz**[1,4]

[1] Department of Learning, Informatics, Management and Ethics, Karolinska Institutet, Stockholm, Sweden, [2] Department of Psychology, Umeå University, Umeå, Sweden, [3] Department of Sport Science and Physical Education, University of Agder, Kristiansand, Norway, [4] School of Health, Care and Social Welfare, Mälardalen University, Västerås, Sweden

Introduction: Digital health technologies such as self-monitoring devices and apps are becoming increasingly important as tools to promote healthy habits and support individuals in their self-care. There is still a scarcity of research that builds on motivational theory to better understand the functioning of digital health technologies. The self-determination theory (SDT) is a macro theory of motivation that delineates three basic psychological needs that are linked to different types of motivation and lead to well-being when satisfied and illbeing when frustrated.

Objective: To explore how the use of a digital tool for self-monitoring and communication with healthcare satisfies or frustrates basic psychological needs across four spheres of user experience: interface, task, behavior, and life.

Methods: The study was conducted in a Swedish primary care setting with individuals who participated in a pilot study of a digital health intervention for self-monitoring in chronic care management. Data from a follow-up survey with participants 7 months after recruitment were analyzed using a thematic approach mixing inductive and deductive analysis. The unit of analysis is based on a total of 642 individual answers to seven open-ended questions, from 121 respondents.

Results: The analysis identified positive and negative influences of self-monitoring and digital communication with healthcare on all three psychological needs. Three main findings are that: (1) data covered all four spheres of user experiences, but most user experiences concerned the behavior and task spheres; (2) satisfaction and frustration of competence needs was more prominent than influences on other needs; (3) the same experience may be perceived as both need frustrating and need satisfying, which suggests a tension that reflects individual differences.

Conclusion: Designers of digital health technologies need to take into account basic psychological needs within all spheres of user experience, from interface to life in general. Because some features may be simultaneously experienced as satisfying and

Edited by:
Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Anne Moen,
University of Oslo, Norway
Gunnar Klein,
Örebro University, Sweden

***Correspondence:**
Carolina Wannheden
carolina.wannheden@ki.se

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frustrating by different users, these types of tools need to be flexible to accommodate for variation of user experiences. Careful design considerations that take motivational theory into account would contribute to the transformation of care for individuals with chronic conditions.

Keywords: self-tracking, digital health (eHealth), persuasive technologies, motivation, design, user experience (UX) evaluation, self-determination theory (SDT), self-monitoring devices

INTRODUCTION

For individuals with chronic health conditions such as high blood pressure or diabetes, self-management is inescapable. What they do throughout the day will have an impact, positive or negative, on their condition (1). Good health outcomes are dependent on self-management of symptoms as well as healthy behaviors such as diet, physical exercise, and sleep (2). The acknowledgment of the patients' knowledge, experience, and influence on their own care has transformed chronic care management, where self-care has been predicted to become the new principal source of care for an increasing number of individuals who have the ability and necessary support to engage in self-care (3).

To promote healthy behaviors, digital health technologies such as self-monitoring devices and apps are becoming increasingly important by facilitating tasks such as identifying symptoms, planning treatment, monitoring key health parameters, and monitoring progress and treatment effects (4, 5). Thus, these types of tools have the potential to support individuals with chronic conditions in their self-care. This assumes that the technology is used, which in turn builds on users being willing to engage with the technology, that is, that they are motivated to use it (6). While theories of acceptance and use of technologies [see e.g., (7)] have long been a concern for designers of digital health technologies, our understanding thereof is still limited (8). Motivation has only recently been taken into account in design considerations for digital technologies. The interest in motivation is visible in fields such as persuasive technology (9), which deals with technologies that are designed to support healthy behavior change. Persuasive technologies have been classified into gamification, quantified-self, and social networking (10). Substantial effort has been put into describing the so-called motivational affordances offered to users, which refers to the properties of a technology that determine if it supports users' motivational needs (8). In the area of health and wellness, some of the most common strategies employed by persuasive technology interventions involve self-monitoring, performance analysis, exercise guidance, rewards, feedback, social recognition, social comparison, watching others, and self-presentation (9, 11).

Yet, the research that builds on motivational theory to better understand the functioning of digital health technologies is still limited (10, 12). For example, a review of the literature on technologies aiming to aid and motivate individuals to engage in healthy life habits concluded that more than half of the studies included in their review were not informed by any motivational theory, and most of those that referred to a motivational theory only mentioned it without specifying how it informed the study (9). Thus, the underlying psychological processes that would explain why individuals may perceive a certain feature as motivating are largely unexplored (13).

Self-determination theory (SDT) is a macro theory of motivation that has been used extensively in over four decades to explain human motivation in various domains (14), including behavior change and health behaviors (15, 16). The theory distinguishes between different types of motivation and delineates three basic psychological needs that explain intrinsic motivation (and autonomous types of extrinsic motivation): autonomy, competence, and relatedness (17). When these needs are satisfied, they are inherently rewarding, lead to psychological well-being and flourishment. When frustrated, they lead to negative experiences, such as passivity, illbeing, and defensiveness (18–21). The three basic psychological needs are assumed to be universal, and the satisfaction of the needs is crucial for well-being and functioning in all contexts and across the lifespan (14).

While there are a number of empirical studies that have explored *interpersonal* need support across various fields [e.g., (15, 22, 23)], need support by other means, such as digital health technologies, is less explored. In the domain of human-computer interaction, it has been shown that playing games is a highly intrinsically motivated behavior (24), considered to satisfy all three psychological needs (25). Thus, SDT has in recent years more commonly also been used as a theoretical frame to study the motivational potential of incorporating gameful elements and processes into information systems and services in other contexts (i.e., gamification), where digital health technologies form one of the largest application areas, preceded by the domain of education and learning (13).

The most studied basic psychological need, both in general and in relation to human-computer interaction and digital health technologies, is *autonomy*, which describes the sense of willingness and volition that stems from activities that are in accordance with one's personal goals and values (14). Studies on gaming have indicated that autonomy, for example, may be supported by offering options for tailored support (26). Tailoring strategies involve personalization (making the information more meaningful to the recipient), feedback (presenting individuals with information about themselves), and content matching (directing messages to individuals' needs in relation to aspired behaviors) (27). Tailoring technologies may also facilitate autonomy by allowing the individual to set individual goals, or by removing obstacles to goal pursuit (28).

The second need is *competence*, which is the psychological need for feeling capable and efficient. It is the psychological need that most consistently has been shown to predict engagement in physical exercise (29). Digital health functions, features and content such as the level of challenge and the degree of feedback on behavior or learning opportunities are factors that may satisfy or frustrate the need for competence. For example, the level of challenge (not too easy and not too difficult) was the most frequently reported design feature explaining youth's motivation to engage in digital health lifestyle games in a systematic review of the literature (28). Positive feedback was another feature found to foster engagement, possibly by making the individual feel capable and efficient (26).

The third basic psychological need is *relatedness*, which describes the need to belong and feel connected to others. In this, it explains why social interaction in itself may not always be related to well-being: social interaction can satisfy or frustrate people's need for relatedness (10). Research on the relationship between need support for relatedness and social media technology, for example, indicate that features that facilitate active direct interaction over passive interaction may be a more need satisfying design choice (30), that recognition from others is important (13), and that in games to promote healthy life habits, identification with characters may increase engagement (28). On the other hand, relatedness may not always be an issue, such as when someone prefers to perform the activity solitarily (such as some prefer to exercise) (29).

To date, there are few studies that have investigated both need satisfaction and need frustration, although the very same features that satisfy a need may also frustrate one (e.g., feeling a sense of belonging or feeling left out) (31, 32). An exception in the health domain is a study that focused on fitness apps using self-monitoring, rewards, and social recognition features (31). The study showed that whereas self-monitoring increased competence satisfaction and decreased competence frustration, the incorporation of rewards and social recognition features concurrently satisfied the need for competence and increased competence frustration (31). A model that allows for the exploration and understanding of simultaneous experiences of need satisfaction and need frustration in relation to digital technology use is the METUX (Motivation, Engagement and Thriving in User Experience) model (12), which is based on SDT to understand the impact of digital technology on motivation, engagement, and well-being. A recent review on ethical issues related to digital well-being suggested that this is the most comprehensive framework to date for evaluating digital well-being (33).

The METUX model outlines the three basic psychological needs as the mediators between technology design and user experience (12). After a technology has been adopted, the model describes four spheres of user experience where psychological needs should be considered: (1) in the interaction with the technology interface, (2) in the engagement with technology-enabled tasks such as self-monitoring, (3) in technology-supported behaviors related to healthy habits (e.g., physical exercise, sleep hygiene etc.), and (4), in an individual's life in general. The model provides a lens through which technologies' impact on user experience can be understood, that is, how technology can satisfy or frustrate the basic psychological needs of users at different levels. This, in turn, can explain paradoxical observations, for example that self-monitoring and self-care can both empower and disempower patients (34).

Moreover, satisfaction of needs in one sphere may unintentionally frustrate needs in another sphere (31, 35). For example, the gaming industry provides illustrative examples of how technology can be need supportive in the interface or task domain but at the same time frustrate healthy life habits (32, 36), and healthy lifestyle technologies may be effective in the sense that it is satisfying to interact with their interface but still not supportive of needs related to the behaviors the app was developed to affect (37). Yet, these cross-sphere implications of need satisfaction have largely been overlooked (12, 38). Thus, while there are studies that explore motivational aspects of the user interface, there are few studies that look at the combined motivational impact across interface, tasks, behaviors, and life in general. Conceptually, it has been suggested that some needs may be more vital to satisfy in some spheres than others (e.g., it may be more important that the interface satisfies the need for autonomy than relatedness, whereas relatedness satisfaction is vital in the life sphere) (12). However, how the different needs are satisfied across the different spheres remains to be empirically investigated. Thus, the aim of this study was to explore how the use of a digital tool for self-monitoring and communication with healthcare satisfies or frustrates basic psychological needs across four spheres of user experience: interface, task, behavior, and life. This knowledge can be useful to inform designers about the potential motivational impacts of digital health technology use, which may in turn guide the choice of design functions, features, and content.

METHODS

The study was conducted in a Swedish primary care setting with individuals who participated in a pilot study of a digital health intervention for self-monitoring and digital communication with healthcare staff in chronic care management. The digital health service that was used was a Swedish adaptation of a service that was originally developed at Dartmouth-Hitchcock Health for managing chronic conditions (39). It consisted of monitoring devices (activity tracker bracelet, blood pressure cuff, scale) and a smartphone application. The smartphone application had three core features: health data tracking through sensors and manual input; a personal profile for documenting health goals, preferences and social data; and secure communication to connect with healthcare staff through chat and video. The application enabled automatic sharing of patients' self-monitored data (activity, sleep, and monitoring of selected health parameters) with healthcare staff. In case of potentially serious deviations, alerts were communicated to both patients and healthcare staff. Motivational features consisted of automatically communicated clinical information and suggestions, nudges, and support to patients. Further, linguistic variation was used to personalize communication, and the choice of color and language

TABLE 1 | Open questions with individual response rates.

#	Question	Responses, *n* (%)[a]	Words, *n* (%)[b]
1	Describe in your own words how often and how you used [eHealth tool]:	113 (93%)	1571 (22%)
2	Did your use of [eHealth tool] lead to any changes in your treatment? If yes, in what way?	89 (74%)	773 (11%)
3	What were the challenges with using [eHealth tool]?	93 (77%)	1012 (14%)
4	Describe in your own words how the use of [eHealth tool] has influenced how you take care of your health:	93 (77%)	1197 (17%)
5	Describe in your own words how the use of [eHealth tool] has influenced your consumption of healthcare services:	75 (62%)	899 (12%)
6	What consequences (positive and/or negative) did the use of eHealth tool] have for you?	91 (75%)	1059 (15%)
7	What have you learned from using [eHealth tool]?	88 (73%)	716 (10%)

For each question, we also indicate the accumulated word count from all individual responses combined.
[a]Percent of total number of respondents (N = 122); [b]Percent of total number of words (N = 7,227).

aimed at supporting positive behavior change, enjoyment, as well as reducing stress and anxiety (39). Further details on the original development and implementation of this technology in a US setting are described here (39).

Recruitment and Data Collection

Participants were recruited through the primary care organization among patients over 18 years of age diagnosed with hypertension, chronic heart failure, or mental health conditions (including reaction to severe stress and adjustment disorders, insomnia, anxiety disorders, and depressive disorders). Further inclusion criteria for participating in the intervention study were that participants had a smartphone, an email account, and were able to communicate in Swedish. Identified patients were invited to a group meeting at the primary care center where they were equipped with all necessary devices. An activity tracker bracelet (tracking steps and sleep) was provided to all participants. Individuals with hypertension were also equipped with a blood pressure cuff and some (in particular patients with heart failure) were equipped with a scale. All monitoring devices could be paired with the mobile application using Bluetooth. One of the researchers participated in these group meetings where she informed about the research study and collected contact details of individuals who volunteered to be contacted with an invitation to participate in pre- and post-intervention surveys. Ethical approval for the study was granted by the Regional Ethical Review Board of Stockholm in 2018 (reg nr. 2018-1717-32).

The present study uses data from open-ended questions in the post-intervention survey that was distributed to participants of the intervention study 7 months after recruitment was completed. All respondents provided their informed consent to participate in the study. A total of 134 individuals responded (after two reminders), out of which 122 provided answers to open-ended questions in the survey. The unit of analysis is based on a total of 642 individual answers. The spread in number of answers per individual was median 6 (IQR 4-7). The questions and their individual response rates are shown in **Table 1**. Participant demographics are described in **Table 2**. The majority of respondents (52%) were female, over 60 years of age (51%), and used the digital health technology to manage hypertension (68%). A considerable proportion (28%) of the participants reported that they used the digital health technology as a support for more than one health condition. Some (4%) did not know why they used the digital health technology, or used it for other reasons than hypertension, heart failure or mental illness (7%). The most frequently used functionality (86%) was the activity tracker bracelet for monitoring the number of steps and sleep, and the majority of respondents (57%) declared to interact with the digital health technology at least once per day.

Analysis

The data were analyzed in several steps mixing an inductive and deductive thematic approach (40). The open-ended responses were labeled with a respondent ID and question number and transferred to a mind mapping software (FreeMind, licensed under the GNU General Public License Version 2) for categorization. The first author read through all the text (7,227 words) and created initial codes inductively, within each of the open questions separately. In the next step of the analysis, overlapping categories across the different questions were merged. Thereafter, a deductive coding framework was applied, based on the satisfaction or frustration of the three basic psychological needs, as described in (18) (**Table 3**). This preliminary analysis was presented to the co-authors and discussed in frequent meetings in which categories were merged, moved, or deleted until negotiated consensus was reached. After this, the spheres of user experience as described in (12) (**Table 3**) were applied to the dataset resulting in another layer of deductive coding. This analytic step was conducted by the first author in close collaboration with the co-authors. All co-authors are full time researchers with training in qualitative research methods.

The deductive coding steps led to the exclusion of some open-ended question responses that could not be classified based on our coding framework. Experiences that described outcomes, without further explanation of which needs were satisfied or frustrated, were not included in the analysis. Examples are: *"I exercise more," "I keep a healthier diet," "My blood sugar was reduced," "I experienced no effects," "Stressful to perform self-monitoring."* We also identified and excluded descriptions of experienced satisfaction of safety and security, which have historically not been considered as basic psychological needs in SDT. Rather, they have been defined as deficit needs or need-substitutes that occur as a response to need frustration (14, 18,

TABLE 2 | Demographic details of respondents ($N = 122$).

Variable	Frequency	Percent
Gender		
Male	46	38%
Female	64	52%
Missing[a]	12	10%
Age in years		
20–29	3	2%
30–39	6	5%
40–49	8	7%
50–59	31	25%
60–69	44	36%
70 or older	18	15%
Missing[a]	12	10%
DHT used for[b]		
Hypertension	83	68%
Heart failure	10	8%
Mental illness	24	20%
Don't know/Other	13	11%
Missing[c]	4	3%
Use of functionalities		
Activity tracker bracelet	105	86%
Blood pressure cuff	95	78%
Scale	12	10%
Chat	42	34%
Phone/Video	9	7%
Frequency of interaction with DHT		
At least once per day	69	57%
At least once per week	36	29%
At least once per month	7	6%
Less than once per month	8	7%
Missing[c]	2	2%

DHT, Digital health technology; [a]Age and gender were only reported in the pre-intervention questionnaire; missing values for respondents who only filled in the post-intervention questionnaire; [b]Numbers add up to more than 100% in this category because some used the DHT for more than one diagnosis; [c]Missing values because it was not mandatory to respond.

41). The reasoning is that people are quick to desire safety-security when their needs are frustrated or thwarted (i.e., when the self is threatened). Hence, safety and security are primarily considered as outcomes of need frustration rather than basic psychological needs in their own right and therefore not included in our analysis. Further, some expressions that were unclear or too difficult to interpret were excluded. This included expressions like: *"Increased motivation," "Motivated more steps and thoughts about sleep."* While some of the excluded responses contribute to evaluate behavioral and health outcomes of the digital health intervention, this was not within the scope of this study.

After exclusion of data, our categorization comprised a total of 312 unique responses, split into 360 descriptive codes. While some qualitative researchers argue against any quantification of qualitative data, we are of the opinion that the display of numerical information makes patterns in our data emerge more clearly (42), without making any suggestions regarding the relative weight or importance of individual themes over others. Thus, in our analysis, we present the number of unique responses that contributed to each of the themes that were identified.

RESULTS

The analysis resulted in the identification of experiences that illustrate satisfaction as well as frustration of the three basic psychological needs, in four spheres of user experience. The results are summarized in **Figure 1** and described with illustrative quotes in the sections that follow.

Autonomy

Autonomy satisfaction was identified in respondent descriptions of the ability to take more responsibility in monitoring their own health parameters (task), controlling their self-care (behavior), and taking themselves more seriously (life). For example, the performance of routine monitoring at home was described to lead to more engagement in physical activities and to increase patients' involvement in healthcare. Respondents described how this made them feel more in control and independent, such that the need for healthcare visits and services may decrease. The following quote provides an example of autonomy satisfaction in the task and behavior spheres:

> *I could keep track of my blood pressure, I stopped eating medications slowly until my current state in which I am completely free from them, I can say that it was the best thing I've taken part of concerning my health, I could really take responsibility for trying to feel well, and have reached several goals thanks to [eHealth service]; it was really a disappointment for me when this service was taken away ☹ I feel that I don't have the same level of oversight that I had before ☹ (ID: 4, question 2)*

Autonomy frustration concerned experiences of inflexibility in the technology (interface), feeling pressured to perform self-monitoring (task), feeling guilty if not engaging in health-promoting activities (behavior), and identification with one's diagnosis (life). For example, respondents expressed that they had been asked by healthcare staff to more frequently self-monitor their health parameters, which can be interpreted as external pressure. As one respondent put it, he/she felt that he/she was no longer expected to visit primary care. Some experienced it as time-consuming and challenging to establish a routine for daily monitoring. There was also some frustration caused by message notifications that could not be turned off. One respondent described how he/she had started to feel more guilt when not engaging enough in physical activities. The following quote illustrates how the use of a digital service for self-monitoring and communication with healthcare negatively influenced an individual's overall experience of life:

> *It feels like I've been marked with psychological illbeing because of a short period of exhaustion disorder and I have not had the chance to change this mark. (ID: 91, question 6)*

TABLE 3 | Coding scheme defining the concepts of needs satisfaction and frustration, based on (18), and spheres of user experience, based on (12).

Concept	Definition
Autonomy satisfaction	Experiences reflecting willingness and volition with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology. Satisfaction is characterized by "a sense of integrity as when one's actions, thoughts, and feelings are self-endorsed and authentic."
Autonomy frustration	Experiences reflecting pressure or conflict, such as being pushed in an unwanted direction with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology.
Competence satisfaction	Experiences reflecting effectiveness, mastery, and opportunities for using and extending one's skills and expertise with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology.
Competence frustration	Experiences reflecting "a sense of ineffectiveness or even failure and helplessness" with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology.
Relatedness satisfaction	Experiences reflecting connectedness, involvement and a feeling of significance in relation to others with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology.
Relatedness frustration	Experiences reflecting "a sense of social alienation, exclusion, and loneliness" with respect to using the digital health technology and/or engaging in behaviors supported by the digital health technology.
Interface sphere	Experiences relating to the interaction with the digital health technology via its interface.
Task sphere	Experiences relating to engaging with digital health technology specific tasks.
Behavior sphere	Experiences relating to the engagement in behaviors that the digital health technology is intended to support.
Life sphere	Experiences reflecting an individual's overall life, beyond the digital health technology.

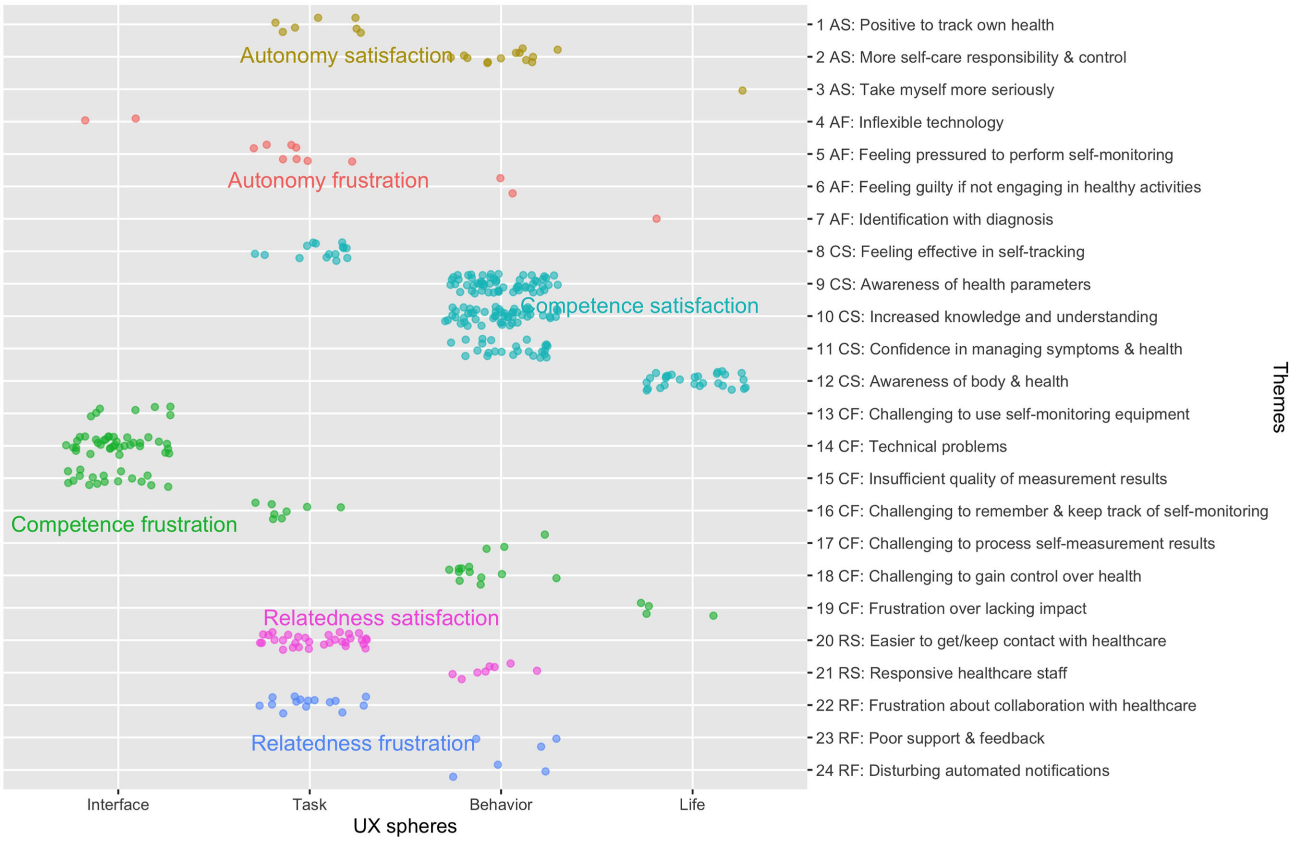

FIGURE 1 | The different themes of need satisfaction and frustration within different spheres of user experience (UX). The dots represent the number of individual codes that contributed to each of the identified themes and user experience spheres. The colored dot fill reflects our classification into autonomy satisfaction (AS), autonomy frustration (AF), competence satisfaction (CS), competence frustration (CF), relatedness satisfaction (RS), and relatedness frustration (RF).

Competence

Competence satisfaction was identified in descriptions of respondents' feelings of effectiveness in self-monitoring (task), increased awareness, knowledge and understanding about health parameters, as well as confidence in managing symptoms (behavior), and awareness about one's body, health and life in general (life). Effectiveness in self-monitoring was described both in terms of the ability to perform their own monitoring and the increased regularity by which this is done. Some explained that their own monitoring reduced the frequency of care visits, which could also be interpreted as a sign of autonomy satisfaction. The increased awareness was described in terms of specific health parameters (e.g., blood pressure, sleep, and physical activity) or in more general terms. As one respondent put it: *"I have a better understanding of myself and that feels good" (ID: 145, question 5)*. Several aspects of knowledge and understanding were raised: the importance of controlling one's health parameters, the importance and effects of one's behavior, effects of treatment, and the ability to pose new questions and make assessments about symptoms and health. The following quote illustrates how increased knowledge and understanding could be used effectively in collaboration with healthcare staff:

> I understood that my blood pressure can vary quite a lot, but because I after a while could prove that my blood pressure was not too high, rather low, the medication could be reduced. My blood pressure was almost always relatively high when it was measured at the primary healthcare center. (ID: 23, question 4)

Competence frustration was identified in all spheres of user experience. In the interface sphere, respondents expressed challenges using the self-monitoring equipment, technical problems, as well as insufficient quality of self-monitoring results that hindered them from feeling effective. In the task sphere, it was described as challenging to remember and keep track of self-monitoring. To remember to monitor health parameters was one challenge, another was to remember certain functionalities that had to be activated in order to properly log activities. In the behavior sphere, some described that it was challenging to be confronted with their self-monitoring results and gain control over their health, for example keeping blood pressure on the right level. Finally, in the life sphere, respondents expressed a general frustration over lacking impact of the digital health intervention. The following quote illustrates competence frustration in the behavior sphere:

> *[What have you learned from using the eHealth service?] – That my blood pressure varies a lot – but not how I should take care of it. I don't know why it varies or what I should do to lower it. I have been prescribed another pill – that's all. (ID: 1, question 7)*

Relatedness

Relatedness satisfaction was identified in respondent descriptions of improvements in getting and keeping contact with healthcare staff (tasks) and responsiveness of healthcare staff on patients' reported health observations (behavior). Respondents described that the digital health technology made it easier for them to get in touch with and access primary care. Some also described that they preferred to use the chat functionality when they felt unable to call due to psychological distress. In terms of responsiveness, respondents described that it felt good that healthcare staff had access to their reported health parameters and sometimes commented with supportive feedback. One of them described this as *"a feeling of being 'surveilled' in a positive sense" (ID: 75, question 6)*.

Relatedness frustration concerned challenges in the communication and collaboration with healthcare staff induced by the digital health technology (task). Some described that they did not get answers to the questions they had posed in the chat. Others described challenges in knowing what types of questions they could pose and daring to write about their needs and experiences. Some also described the lack of personal contact by communicating digitally and the desire to meet healthcare staff face-to-face. Frustration was also expressed in relation to the experience of insufficient support and feedback from healthcare staff in one's self-care (behavior). Few expressed that they experienced the feedback that was provided as disturbing or mechanic. As one of the respondents put it:

> I experienced it as very negative that what I experience as an organization behind the app took part of my data and made brisk comments like "Well done" because my blood pressure had changed between two measurements. That is unlikely an effort on my side for such a change to occur. That made me not want to use the app after a while. Also, I didn't understand why the selected measurement methods were included to communicate with primary care. I don't feel a need to continuously show my weight and physical activity to the primary care center. (ID: 41, question 1)

DISCUSSION

This study explored how the use of a digital health technology for self-monitoring and communication with healthcare in chronic care management satisfied or frustrated users' basic psychological needs of autonomy, competence, and relatedness over four spheres of user experience. Three main findings attracted our attention in the analysis and will be discussed below. First, most user experiences concerned the behavior and task spheres, rather than the interface and life spheres. Second, experiences of influences on the need for competence were more prominent than the influence on other needs in our data, both in terms of need satisfaction and need frustration. Third, tensions were revealed between the satisfaction and frustration of all three needs, which may indicate individual variations. Our findings call for increased flexibility in the design and use of motivational affordances in the design of digital health technologies to support self-care of chronic conditions.

User Experiences Across Four Spheres

Influence on the satisfaction and frustration of basic psychological needs was reflected in four explored spheres of user experience in the METUX model (12), from interactions with the interface and technology-specific tasks to behaviors and life in general. Most of our data, in terms of quantity, concerned the behavior and task spheres of user experience. While all themes in the interface sphere reflected need frustration, experiences of need satisfaction stood out in the behavior and life spheres. Thus, despite reported challenges in the interaction with self-monitoring equipment and a perception of insufficient quality in monitoring results (i.e., challenges related to the perceived usability of the digital health technology), individuals experienced that their awareness of both specific health parameters and their health in general increased. This suggests that the satisfaction or frustration of a psychological need in one sphere does not necessarily predict experiences in other spheres. We identified both satisfaction and frustration of needs in the behavior and task spheres. Some experiences reflected autonomous motivation whereby respondents expressed an identified value or importance of engaging in digital health-supported tasks and behaviors (*identified regulation*). Other experiences reflected controlled motivation that was characterized by individuals feeling pressured by healthcare to perform self-monitoring *(external regulation)* or by feeling guilty if not engaging in healthy activities (*introjected regulation*). These types of controlled motivation are known to have a negative impact on long-term adherence to healthy behavior change (43, 44). Thus, further research is needed to explore long-term effects as well as the relation between the satisfaction and frustration of needs in different spheres of user experience.

It has been suggested that all three psychological needs do not necessarily have to be satisfied at all levels (12). In particular, it has been suggested that relatedness does not need to be satisfied in every interaction with technology and may not be essential in the interaction with an interface (12, 45). In our study, satisfaction and frustration of relatedness was found mainly within the task and behavior spheres, but not in the interface sphere. This supports the claim that satisfaction of some needs may only be detected beyond the level of the interface (12, 35). Our findings emphasize the importance of considering the whole spectrum of user experience in both design and evaluation of digital health technologies. In particular, usability testing, which focuses mainly on the interface and task spheres, should be combined with other evaluation strategies, such as field deployments (46), that capture user experiences from real use in naturalistic settings, beyond individuals' interactions with the user interface.

Competence Satisfaction and Frustration Most Prominent

The influence of the digital health technology on competence, in comparison to autonomy and relatedness, was most prominent in our data. Two themes, in particular, distinguished themselves in terms of typicality. *Increased knowledge and understanding* and *Increased awareness of health parameters* were clearly the most commonly occurring themes in our data. Respondents consistently reported an increased level of awareness and understanding about their behavior and lifestyle that created opportunities for developing their self-care skills. These experiences were mainly related to the provision of visual feedback, which belongs to the most common motivational affordances of persuasive technologies (47), and has been related to intentions to continued technology use (45). These examples of competence satisfaction may also be closely linked to an increased sense of autonomy, and are likely also promoted by autonomy-supportive strategies, such as provision of relevant information and a meaningful rationale for change (43). As highlighted in the SDT model of health behavior change, autonomy-support influences all three psychological needs and the satisfaction of competence is facilitated by autonomy (43). Thus, it should be considered that our examples reflecting competence satisfaction may also include experiences of autonomy satisfaction.

While competence satisfaction dominated in our data, we also found some indications of competence frustration. Some individuals described experiences of discouragement due to failure, which has been described as an unintended side effect of health behavior change support systems using gamification (32). The most common theme of competence frustration in our data concerned technical problems such as sync issues between the monitoring devices and the digital health app, non-functioning activity bracelets and poor perceived quality of monitored data (e.g., tracked number of steps not aligned with personal experiences). With reference to previous research on negative impacts of gamification, the technical problems can be understood as limiting issues that are related to unsuccessful implementation of features (36). One way to interpret the competence frustration resulting from technical problems is that, when interacting with technology, we may need to consider that the satisfaction of needs may be hierarchical. Hereby we mean that some basic needs may need to be satisfied before other needs can be supported. For example, in our study, usability challenges on the interface level may have prevented (some) users to experience the satisfaction or frustration of other needs with respect to using the digital health technology. If the technology does not work as intended or if a user does not know how to use it, its potential influence on psychological needs cannot be explored. Thus, to some extent, the satisfaction of competence needs on the interface and task levels may be a prerequisite for other needs to be supported by the technology. This may be a partial explanation for the relative scarcity of data reflecting the influence on the psychological need of autonomy in particular. However, as pointed out above, the satisfaction of autonomy and competence are likely linked, such that the satisfaction or frustration of one need may influence the satisfaction or frustration of other needs. Another possible explanation is that the design features of the digital health technology that was used in this study were more supportive of competence than autonomy and relatedness. Autonomy support can be provided by personalization and tailoring to enable users to tailor the technology to their individual needs, such as defining which health parameters to monitor and set their own aspired health goals (e.g., a physical activity target) (35, 37). The digital health technology that was used in this study contained some tailoring features that allowed users to customize their personal profile in terms of health goals, personal preferences and social data. However, based on the questionnaire data alone, we could not identify any impact on perceived autonomy.

Tensions Between Satisfaction and Frustration of Psychological Needs

Our data revealed tensions in the satisfaction and frustration of all three psychological needs. The discussion has already touched upon tensions related to autonomy (autonomous vs. controlled behavior regulation) and competence (increased awareness, knowledge and understanding vs. discouragement as a result of failure). With respect to relatedness, some felt that the digital health technology made it easier for them to get and keep contact with healthcare, while others experienced frustration about digital communication, mainly due to the experience of insufficient or lacking responses from healthcare to expressed needs. Similarly, while some experienced healthcare staff as responsive to their behavior changes, others were frustrated by what they experienced as poor support or even disturbing use of external praise and rewards for accomplishments. Self-monitoring technologies, in particular, have raised polarized discussions, highlighting how it may either contribute to strengthen individual's autonomy or, conversely, contribute to increased control and surveillance over individuals (48).

We believe that the tensions in our data may be explained by individual variations in user profiles and preferences. Insufficient fit of the technology to the context and target users, and unsatisfactory interaction design (e.g., exaggerated feedback) have been identified as primary issues that may lead to negative experiences (49). It has also been shown that the use of tailoring, and personalization in particular, may lead to both positive and negative experiences (50). Previous research has found that the value of different design features may depend, for example, on variations in goal profiles (10). Gamification for the provision of feedback and external rewards suits individuals who are outcomes-focused, rather than focused on the process that leads to aspired outcomes. Similarly, quantified-self features may provide feedback that supports goal-setting, as well as evaluation of progress and behavior outcomes (51). However, users with less specified goals may not find quantified-self features as useful, perhaps because the actionability of data they receive through these features is low. Social networking features suit individuals who validate their performance based on comparison with others, while social networking does not fit individuals who have a tendency to avoid setting goals (10). Thus, even if the psychological needs are generic, there may be individual variations that may be addressed, for example by adequate tailoring. While a number of different tailoring design concepts have been described, it has also been emphasized that the use of these to promote healthy behaviors (e.g., through physical activity coaching) is still in its infancy (52). It has also been highlighted that the user profiles of older adults, in particular, have been given limited attention in the gamification research domain (53).

Limitations

We acknowledge that our study has several limitations. We focused on individuals' perceptions of using a digital health service after it had been adopted and used for ∼7 months. When studying this type of technological services, it is not always evident what behaviors and experiences are related to technology use as opposed to other factors. The METUX model was useful to separate user experiences into different spheres, although some experiences were challenging to classify. For example, are all self-monitoring activities that are supported by a digital health technology to be regarded as technology-specific tasks or should some of them be viewed as self-care behavior beyond technology use? For example, individuals may monitor their blood pressure, sleep or weight irrespective of using a particular health technology. However, any possible misclassifications will not have affected our results in terms of the identified themes of need satisfaction and need frustration that can be triggered by digital health technologies. Two spheres of user experience that are also described in the METUX model were not captured in our study: adoption and society (12). While we identified some reflections about the influence on needs on a society level, these were not descriptive enough in detail to classify which type of need they could be related to. Potential societal benefits in terms of public health, healthcare spending and productivity would be of value to explore further in future studies.

We acknowledge that the distinction between need frustration as opposed to low levels of need satisfaction was not always evident in our data. In SDT, satisfaction and frustration of basic needs are considered as two independent and asymmetrical dimensions (18, 19). Whereas need frustration by definition involves low need satisfaction, the opposite is not necessarily true. Need frustration can be described as an active and direct act in contrast with low levels of need satisfaction that are more passive and indirect (19). The distinction is important because it has been shown that experiences of need frustration are more predictive of illbeing (20). We believe that some of the examples in our data may clearly describe experiences of need frustration (e.g., *feeling pressured to perform self-monitoring),* whereas others may in fact represent low levels of need satisfaction rather than need frustration (e.g., *insufficient quality of measurement results*). Thus, our results should be viewed as indicative, giving rise to hypotheses that need further exploration, preferably in combination with health and well-being outcomes data.

A recent review of motivational information systems discussed several future research trajectories, such as paying attention to different types of feedback, design features, and their effects on users, and the need to further take into account individual user attributes (13). Gamification design principles and a list of relating research questions for future research have also been proposed (54). We acknowledge that our study does not allow us to draw generalizable conclusions about the impact of individual design features on the satisfaction or frustration of psychological needs. While an in-depth study of individual design features and their effects was beyond the scope of our study, we may nevertheless suggest some general design considerations that may be applicable in similar contexts. Need satisfaction in our data was most prominent in relation to two of the main functional areas in the studied digital health technology: first, the visual feedback of self-monitored health parameters that was associated with competence satisfaction; and second, the communication feature that improved patients' access to healthcare staff and was associated with relatedness satisfaction. Thus, based on our study population, we suggest that functionalities for visual feedback of health parameters and chat/video communication with staff may be central need-supportive design features in digital health technologies supporting self-care in chronic care management. However, as discussed above, automated messages and nudges triggered both satisfaction and frustration. Therefore, we suggest that the value of personalization features and how to successfully design them should be explored further, ideally in relation to individual user attributes. Finally, as our results indicate that the shifting of health monitoring tasks traditionally performed by healthcare staff to patients may lead to both satisfaction and frustration of autonomy, we suggest that the design of self-monitoring technologies should provide tailoring that allows users to control at least the frequency of self-monitoring, and enable full privacy and control over their own health data (55), to prevent individuals from feeling controlled and monitored by healthcare or a third party.

The study was exploratory in nature and used survey responses to open-ended questions for a deductive thematic analysis. It has been argued that qualitative studies are well-suited to identify the manifestation of need satisfaction and frustration in individuals' narratives (18). The use of questionnaire data in qualitative research has been questioned as it is deemed difficult to fulfill excellence criteria for qualitative research with such data (56). Meeting these criteria requires timely and relevant research questions and findings, as well as rich and appropriate data (57). The research should "meaningfully interconnect literature, research questions/foci, findings, and interpretations with each other" (57). The data included in this study was purposefully gathered with the research question in mind, as part of a larger project exploring how individuals engaged in self-care experience the support from both healthcare and digital health technologies (unpublished). The data included 642 open-ended responses from 122 respondents. Many responses were elaborate and detailed, as showed in the citations presented in the findings. Nevertheless, we acknowledge the limitations at hand, such as the lack of opportunity to probe respondents for further details, which resulted in the exclusion of a number of items in our dataset that could not be used in the analysis. Thus, other means of data collection and analysis, such as individual interviews, possibly combined with data analytics on users' interactions with the digital health technology and behavior over time, would have provided more depth to our data and results. The strength of this qualitative study lies in its coverage, rather than depth. Nevertheless, we suggest that our analysis enriches the understanding of the phenomenon explored and that the data is appropriate for answering the a priori determined research question. In line with Braun et al. (58), we argue that qualitative survey questions can produce the rich accounts of the type of sensemaking typically explored using more common qualitative research methods such as interviews.

Given the limitations that have been addressed, we believe that we can motivate transferability of our findings to the field of persuasive technology focusing on quantified-self in chronic care management (9). While our sample covered individuals with some of the most common chronic conditions (cardiovascular diseases and mental illness) affecting public health, contextual factors, including the study setting and the digital health technology itself, need to be considered when transferring our findings to other settings. The design of gamification and social networking features, which are common in commercial apps promoting a healthy lifestyle, was less explored in our study. In contrast to these types of commercial digital health technologies, the use of digital health technologies in a healthcare setting involves a transition of care activities from healthcare staff to patients, which may entail a number of ethical dilemmas, such as accountability, intelligibility, and accessibility issues (33). One purpose of using digital health technologies in a healthcare setting is to enhance quality of care while limiting costs, which should be taken into consideration when discussing and comparing different types of digital health technologies and the setting they are used in. Our aim was not to evaluate specific design features, but rather to gain a general understanding of the satisfaction and frustration of psychological needs that a typical digital health technology that aims to support self-care in chronic care management can evoke. Nevertheless, we hope that our findings may trigger further research into exploring design issues in more depth.

CONCLUSION

Our study contributes to the field of persuasive technology, in particular in relation to motivational design affordances based on quantified-self. We have focused on the exploration of the satisfaction and frustration of psychological needs that determine autonomous motivation. Based on theory, we know that the satisfaction of psychological needs is central to the maintenance of target behaviors and well-being. To develop digital health technologies that satisfy these needs, designers need to take into account these needs not only at the technology interface level, but at higher levels of user experience. We have demonstrated that engagement with digital health technologies in self-care may influence users in both positive and negative ways. This emphasizes the importance of being aware of the possible variability of goal profiles or other factors among users that may not all be equally compatible with different design features. Therefore, digital health technologies need to be flexible enough to accommodate for variation of user profiles. Future research should further explore variations in user profiles and how to design for flexibility. We believe that careful design considerations that take motivational theory into account will be necessary to transform care for individuals with chronic conditions.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Regional Ethical Review Board of Stockholm (reg nr. 2018-1717-32), Tomtebodavägen 18A, 171 77 Stockholm, Sweden. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

CW and UvT designed the study and collected data, in collaboration with research colleagues acknowledged below. CW was mainly responsible for data analysis. CW, TS, and UvT drafted the manuscript. AS was expert on the theory that was applied, contributed with critical revision of the manuscript, and contribution of important intellectual content. All authors contributed to the interpretation of data, approved the final version of the manuscript, and agree to be accountable for all aspects of the work.

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Toward a Conversational Agent to Support the Self-Management of Adults and Young Adults With Sickle Cell Disease: Usability and Usefulness Study

David-Zacharie Issom[1]*, *Marie-Dominique Hardy-Dessources*[2†], *Marc Romana*[2], *Gunnar Hartvigsen*[3] *and Christian Lovis*[1]

[1] *Department of Radiology and Medical Informatics, Faculty of Medicine, University of Geneva, Geneva, Switzerland,* [2] *INSERM U1134 Biologie Intégrée du Globule Rouge, Paris, France,* [3] *Department of Computer Science, UiT the Arctic University of Norway, Tromsø, Norway*

Edited by:
Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Jane Hankins,
St. Jude Children's Research Hospital,
United States
John Joseph Strouse,
Duke University, United States

***Correspondence:**
David-Zacharie Issom
david.issom@unige.ch

†ORCID:
Marie-Dominique Hardy-Dessources
orcid.org/0000-0003-0861-3648

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Sickle cell disease (SCD) is the most common genetic blood disorder in the world and affects millions of people. With aging, patients encounter an increasing number of comorbidities that can be acute, chronic, and potentially lethal (e.g., pain, multiple organ damages, lung disease). Comprehensive and preventive care for adults with SCD faces disparities (e.g., shortage of well-trained providers). Consequently, many patients do not receive adequate treatment, as outlined by evidence-based guidelines, and suffer from mistrust, stigmatization or neglect. Thus, adult patients often avoid necessary care, seek treatment only as a last resort, and rely on self-management to maintain control over the course of the disease. Hopefully, self-management positively impacts health outcomes. However, few patients possess the required skills (e.g., disease-specific knowledge, self-efficacy), and many lack motivation for effective self-care. Health coaching has emerged as a new approach to enhance patients' self-management and support health behavior changes. Recent studies have demonstrated that conversational agents (chatbots) could effectively support chronic patients' self-management needs, improve self-efficacy, encourage behavior changes, and reduce disease-severity. To date, the use of chatbots to support SCD self-management remains largely under-researched. Consequently, we developed a high-fidelity prototype of a fully automated health coaching chatbot, following patient-important requirements and preferences collected during our previous work. We recruited a small convenience sample of adults with SCD to examine the usability and perceived usefulness of the system. Participants completed a post-test survey using the System Usability Scale and the Usefulness Scale for Patient Information Material questionnaire. Thirty-three patients participated. The majority (64%) was affected by the most clinically severe SCD genotypes (Hb SS, HbSβ0). Most participants (94%) rated the chatbots as easy and fun to use, while 88% perceived it as useful support for patient empowerment. In the qualitative phase, 72% of participants expressed their enthusiasm using the chatbot, and 82% emphasized its ability to improve their knowledge about self-management. Findings suggest that chatbots could be used to promote the acquisition of recommended health behaviors and self-care practices related to the prevention of the main symptoms of SCD. Further work is needed to refine the system, and to assess clinical validity.

Keywords: sickle cell disease, conversational agent, mhealth, high-fidelity prototype, user testing and evaluation, usability evaluation, self-management, patient innovation

INTRODUCTION

Sickle cell disease (SCD) is the most prevalent monogenic disorder worldwide, and represents an increasing global health issue (1). Annually, over 300'000 infants are born with it and this number is expected to raise above 400'000 in 30 years (2). SCD is mainly widespread throughout Africa, India, Middle East, the Caribbean and Mediterranean countries. With population movements, the distribution of SCD has spread worldwide, both in high-income and lower-income countries. In Africa, 50%-90% of affected children die before their fifth birthday, and up to 90% of survivors will not reach 18 years of age (3). In contrast, in high-income countries, where access to high quality healthcare is more available, median life expectancy is estimated at 50 years (4).

SCD is an autosomal recessive blood disorder caused by a change in the beta globin gene (2). People with SCD may have any of a number of hemoglobin genotypes of variable clinical severity (e.g., HbSS, HbSC, HbSβ0, HbSE, Hb SLepore, HbSD) (5). Furthermore, SCD presents a complex pathophysiology, shows considerable clinical variability and is sensitive to various modifying factors (e.g., socio-economical, genetic, biochemical, environmental and behavioral) (2, 6). The disease causes severe complications such as chronic hemolytic anemia and vaso-occlusive pain crises (VOCs) (7). Patients often suffer from a wide spectrum of acute symptoms and chronic complications such as organ damages, chronic inflammation, lung diseases, or sleep disturbances. With aging, SCD manifestations worsen, requiring comprehensive, preventative life-long care.

Simple public health measures and prevention of acute complications include: newborn screening, parental and patient education, antibiotic prophylaxis, up-to-date immunizations, and routine health management with a hematologist or a healthcare provider with expertise in SCD (5). The last decade has seen important advances in the treatment of SCD (8). However, treatments remain limited to a few approved disease-modifying therapies (i.e., Hydroxyurea, Voxelotor, l-Glutamine, Crizanlizumab), symptomatic pain medication, and chronic blood transfusions. Additionally, impacted by their social determinants of health (e.g., genetics, socio-economic status, access to quality healthcare, environmental factors), some patients respond poorly to treatments (9). Consequently, they will have little reduction of symptoms, and the disease will continue to progress. Finally, the only established cure, hematopoietic stem cell transplant is not available to most patients, because of the need for compatible donors, potentially life-threating side effects, procedure-related toxicities, and high costs (10).

Furthermore, compared to the pediatric population, access to comprehensive and preventative care is challenging for the adult and young adult (AYA) population (11). These disparities are mainly caused by shortages of well-trained healthcare providers, and under-resourced specialized sickle cell centers. With such health inequity, mistrust levels are high among AYA with SCD, and many miss routine care appointments (12). Thus, AYA with SCD rely on sub-optimal emergency care (13). Because they often are prone to stigma, neglect or under-treatment, patients often avoid emergency departments and seek treatment only as a last resort, which negatively impacts long-term health outcomes and may lead to early mortality (14).

Consequently, to avoid disastrous consequences and maintain a certain level of Quality of Life, patients must take charge of their own health. Self-management in SCD is key to reduce symptoms frequency and extend quality-adjusted life expectancy (4, 15, 16). However, similarly to other chronic diseases requiring complex healthcare needs (17, 18), SCD self-management is particularly demanding (19). Patients must pay attention to numerous precipitating factors of symptoms, including inadequate eating behaviors, stress, hypoxia, acidosis, infections, dehydration, fatigue, physical exertion, climate (e.g., extreme of temperatures, wind), air pollution, altitude (10, 20, 21). As well, SCD self-management aspects cover self-care in hospitalization, post-hospitalization care, hospital-at-home care, preventive care, health maintenance, self-monitoring, self-diagnosis, or self-treatment (22, 23). Managing effectively such complexity requires an array of skills (e.g., high cognitive capabilities, good disease-specific knowledge, high levels of self-efficacy, problem solving) that only few patients possess (16, 18, 24, 25).

Given the limited resources of healthcare service delivery, scalable and low-cost Mobile health (mHealth) interventions could offer a potential route to support the self-management needs of this population (26). To date, although evidence on feasibility and acceptability is robust, mHealth interventions targeting AYA with SCD are rare, and only offer limited features (27–32). Most research-based apps for SCD typically focus on pain symptoms monitoring or medication adherence. The few publicly available self-management apps propose manual self-tracking (e.g., pain symptoms, hydration) (33, 34). All these features are typically perceived by patients as an additional burden (35). Therefore, long-term engagement in these apps is low, and frequency of use decreases over time. With discontinued or inconsistent use, it is less likely that the intended effectiveness of the mHealth interventions can be realized. Consequently, patients who stand to benefit most from them are least likely to download or use them (36–38).

To address these gaps, prior studies have demonstrated that long-term engagement can be increased when mHealth interventions provide clear utility, personalization, ease of use and seamless integration in daily life (39–43). In addition, recent studies have demonstrated that using conversational agents (i.e., software that imitate communication with humans) such as chatbots could effectively encourage behavior changes and improve health outcomes (44, 45). Chatbots have several natural advantages: anonymity, asynchronicity, personalization, scalability (46). In addition, by living inside messaging apps, increasingly the most used feature of smartphone users (47), conversational agents provide a convenient way to engage with users where they already are. Consequently, this could lead to high acceptance, and ease long-term user engagement through the development of an attachment bond between the user and the system (48, 49). Finally, creating conversational agents that are empathetic and effective could reduce the need for in-person appointments and direct patient-provider interaction, providing much-needed scalability to relieve pressure on the current limited health care resources.

To our knowledge, no work has been done to design chatbots for the specific self-management needs of people with SCD. There is a clear need to understand the usefulness of conversational agents to achieve this intended outcome, and facilitate the user experience with these particular agents. This information can then be used to determine the direction that these technologies are most likely to follow. Consequently, we developed a high-fidelity prototype of a fully automated mHealth coaching app (TREVOR, the sickle cell robot coach), following patient-important requirements and preferences collected during our previous work (50–52).

TREVOR has been designed to deliver simple text-based messages and media objects (e.g., videos, podcasts) to patients in an empathetic way. The chatbot has three objectives. The first aim is to educate patients with evidence-based knowledge on SCD self-management. The second is to inform them on the self-care practices that other patients have ranked as effective in reducing the incidence of VOCs. The third is to connect patients together for community peer-support.

This paper is the last component of a study from which preliminary results have already been published (53). This prior publication was the first to elaborate on mHealth coaching apps to promote the knowledge acquisition of recommended health behaviors related to the prevention of SCD main symptoms. The authors explored a smaller subset of the studied population and focused on a partial analysis of patients' perceived usefulness of the information provided by the chatbot.

The objectives of this paper are to (1) present the chatbot, (2) assess its usability using a group testing approach, (3) evaluate patients' perceived usefulness of the information provided by the system, and to (4) evaluate patient satisfaction in the provided features.

MATERIALS AND METHODS

Study Design

The study was divided in two phases. Phase 1 employed a mixed-methods design, combining quantitative and qualitative data to explore patients' experiences of using the chatbot. Phase 2 exploited qualitative design to explore patients' satisfaction and specific recommendations for better designing conversational agents.

Participants

To be eligible, AYA had to be diagnosed with SCD, possess a smartphone with Facebook Messenger pre-installed, be at least 16 years old [minimum age to have a Facebook account in Europe (54)], and be able to understand French. Individuals who had been cured through bone marrow transplantation gene therapy were excluded. AYA with known cognitive impairment or disabilities that would interfere with completion were accompanied by their caregiver.

Patients were recruited in June 2019 through patient associations and healthcare providers in Guadeloupe and Martinique, prior to the World Sickle Cell Awareness Day. Recruitment was carried out via ads posted on social networks (i.e., WhatsApp, Facebook), as well as through paper posters disseminated in three hospitals (2 in Guadeloupe, 1 in Martinique), and through contacts with sickle cell associations present locally. Interested individuals were prompted to contact the research coordinators from the CAREST network, and could then register for participation. Prior to beginning the evaluation, individuals were invited to download Facebook Messenger via the project webpage or directly via Apple App Store or Google Play Store.

Procedure

All participants gave informed consent before the evaluation and all responses were anonymous. Tests were executed by the first author (DZI), an expert patient, two medical students, two specialized nurses and one medical doctor. Patients were invited to a room in small groups so facilitators could make sure to observe one user at a time. All the tests were video-recorded. Evaluations were conducted using the guide presented in **Table 1**. The guide was developed so patients would have to perform six tasks in the chatbot following a scenario. These tasks were used to simulate the actions that a user may be required to perform by interacting with the chatbot. The goal was to see if users could find information quickly, navigate the application easily, and thus allow us to identify strengths and weaknesses in the system.

First, AYA received a presentation of the mHealth coaching chatbot to understand its aim. Anytime, participants could ask questions relevant to the research aims. Second, participants completed baseline demographic measures. Third, patients tested the chatbot during about 45 min. Fourth, participants completed a post-test survey to measure perceptions of usability and

TABLE 1 | Tasks that patients had to perform.

#	Task (duration)
1	Provide basic information, demographics and general health status (10 mn)
2	Enter your own self-care practices (10mn)
3	See the best practices of the patient community (5mn)
4	See your evaluation (5mn)
5	Request a health coaching from a human (1mn)
6	Talk to a coach or join the online peer-support community (1mn)

TABLE 2 | Debriefing questionnaire.

#	Task (duration)
Q1	What did you think of the chatbot, as a whole?
Q2	Did you have difficulty finding the information? If so why?
Q3	What are the strengths of this chatbot?
Q4	In your opinion, are there points to improve, if so which ones?
Q5	If TREVOR was omniscient, what would you like to ask him?
Q6	If you don't already have it, would you install Messenger (or another messaging app) for TREVOR? Why?
Q7	Do you have any other comments to make?

usefulness, which lasted about 15 min. Finally, AYA could share additional insights on their satisfaction using the chatbot by completing a 7 items non-mandatory questionnaire. See **Table 2**.

Measures

We chose to combine three questionnaires to gain more detailed insights from patients. We first used the system usability scale (SUS) questionnaire (55) to measure the usability of the conversational agent. SUS is a highly robust and versatile tool for usability professionals. The usability questions are composed of five attributes: learnability, efficiency, memorability, errors, and satisfaction. The questionnaire consists of 10 questions on a 5-point Likert scale. High scores (min. 0, max. 4) indicate high usability of the chatbot. A total SUS score above a 68 is considered above average, and anything below 68 is considered below average (56).

Then, to assess patients' perceived usefulness of the chatbot, consistently with the concept of patient empowerment, we used the Usefulness Scale for Patient Information Material (USE) questionnaire (57). Usefulness is measured on a global scale over three subscales which assess cognitive, emotional and behavioral subdimensions. The USE questions consist of 9 questions on a 5-point Likert scale. High scores (min. 0, max. 4) indicate high usefulness of the chatbot. Total maximal score is 36.

Prototype Design

The high-fidelity prototype of TREVOR was developed with Chatfuel (58), the leading chatbot development platform for Facebook Messenger (59). This platform allows to design fully automated and script-based conversational agents. We chose to develop for Facebook Messenger because it is the second most downloaded messaging app after WhatsApp (47), and development for the latter was not yet available at the time.

TREVOR intends to support the daily lives of people with sickle cell disease. Its main goal is to help them better understand how to avoid triggering vaso-occlusive crises. To achieve this, the robot first asks patients to enter a comprehensive set of information including socio-demographics (i.e., educational attainment, location), prescribed treatments, physical and emotional health status, measurable biomarkers (e.g., oxygen saturation, basal hemoglobin level), history of complications, role functioning, self-care practices, empowerment levels, and exposure to potential triggers of VOCS (e.g., physical activity, sleep quality, dietary habits, exposure to cold). Then, the chatbot propose patients to:

- Identify what are the best self-management practices within the patient community;
- Compare their own self-care practices against those of the community;
- Assess their level of empowerment and identify their weaknesses;
- Learn how to adopt patient-recommended self-care practices through educational modules;
- Receive therapeutic accompaniment by a healthcare provider or an expert patient;
- Join online peer-support patient communities.

Participants are also informed that the program should not be used as a replacement for standard care and are urged to make an emergency call or contact their dedicated healthcare provider if necessary.

To support establishment of an emotional bond, enhance user engagement, and motivate patients, TREVOR addresses participants' accountability by referring to earlier data entered, tasks or activities performed (e.g., "Hi Robert, would you like to share more about your dietary habits?"). Furthermore, each message sequence begins with a warm greeting, in which the chatbot enquires about the participant's mood and replies in an empathic way (e.g., "Hello Alexandra, are you feeling better since last time we talked?"). Dialogues have been designed using the World Health Organization' handbooks on how to implement text-based mHealth interventions (60–65). In addition to text messages, media (i.e., videos clips, hyperlinks, audio messages) can be provided to support content delivery. **Figure 1** provides representative snapshots of conversational interactions with TREVOR.

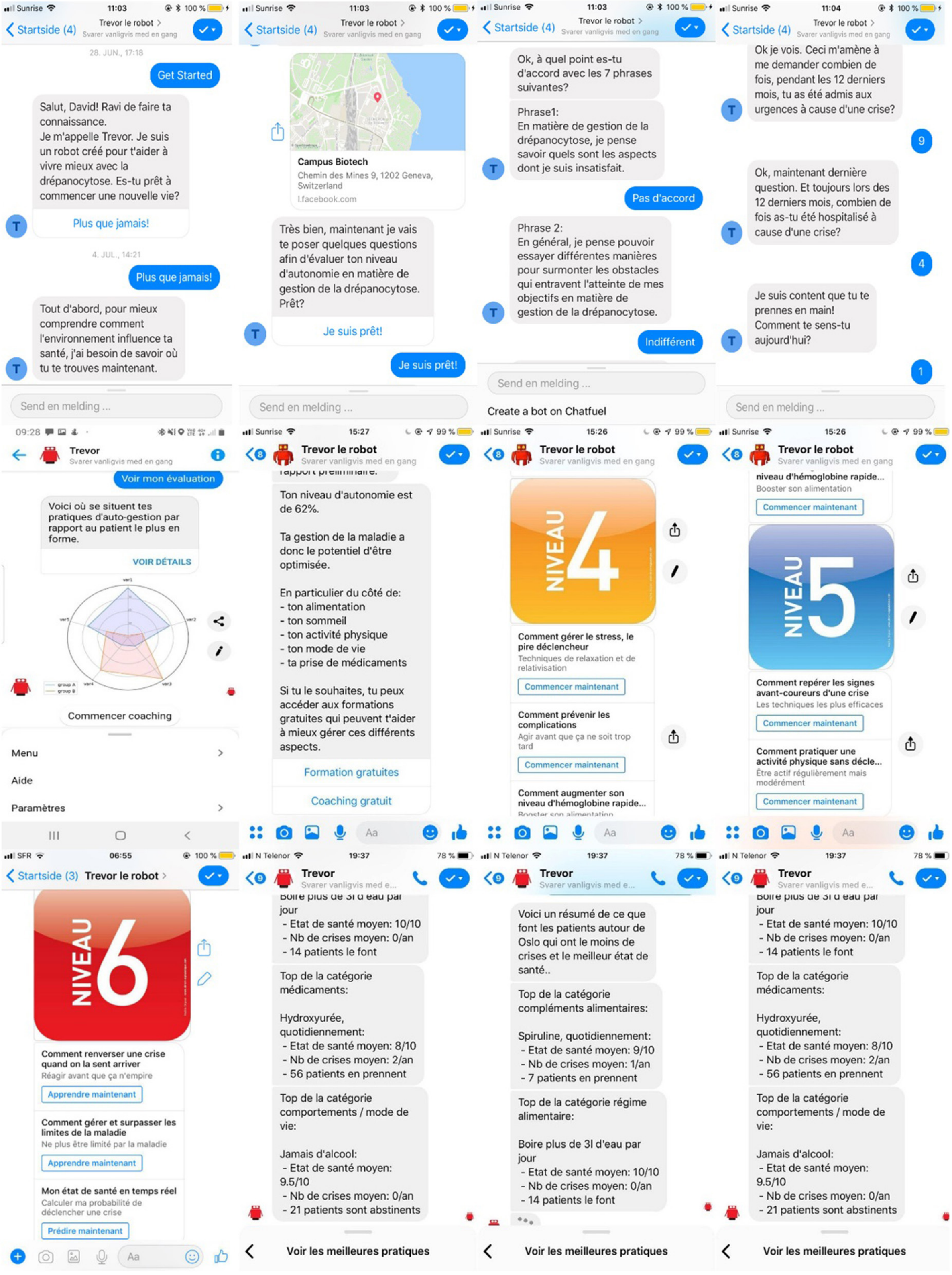
Analysis

Descriptive statistics were computed for demographic and the survey data using STATA version 15 (StataCorporation, College Station, TX, USA). Data are presented as mean (SD) or number (percentage). Transcripts were organized and coded using ATLAS.ti version 8.3.20.0 (ATLAS.ti Scientific Software Development GmBH, Berlin, Germany). An inductive thematic analysis was applied to the data, and a coding framework was developed iteratively during analysis using the guidelines and checklist from Braun et al. (66). Once coding was complete, key themes were identified, explored, and interpreted by DZI. Emerging patterns were clustered together and checked for variability and consistency. Themes were interpreted by reading the codes back and forth.

RESULTS

Participant Characteristics

Thirty-three patients participated in the test and two-third were females. Median age of the participants was 38 years. In addition, the majority of participants (23/33, 70%) were active, either studying or employed. More than half of patients (21/33, 64%)



Salut, David! Ravi de faire ta connaissance.
Je m'appelle Trevor. Je suis un robot créé pour t'aider à vivre mieux avec la drépanocytose. Es-tu prêt à commencer une nouvelle vie?

Tout d'abord, pour mieux comprendre comment l'environnement influence ta santé, j'ai besoin de savoir où tu te trouves maintenant.

Campus Biotech
Chemin des Mines 9, 1202 Geneva, Switzerland
l.facebook.com

Très bien, maintenant je vais te poser quelques questions afin d'évaluer ton niveau d'autonomie en matière de gestion de la drépanocytose. Prêt?

Ok, à quel point es-tu d'accord avec les 7 phrases suivantes?

Phrase1:
En matière de gestion de la drépanocytose, je pense savoir quels sont les aspects dont je suis insatisfait.

Phrase 2:
En général, je pense pouvoir essayer différentes manières pour surmonter les obstacles qui entravent l'atteinte de mes objectifs en matière de gestion de la drépanocytose.

Ok je vois. Ceci m'amène à me demander combien de fois, pendant les 12 derniers mois, tu as été admis aux urgences à cause d'une crise?

Ok, maintenant dernière question. Et toujours lors des 12 derniers mois, combien de fois as-tu été hospitalisé à cause d'une crise?

Je suis content que tu te prennes en main! Comment te sens-tu aujourd'hui?

Voici où se situent tes pratiques d'auto-gestion par rapport au patient le plus en forme.

Ton niveau d'autonomie est de 62%.

Ta gestion de la maladie a donc le potentiel d'être optimisée.

En particulier du côté de:
- ton alimentation
- ton sommeil
- ton activité physique
- ton mode de vie
- ta prise de médicaments

Si tu le souhaites, tu peux accéder aux formations gratuites qui peuvent t'aider à mieux gérer ces différents aspects.

Comment gérer le stress, le pire déclencheur
Techniques de relaxation et de relativisation

Comment prévenir les complications
Agir avant que ça ne soit trop tard

Comment augmenter son niveau d'hémoglobine rapide...
Booster son alimentation

Comment repérer les signes avant-coureurs d'une crise
Les techniques les plus efficaces

Comment pratiquer une activité physique sans décle...
Être actif régulièrement mais modérément

Comment renverser une crise quand on la sent arriver
Réagir avant que ça n'empire

Comment gérer et surpasser les limites de la maladie
Ne plus être limité par la maladie

Mon état de santé en temps réel
Calculer ma probabilité de déclencher une crise

Boire plus de 3l d'eau par jour
- Etat de santé moyen: 10/10
- Nb de crises moyen: 0/an
- 14 patients le font

Top de la catégorie médicaments:

Hydroxyurée, quotidiennement:
- Etat de santé moyen: 8/10
- Nb de crises moyen: 2/an
- 56 patients en prennent

Top de la catégorie comportements / mode de vie:

Jamais d'alcool:
- Etat de santé moyen: 9.5/10
- Nb de crises moyen: 0/an
- 21 patients sont abstinents

Voici un résumé de ce que font les patients autour de Oslo qui ont le moins de crises et le meilleur état de santé..

Top de la catégorie compléments alimentaires:

Spiruline, quotidiennement:
- Etat de santé moyen: 9/10
- Nb de crises moyen: 1/an
- 7 patients en prennent

Top de la catégorie régime alimentaire:

Boire plus de 3l d'eau par jour
- Etat de santé moyen: 10/10
- Nb de crises moyen: 0/an
- 14 patients le font

Boire plus de 3l d'eau par jour
- Etat de santé moyen: 10/10
- Nb de crises moyen: 0/an
- 14 patients le font

Top de la catégorie médicaments:

Hydroxyurée, quotidiennement:
- Etat de santé moyen: 8/10
- Nb de crises moyen: 2/an
- 56 patients en prennent

Top de la catégorie comportements / mode de vie:

Jamais d'alcool:
- Etat de santé moyen: 9.5/10
- Nb de crises moyen: 0/an
- 21 patients sont abstinents

FIGURE 1 | Snapshots of TREVOR conversational agent.

TABLE 3 | Characteristics of the study participants.

Characteristic	Value (*N* = 33)
Gender, *n* (%)	
Females	22 (66.67)
Males	11 (33.33)
Age, years, mean (SD; range)	37.37 (11.98; 19–59)
Genotype, *n* (%)	
Hb SS	19 (57.58)
Hb SC	11 (33.33)
HbSβ0	2 (6.06)
Hb S Lepore	1 (3.03)
Children in household, *n* (%)	
Yes	12 (36.36)
Employment status	
Student	30.3
(Self) Employed	39.4
Unable to work	12.1
Unemployed	9.1
Homekeeper	9.1
Country of residence, *n* (%)	
Guadeloupe	28 (84.84)
Martinique	5 (15.16)
Smartphone Operating System, *n* (%)	
Google Android	30 (90.9)
Apple iOS	3 (9.1)
Years since using current Smartphone, *n* (%)	
Less than 1 year	3 (9)
1 to 2 years	2 (6)
More than 2 years	28 (85)
Frequency of Smartphone usage	
Often (daily)	29 (88)
Regularly (several times a week)	2 (6)
Sometimes (1 to several times a month)	2 (6)
Preferred messaging app	
WhatsApp	26 (79)
Facebook Messenger	2 (6)
E-Mail	4 (12)
No preference	1 (3)
User of existing mHealth app for SCD	
SickleOScope	2 (6.06)
DrepaCare	4 (12.12)

were affected by the most clinically severe SCD genotypes (Hb SS, HbSβ0). See **Table 3** for further details.

Perceived Usability and Usefulness

The results of the usability questionnaire are summarized in **Table 4**. Only two patients (6.1%) gave a total score below average (67), respectively 55 and 65. Mean scores of each positive question were at least 3.2, which was above the midpoint of the scale 0 to 4. The maximum mean score of negative questions was 0.9, which was below the midpoint of the scale 0 to 4, and indicates little need for assistance. The average SUS score was 83 (SD 11) out of the total of 100, and the median was 85, indicating a very usable system. Among the 15 participants older than 40 years old, 7 (47%) gave a SUS score above the median, while among the 18 patients younger than 40 years old, 11 (61%) gave a SUS score above the median.

> *"Concrete questions and indications; Easy and intuitive" Patient 20, 32 years old*
> *"Fast processing, accurate and consistent information. No complexity due to reading or using the application." Patient 8, 19 years old*

The results of the usefulness questionnaire are summarized in **Table 5**. Only four patients (12%) did not find the information provided useful, giving a score below average of respectively 13, 14, 15 and 16 out of 36. The minimum mean score was 2.2, and the maximum mean score was 3.1. The average USE score was 25 (SD 6.4) out of the total of 36, and the median was 26, which shows that patients found the information provided by the system useful. Among the 15 participants who were older than 40 years old, 5 (33%) gave a usefulness score higher than the median. In contrast, among the 18 patients younger than 40 years old, 10 (56%) gave a score higher than the median.

> *"Rich information (with scientific sources)" Patient 20, 32 years old*

Among the 4 participants (12%) who did not find the information provided very useful, 2 shared more insights about what they would like to receive. One of these patients, aged 41, asked for more content related to ulcer treatment. The other patient, aged 37, asked to receive more information about dietary supplements and phytomedicines for SCD. Finally, several patients (6/33, 18%) particularly appreciated the empathy conveyed by the chatbot:

> *"It looks like we are communicating with someone who understands our health status" Patient 23, 37 years old*

Debriefing Survey and Suggestion for Improvements

Twenty-four patients (73%) commented positively on the convenience of the design (e.g., ease of use, fun). Twenty-seven patients (82%) found the content particularly useful or interesting. **Table 6** lists patients' suggestions for improvements in seven categories, for items that were expressed by more than one participant. Regarding content, more than one patient suggested to receive information about how to prevent and early detect VOCs, learn more about research advances, or learn more about how to manage their physical limitations (e.g., while hiking). **Table 7** lists the suggestions for novel features extracted from the answers to open-ended questions. Regarding usability, the most typical request (10/33, 30%) for design improvements clustered around more flexibility in the choice of answers:

> *"Sometimes there are several response options but you can only choose one" Patient 31, 19 years old*

TABLE 4 | Results of the SUS questionnaire.

Question	**Mean (SD)**
I thought the system was easy to use.	3.5 (0.7)
I would imagine that most people would learn to use this system very quickly.	3.5 (0.5)
I think that I would like to use this system frequently.	3.3 (0.5)
I found the various functions in this system were well integrated.	3.2 (0.7)
I felt very confident using the system.	3.2 (1.1)
I needed to learn a lot of things before I could get going with this system.	0.9 (1)
I think that I would need the support of a technical person to be able to use this system.	0.7 (1)
I found the system unnecessarily complex.	0.7 (1)
I thought there was too much inconsistency in this system.	0.7 (0.9)
I found the system very cumbersome to use.	0.6 (1)

TABLE 5 | Results of the USE questionnaire.

The chatbot….	**Mean (SD)**
…contains information I need.	3.2 (0.8)
…encouraged me to become more active in order to improve my condition.	3.1 (1)
…showed me how I can contribute to the success of the treatment.	3.0 (0.8)
…has given me courage.	2.9 (0.9)
…helps me to participate in decisions made about my treatment.	2.8 (1)th
…helped me to understand the treatment options.	2.7 (1.2)
…has given me the hope that I will feel better again.	2.7 (0.8)
…reduced my worries about my disease/illness.	2.4 (1.3)
…helped me to understand the disease/illness.	2.3 (1.2)

TABLE 6 | Summary of suggestions of improvements.

Suggestion	**Number of quotes**
Enhance diversity of questions and choices of answers	6
Ease the modification of answers	4
Receive additional content	4
Improve readability / esthetics	3
Develop a standalone application	3
Have casual conversations with the chatbot	2

Some participants (3/33, 9.1%) felt that the readability of the context displayed was not optimal:

> *"It might be preferable to create a standalone app, for better aesthetics" Patient 1, 36 years old*

Furthermore, some respondents (4/33, 12%) proposed to add more content:

> *"Give advices to avoid reckless behaviors and inform about what to do when I have been reckless." Patient 26, 46 years old*

From a usability point of view, some respondents (4/33, 12%) wished to be able to modify their answers more easily:

TABLE 7 | Patients' suggestions for information that TREVOR should provide.

Suggestion	**Number of quotes**
How to prevent VOCs?	3
How to stop a VOC?	3
What are new research advances?	3
At what level are my important biomarkers (e.g., oxygen saturation, hemoglobin)?	2
Can I do a mountain hike /physical exercise today?	2
What are the new / best treatments?	2
What should I eat / drink?	2
How to early detect VOCs?	1
How to erase taboos and stigma?	1
What is my life expectancy?	1

> *"For corrections in case of input error, just go back straight to the error" Patient 30, 37 years old*

Although there exist some design issues, these problems did not cause severe inconveniences in using the chatbot. Both quantitative and qualitative results reflected that participants had a high intention to use TREVOR once ready:

> *"Yes, I will use this app regularly, it contains information that are useful for me daily" Patient 4, 26 years old*

Overall, participants were satisfied by the chatbot, appreciated its ease of use and the content offered:

> *"I like it a lot, it is very practical, interactive, fun, and easy to use" Patient 2, 59 years old*

Patients were particularly enthusiastic to be able to converse with the system anonymously:

> *"As a strong point, it is really the anonymity" Patient 10, 29 years old*

Unexpected Observations

Four patients (12%) encountered a bug while performing the tasks. The chatbot would not respond anymore until they closed and re-opened the conversation. This issue only appeared with Huawei smartphones. Two patients (6.1%) were assisted by their caregiver because of sight issues. Finally, one patient (3%) reported difficulties in understanding the meaning of some questions.

DISCUSSION

Principal Findings

A small convenience sample of adults and young adults with SCD was recruited to examine the usability and usefulness of TREVOR, a conversational agent we designed to support SCD self-management. We used mixed-methods, combining quantitative and qualitative data. Following the evaluation, quantitative results showed high usability and usefulness scores. Qualitative findings provided insights into usability issues, usefulness and suggestions of improvements and new features. This study adds to the currently limited body of knowledge of chatbots for chronic disease health coaching, and suggests that conversational agents are welcomed by AYA with SCD.

As it is often the case in SCD research (68), women were predominant among participants, and men were under-represented (67). This suggests more incentivization (e.g., build a personal rapport, offer compensation) to male individuals with SCD may be necessary (69).

Consistently with most smartphone users (47), the large majority of respondents (88%) were daily users of messaging apps, and particularly WhatsApp. Although our prototype was available only on Facebook Messenger, patients did not suffer from an adaption period and felt confident using it. This is likely due to the similarity of conversational interfaces. In addition, most participants imagined that most other patients would learn to use the system very quickly. Congruently with prior research showing that chatbots are highly usable due to their simple and familiar user interface (70), our findings suggest that chatbots for chronic disease self-management can have high acceptance rates and usability scores.

An important finding is that the highest USE score was about the question: "the chatbot contains information I need." This indicates that patients value learning from other patients' experiential knowledge, and in particular learning about what could be effective self-care practices. As well, participants seemed to appreciate receiving evidence-based knowledge on recommended self-management. As with other patient communities such as PatientsLikeMe or Crohnology (71), such features could inspire patients to participate in and contribute to the growth of commons-based peer production models and community-based research (72). However, some participants (12%) did not find the information provided particularly useful. Due to their age and according to what some suggested, it is likely that they already had good disease-specific knowledge, and therefore simply wished to have more specific information.

Participants emphasized having been able to learn about their disease in a ludic and empathetic way. This finding is not surprising since TREVOR has been conceived to have an empathetic personality, and since personification is known to lead to high user satisfaction, user engagement and dialogue quality (73). In addition, since motivation is an important factor for patient empowerment, can exert an influence on self-management, and on the adoption of healthy behaviors (74), such personalization may be able to enhance patient engagement in the long-run (75). Consequently, it is important to further investigate similar approaches to better understand how using chatbots for mHealth interventions could have a positive impact on health outcomes.

Patients highlighted their desire to prevent and detect early VOCs. Currently, a growing number of mHealth apps are being developed, but none provides information on such a patient-important aspect of disease management. We think that since our findings indicate that conversational agents could be a useful channel of communication for mHealth interventions, further research should focus on how to provide targeted information on particular domains of self-care management such as the prevention of VOCs.

By implementing such features, future chatbots could increase their utility. Therefore, in our opinion, it is particularly important to conduct profound research, both in low- and middle- as well as in high income countries, to collect information about the various ways that patients self-manage all over the world. Afterwards, giving back such information through a conversational agent could be effective.

LIMITATIONS

We acknowledge that it is difficult to generalize our findings because of small sample size and non-probability sampling methods. There is likely a selection bias. Since some of the participants were recruited by contacting patient associations, were asked to bring their own smartphone, and given most were students or employed (presumably people with good health functioning and self-efficacy), it may have attracted the most active and motivated ones, and those particularly at ease with social media apps. However, in view of the results, participants may be willing to inform other patients about the potential benefits of TREVOR, helping to recruit more diverse participants in future studies. Precise interpretation remains difficult since research applying a socio-demographic determinants of health lens in people with SCD in French West Indies is lacking. Highly acceptable digital health tools such as TREVOR could be useful to collect real-life data and socio-demographic data in such studies.

Another limitation is that patients did not use the app for a prolonged period of time. We think it would also have been useful to determine the average chatbot session length. Therefore, results should be considered with due caution.

The principal investigator being an expert patient, it is likely that it enhanced participants' interested, and that patients were particularly open-minded in contributing to the development of new means of health service delivery designed to meet their needs.

Our study is limited by the participant characteristics, which may not reflect the whole population of adults with SCD. First, the study was carried out only on a West Indian SCD population, but this should have little impact given the similarity of the challenges faced by adults with SCD all over the world (76).

It is also important to note that conversations have been designed by French-speaking people from a French cultural influence. Adaptations to make conversations appropriate to different languages and culture could be needed in future versions. Another limitation is that the reading level was not assessed. However, the text was reviewed by nurses practicing patient therapeutic education. Then, given participants' relatively young median age (38), it is likely that patients were already comfortable using messaging apps.

Although the sample size is small, patients above the median age found the system slightly less easy to use and less useful, suggesting that chatbots may be less adapted to older populations. Furthermore, since our sample did not include younger people with SCD, and since the chatbot was conceived for adults and young adults, we do not know if pediatric patients or their caregivers would have preferred other communication channels or different content.

In order to facilitate user experience, we did not enable the possibility for patients to enter free-text. However, some patients wished to have this possibility. Finally, extensive tests with various smartphone brands will be needed in order to comprehensively debug the system.

Recommendations for Future Design and Implementation Research

On the basis of the findings of this study and patients' suggestions of improvements, we formulate eight recommendations for the future developments of chatbots:

1. Simplify the readability of the system (77):
    a. Patients reported that displaying a long list of information could be challenging to read. We recommend developers to make sure that content is written at an appropriate reading level. As well, since cognitive function may be decreased in symptomatic people with SCD (78, 79), making the content more readable could be beneficial to patients. This could be done for instance by providing more media (e.g., images, infographics, animations), short and simple sentences, by enabling text-to-speech features, by making sure the user has enough time to read the text and respond to the message, and by developing content in collaboration with patients with various reading skills, health literacy levels and neuropsychological problems.
2. Improve the flexibility and efficiency of user input:
    a. combine text-based interface with buttons and media;
    b. add auto-suggestion buttons (e.g., using Natural Language Processing);
    c. enable multiple-choice questions;
    d. enable casual conversations and free-text answers.
    e. enable modification of previously entered answers and explicitly design dialog failures interactions (e.g., automatically go back to the point of failure);
    f. integrate automatic data collection of important biomarkers (e.g., oxygen saturation) from wearables and health-tracking platforms (e.g., Google Fit, Validic) (80, 81).
3. Address various levels of patient health literacy (82):
    a. One patient (3%) had troubles interpreting the meaning of some questions. Prior research has demonstrated that people with SCD had suboptimal levels of health literacy (83). Therefore, it is important to tailor health information to the skills of patients. As McClure et al. (84) demonstrated, several tools can be used to assess patient education material. As well, Alberts et al. (85) successfully used the Newest Vital Signal instrument to measure health literacy and numeracy in patients with SCD (86). We recommend further studies to pay attention into matching the language and content with patient abilities, and to provide links to additional explanations (87).
4. Encourage participatory research and co-design:
    a. To satisfy highly literate patients and help improve the quality of the content provided, we recommend researchers to invite such knowledgeable patients into the elaboration of mHealth chatbots.
5. Disseminate chatbots on as many messaging platform as possible, including as a native app:
    a. To provide patients with an agreeable user experience on their favorite messaging app, attention should be paid on measuring, and comparing performance on various messaging platforms. This could be achieved by comparing metrics such as usability, esthetics, speed, or by investigating alternative methods for conversational user interface evaluation (88, 89).
6. Build a knowledge base into which the chatbot could tap:
    a. Since most of the suggestions of new features were related to answering specific questions about SCD, building such a base could contribute to the evidence base.
7. Provide effective chatbot discovery:
    a. Chatbots are not listed in Google Play or Apple App Stores. Thus, since chatbot directories are manifold (90), a version

of the chatbot could be developed as a native app for Android or iPhone users to facilitate discovery.

8. Add empathetic small-talk and psycho-social support capabilities;
    a. Since some patients have asked to be able to discuss about life matters, future chatbots should include the possibility to answer to a variety of conversation types, or redirect the conversation to humans (91).

CONCLUSION

Self-management of people with SCD is a never-ending task. It is therefore important to seek to develop systems that can fit into patients' daily life with the least disturbances possible. Messaging apps are among the most popular smartphone apps. Therefore, building mHealth interventions that meet patients directly where they are may facilitate adoption and long-term engagement.

This study is the first to contribute to the evidence base regarding the utility and effectiveness of chatbots for adults with SCD. As well, findings contribute to the growing literature demonstrating how usability assessment of mHealth apps provides invaluable information for iterative developments. This study was achieved by testing a high-fidelity prototype of a mHealth coaching app in terms of usability and usefulness if information provided. We used a non-clinical convenience sample of adults with SCD living in the French West Indies.

Quantitative results suggest that chatbots for health coaching can be easy and fun to use, while providing useful support for patient empowerment. In the qualitative phase, participants expressed their enthusiasm using the system, and emphasized on the usefulness of such system for disease-specific knowledge acquisition. The large majority of participants found the content interesting and useful to learn more about recommended self-care practices related to the prevention of symptoms.

However, to better understand if chatbots for SCD can become an useful complement to clinical care, controlled studies will be needed to evaluate over longer periods aspects such as clinical utility, clinical safety, acceptability, usage, or engagement. Finally, future studies could attempt to recruit participants from a wider range of backgrounds, and other in-depth evaluation methods could be carried out.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

DZI is the principal investigator and made a direct and substantial contribution to this work by providing the project idea, study topic, conception, and design of the study and also conceived the prototype and contributed to data collection and analysis. MDHD and MR significantly contributed to patient recruitment and the usability tests. GH and CL supervised the study and provided critical revisions that are important for the intellectual content of the manuscript. MH-D, MR, GH, and CL revised the manuscripts. All the authors have read and approved the final version of the manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2021.600333/full#supplementary-material

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Patent Landscape of Automated Systems for Personalized Health Management (ASHM): Features, Shortcomings, and Implications for Developing an Optimal ASHM

Andrey Martyushev-Poklad and Dmitry Yankevich*

Federal Research and Clinical Center of Intensive Care Medicine and Rehabilitology, Moscow, Russia

The current struggle of national health care systems against global epidemic of non-communicable diseases (NCD) is both clinically ineffective and cost ineffective. On the other hand, rapid development of systems biology, P4 medicine and new digital and communication technologies are good prerequisites for creating an affordable and scalable automated system for personalized health management (ASHM). The current practice of ASHM is better represented in patent literature (36 relevant documents found in Google Patents and USPTO) than in scientific papers (17 documents found in PubMed and Google Scholar). However, only a small fraction of publications disclose a complete self-sufficient system. Problems that authors of ASHM aim to address, methodological approaches, and the most important technical solutions are reviewed and discussed along with shortcomings and limitations. Technical solutions for ASHM currently commercialized or described in literature generally fail to enable practicable, scalable and affordable automated and individualized screening, monitoring, prevention and correction of human health conditions. They also fail to provide a decision support system to patients that would help effectively prevent major NCD and their complications, be accessible and cost effective, consider individual lifestyle factors and involve patients in management of their individual health. Based on analysis of the literature, models of health and care, we propose conceptual framework for developing an ASHM that would be free from the mentioned problems.

Keywords: health management system, preventive medicine, personalized medicine, continuity of patient care, patient-centered care (MeSH term), lifestyle interventions, behavior modification, decision support systems

Edited by:
Maria Hägglund,
Uppsala University, Sweden

Reviewed by:
Rebeca Isabel García-Betances,
Polytechnic University of Madrid, Spain
Maria Vittoria Bulgheroni,
Ab.Acus, Italy

****Correspondence:***
Andrey Martyushev-Poklad
avmp2007@gmail.com

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INTRODUCTION

In the context of global epidemic of non-communicable diseases (NCD) and active progress of digital technologies, there is a growing understanding that automated health management systems could be of great help to improve patient outcomes and reduce health care costs.

Health management is essentially the meaning and the major content of medical practice. However, if we compare the definition of health given by the World Health Organization (1) with goals and objectives of real clinical practice, it is obvious that today's health care focuses on a narrow range of health continuum (2, 3)—namely, on managing diseases. This is true not only for healthcare institutions but also for companies involved in digital health: only 23.8% of them focus on prevention, while the rest develop products and services for diagnostics and treatment of health conditions (4).

With all the above, there is a considerable gap between general theoretical understanding of the causes behind NCDs and the instruments and interventions that health professionals practice on daily basis. Thus, for example, it is generally understood that more than 80% of health status is determined by lifestyle factors (5); however, worldwide the major instrument of health interventions are not lifestyle interventions but pharmacotherapy.

From economic viewpoint, preventive measures are much more cost effective (in terms of health improvement per invested resources) than the treatment of disease complications. This is why "reactive" strategy of treating already existing NCDs and their complications will always face scarcity of resources. Another major factor of scarcity is allocation of roles in today's prevalent model of health care: the burden of decision making, interventions and responsibilities is born by the doctor, whereas the most efficient measures leading to health improvement are closely related with the patient's behavior, with his/her ability to manage one's own health.

The trend toward a more efficient model of health care is connected with the paradigm of "P4 medicine"—predictive, preventive, personalized, and participatory (2, 6). An important prerequisite of improving healthcare efficiency are digital and communication technologies (e-Health, including telemedicine) and patient-centered technologies (individual wearable devices, health trackers, etc.) used to address patients' needs across the whole continuum of health care (7–9).

However, at the level of scalable technologies, the new more effective paradigm of P4 medicine is far from implementation.

This paper reviews current industry practices and technical solutions in automated management of individual health proposed in marketed services and patent literature: (1) the problems that they address, (2) their actual capabilities, and (3) their limitations. We also discuss promising directions and potential framework for developing an optimum automated system for personalized health management (ASHM).

SOURCES OF INFORMATION ABOUT CURRENT PRACTICES IN AUTOMATED SYSTEMS FOR PERSONALIZED HEALTH MANAGEMENT AND SEARCH CRITERIA

There is a wide range of technical solutions on the market for managing patient's medical data. These include medical information systems, health information systems, hospital information systems, clinical information systems. They are all intended to manage electronic medical records or electronic health records and support clinical decision making. At the national level, such systems serve to evaluate and improve the quality of health care and to manage the whole health care system (10, 11). However, they cannot solve the tasks of managing the health of individual patients, the more so in automatic mode.

Before going into analysis of available data on ASHM we need to first define this term. The field that it belongs to is Digital Medicine, Digital Health and Care. "Digital medicine" describes a field concerned with the use of technologies as tools for measurement, and intervention in the service of human health (12). According to Ejehiohen (13), "digital health" is an improvement in the way healthcare provision is conceived and delivered by healthcare providers through the use of information and communication technologies to monitor and improve the well-being and health of patients and to empower patients in the management of their health and that of their families. Another very broad definition was given by Frost and Sullivan (14): "Digital health refers to a vast market of information technology applications, platforms and services leveraged by healthcare providers, payers, med tech and life sciences companies, patients, and consumers."

We see ASHM as an integrated, self-sufficient technology solution designed to solve a wide range of tasks of long-term personalized health preservation, disease prevention and treatment through automated collection, storage, management and exchange of health-related information.

ASHM can be considered as one of possible information technology applications within digital medicine and digital health fields. This should be an integrated solution (product or service), so ASHM has to involve to certain extent all four aspects of digital health according to Deloitte (15): Telehealthcare (with remote monitoring and consultation), mHealth (smart mobile devices and applications), data analytics (for data-driven decision making), and digitized health systems (management, storage, and exchange of electronic health records).

We are developing such an integrated solution, so this review was initially plotted and designed as an analysis of prior art for a patent application on ASHM. Therefore, its main purpose is to reveal and systematize the key features of published potentially scalable relevant technical solutions having a commercial potential. That is, we focus not on just any technology of digitalization or automation of health care, health measurement or health intervention. We are rather interested in a self-sufficient automated system of collecting, processing and use of health-related information that should provide a measurable clinical result to an unmet problem or need of a real customer (patient). Our idea was to understand both the organizational model and technical IT solutions that are able to give a new result in the form of restoring or improving measurable parameters of health, along with understanding the shortcomings and gaps of the existing solutions.

Therefore, we had quite strict and narrow requirements to the documents we were looking for; they had to describe:

(1) an integrated (self-sufficient) system capable to solve major tasks of health care continuum, not only improve certain steps of an existing system;

(2) the scientific and organizational model of managing health that the system is based on (namely, biomedical or biopsychosocial model);
(3) the types of information collected, the purpose and mode of collection;
(4) the way this information is processed or analyzed;
(5) the logic of decision making regarding patient's health, and the type of health-related decisions it supports;
(6) measurable health-related results it provides as the consequence of better decision making.

Based on the above criteria, we used primarily the following key words that had to be present in the summary of searched documents: "system," "health," "automated," "management," "human," "personal*" (for example, "automated" AND "health management system"). All documents matching these key words were further analyzed for the criteria described above.

In our search of the current practices, we first performed search in two open databases: PubMed and Google Scholar. With PubMed database (https://pubmed.ncbi.nlm.nih.gov/) we used key words "health management system," with and without "automated."

With probe and error we chose the most productive keywords for search in Google Scholar (https://scholar.google.com/): "human" AND "personal*" AND "health management system." We opened all sources containing the whole phrase "health management system" and checked them for the above criteria of a self-sufficient ASHM.

We understand that with technologies bearing a commercial potential it is a routine strategy that their authors use a specific logic of bringing them to public. To avoid anticipation of novelty of their products and technologies, inventors tend not to publish them in peer reviewed journals but instead disclose them in the first place through analysis of prior art and detailed description of the invention in patent application. Also patent sources were somewhat preferred to non-patent literature due to other reasons:

1) Patent applications usually don't have space and format limitations inherent in peer reviewed research papers, as well as quality of data supporting the results the system provides (i.e., the system can be described as early as at the stage of idea);
2) Patent applications have to provide adequate technical description of the claimed invention to meet patentability criteria;
3) Patent applications focus on practical results and advantages that the invention can provide, and outline their distinctive features from similar solutions; on the other hand, they can disclose ideas not yet put into practice.

We analyzed granted patents and published patent applications covering systems for health management. Keyword search in Google Patents (https://patents.google.com/) was performed with keywords in Abstract (AB = "health management system" AND "human" AND "personal*"). We then analyzed separately patent documents filed with major national patent offices (USPTO, EPO, in Japan, China, and Korea). To make sure that all potential patent documents are analyzed, we also performed search in the database of US Patent and Trademark Office (USPTO, http://patft.uspto.gov/) over the whole available time frame (2001-present for applications, 1976-present for full text patents) with the following broad key words in claims: "health management."

In rating the relevance and quality of the found published descriptions on ASHM, both in patent and non-patent literature, we proceeded from understanding that the currently prevalent biomedical (BM) disease-centered model of health and care is effective in managing acute disease and urgent conditions. On the other hand, chronic conditions cannot be effectively managed without use of the biopsychosocial (BPS) patient/person-centered model of health, disease and care, also known as "P4 medicine" (2, 6).

Meeting criteria of a self-contained HMS meant that in addition to just claiming a HMS the document had to describe the scientific model behind health management, the target patient audience, the types of collected data and/or principles of data collection, the principles of data processing and analysis, the logic of decision making and health intervention, and/or measurable health-related results. Automation of at least one step of the whole process was mandatory.

HEALTH MANAGEMENT SYSTEMS DESCRIBED IN NON-PATENT LITERATURE

PubMed retrieved only 5 results with search string "health management system" AND "automated." This either means that the authors of peer reviewed papers use different key words to describe their subject in the Abstract, or indeed only very few papers focus on the broad problem of designing a robust automated system for managing individual health. The search "health management" and "system" and "automated" gave 54 results, only 3 of them being relevant to our narrow criteria. The search "health management system" retrieved 151 results, 19 of them relevant to our understanding of a self-contained ASHM. Analysis of their relevance to the criteria set in section Sources of Information About Current Practices in Automated Systems for Personalized Health Management and Search Criteria is summarized in **Table 1**.

Our Google Scholar search with keywords "human," "personalized," and "health management system" retrieved 694 sources without patents, and 2,860 sources with patents—i.e., patents accounted for 76% of search results. Despite the term "human," many found papers covered health management of non-human systems (technical or animal). In addition to peer reviewed papers, the sample also contained conference proceedings and books. We opened and read all found entries with the phrase "health management system." Out of 694 Google Scholar entries some overlapped with PubMed results, and only 3 represented additional publications relevant to a self-contained ASHM, they are included in **Table 1**. All sources mentioned in **Table 1** are further briefly commented below.

TABLE 1 | Publications on automated systems for personalized health management found in patent and non-patent literature ranked by their correspondence to criteria for a self-sufficient integrated solution (criteria are described in section Sources of Information About Current Practices in Automated Systems for Personalized Health Management and Search criteria).

References	Criteria set for a ASHM that description has to meet					
	Integrated	**BM/BPS model**	**Info flow**	**Info analysis**	**Provide decision making**	**Provide results**
(16–19)	+	BPS	+	+	+	−
(20)	+	BPS	+	−	+	+
(21)	+	BPS	−	−	+	−
(22–28)	+	BPS	+	−	−	−
(29, 30)	+	BM, BPS	+	−	−	−
(31)	−	BPS	+	−	+	+
(32)	−	BPS	+	+	−	+
(33)	−	BPS	+	+	−	−
(34–36)	−	BPS	+	−	−	−
(37)	−	BPS	−	−	+	−
(38)	+	BM	+	+	+	+
(39, 40)	+	BM	+	−	−	−
(41–45)	−	BM	+	+	+	+
(46–48)	−	BM	+	+	+	−
(49–61)	−	BM	+	+	−	−
(62)	−	BM, BPS	+	−	−	−
(63–67)	−	BM	+	−	−	−
(68)	+	BM	−	−	−	−

BPS, biopsychosocial (patient/person-centered) model; BM, biomedical (disease-centered) model of health, disease and care.

The earliest article, by Risk et al. (49), describes Anscore Health Management System for evaluation and interpretation of heart rate variability, developed by Boston Medical Technologies (USA). Although presented as a "health management system," it can only be used for early detection and monitoring of autonomous dysfunction in different neurological disorders. On the other hand, heart rate variability measured by a wearable device can be a useful instrument in self-monitoring and self-management of a chronic condition (69), hence this is a promising universal component for an ASHM.

Lim et al. (41) describe a concept of ubiquitous healthcare ("u-healthcare") as an individualized health management system for diabetic patients. The paper demonstrates how advanced technologies enable individualized approach to control blood glucose, ease health education and patient involvement, as well as improve patient autonomy in health management. Outpatients can independently monitor blood glucose levels, and glucometer transfers the readings through mobile phone into automated clinical decision support system (CDSS). Based on the readings, the CDSS reminds patients about regular measurement of glucose levels and give instructions on medications through text messages. This approach improves long-term (6 month) outcomes in diabetes assessed by HbA1c levels.

A more general description of u-healthcare system (42–45) reveals its 3 basic components: (1) a portable device for reading patient's biological parameters (blood glucose, ECG, EMG, blood pressure, oxygen saturation, and body temperature) and/or diet diary, (2) a smartphone application and a special device to transfer the readings to a server, and (3) a server monitoring and analyzing the readings. The described u-healthcare system has at least the following limitations: (1) It can only be used in patients with established NCD diagnosis. (2) It monitors mostly biological parameters. (3) It practically fails to involve correction of lifestyle factors, the major cause of NCD progression. Generally the idea of u-healthcare is a great step forward in adapting healthcare to patients' needs and introducing self-health management. However, as proposed so far it has very limited utility.

An article by Lau et al. (29) and three other papers by this team from New Zealand describes a new eHealth solution, Web-based personally controlled health management system (PCHMS, *Healthy.me*), and its utility in involving mostly young adults (university students and staff) in more effective help-seeking behaviors for emotional well-being, raising awareness of personal well-being, and mastering certain self-care tools. Novel features of this solution included personal health records, social networking (forum) and a diary encouraging self-reflection and self-awareness. The major advantages of PCHMS reported by Lau et al. are: it is closer to the biopsychosocial model of well-being; it extends continuum of health and continuum of care that it can cover; it raises awareness and involvement in help-seeking and self-care activities; this is a personalized approach; it focuses on disease prevention and early interventions. However, the proposed system lacks some features crucial for its long-term workability: (1) It is so far used for narrow disease-centered purposes (it is currently recruiting patients with asthma diagnosis) and with time limits (a 12-month study); (2) It doesn't provide a comprehensive decision making support tool and relies much on a medical professional.

Paper by Dhillon et al. (22) covers in detail a concept of developing a patient-centered HMS with a focus on psychosocial aspects of well-being in senior patients. However, it lacks essential features of information analysis and decision making, hence it cannot provide measurable health-related results to its users.

Gutenbrunner et al. (38) describe a HMS to improve workability of medical staff with musculoskeletal conditions. Its limitations are no use of digital medicine and a narrow disease-centered focus.

Bloss et al. (50) describe an online HMS with active use of wearable devices to monitor parameters of an established chronic health condition; the study focuses on health care costs and provides no measurable health-related results.

Soh et al. (63) describe a mobile care system for advanced cancer patients; its functionality is limited to self-monitoring.

Hsieh et al. (64) describe a patient-centered mHealth application for self-assessment and medication management; its utility is limited to better use of pharmacological treatments.

Neubert et al. (65) describe a system for integration of data from multiple sensors and data sources that can be used in preventive and occupational medicine. But this system lacks an integrated approach to health management, so it is a purely technical solution.

Nedungadi et al. (16) describe a patient-centered health awareness and monitoring system for rural areas; it is based on physiological data obtained with wearable devices, processed through an e-health platform to support individualized doctor's decision making on emergency interventions, preventive care, and lifestyle interventions (including Ayurveda and yoga).

Gandarillas and Goswami (23) propose methodology of building a home-based and community-centered Integrated Healthcare Management System with special focus on biopsychosocial model and aging patients with chronic disease. It describes in detail the possible organizational structure of services and their communication structure. With an in-depth overall design, it lacks specific algorithms of data collection, analysis and use in decision making.

A very important aspect of health management, namely health coaching, is covered by Andreou and Raspopoulos (24). With detailed concept description, this paper however lacks specific technologies and algorithms needed to produce specific results.

HEALTH MANAGEMENT SYSTEMS DESCRIBED IN GOOGLE PATENTS AND THE USPTO

Search in Google Patents (as of 2021-01-15) provided a total of 302 results matching key words "health management system," "human," and "personal*" in Abstract, 12 of them relevant to an integrated HMS: 31 in WIPO (3 relevant), 24 in USPTO (4 relevant), 6 in EPO (0 relevant), 71 in JPO (1 relevant), 148 in Chinese Patent Office (3 relevant), 22 in Korean Patent Office (1 relevant).

A separate patent search in the USPTO database with key words in claims "health management" retrieved 490 applications (as of 2020-06-03); "health management" and "human" retrieved 36 applications. Out of all found records (partially overlapping with Google Patent search), we selected 204 that were actually relevant to human health. The rest were either focused on non-human systems or business operations. They also had to meet criteria of a self-sufficient system, that's why many local methods and devices used for managing health and data management systems were excluded. A total of 29 documents appeared relevant to an integrated HMS. All these documents are ranked for criteria of ASHM in **Table 1** and each one is analyzed or briefly commented below.

In this section, we outline authors' motivation to develop an AHMS (problems they address), and briefly describe technical solutions within two models of care, disease-centered reactive and patient-centered preventive models.

Problems That Health Management Systems Are Designed to Address and Proposed Solutions

The problems, factors and objectives that authors of health management systems address are summarized in **Table 2** along with the essence of proposed solutions.

A major objective of inventors is to create an automated interactive system that would enable regular remote interaction with multiple patients suffering from NCD in order to educate, inform them on their health state, to motivate behavioral changes related to their health (to modify risk factors of NCD), to improve compliance with medical measures, to monitor health indicators, and to enable early interventions designed to improve health (46, 47).

Management of NCD requires continuous interaction with patients, where costs of follow-up can be reduced by organizing interaction in outpatient setting or at home. Success of such programs depends on effective monitoring of patients' state, detection of abnormalities and early interventions to prevent possible complications which are much more difficult and expensive to treat. The overall success is determined by patients' motivation and their active efforts to modify their lifestyle (51).

The current system of health care is "reactive"; the doctor reacts to patient's phone call or visit to clinic. As the result, the doctor interacts mainly with the most motivated patients or with those in emergency. From the viewpoint of long-term outcomes and health improvement, the most efficient interaction would be "proactive" scheduled contacts with least motivated patients who are not inclined to visit or call the doctor. The least motivated patients often develop emergencies that could have been prevented through planned, "proactive" communication. Therefore, the cost of treating such NCD patients could be reduced by planned interaction and by increasing their motivation to change behavior and lifestyle. Patient's motivation is an important factor that should be considered in the plan of health management (51).

Patients with higher risk of disease complications, those who need additional examination and care, can be timely identified through planned communication; this is necessary to improve the efficiency of care providers (51).

TABLE 2 | Problems that a system of personal health management should address and certain common technical solutions for them found in automated health management systems (AHMS) proposed in patent literature.

	Groups of problems	Proposed solutions
1.	Reactivity of health care: Lack of planned, regular, continuous proactive interaction with the patient Lack of adequate feedback from the patient, including feedback concerning assessment of health state and its changes over the course of treatment or follow-up Too late interventions due to lack of opportunity for mass screening, monitoring, and prevention	Questionnaires to evaluate current health condition and NCD risks (17, 18, 31, 32, 35, 39, 47) Individualized questionnaires (37) Questionnaires to evaluate treatment efficacy (35) Consideration and analysis of early premorbid changes of health (17) Remote collection, transfer and analysis of information about symptoms and lifestyle factors (17, 18, 31, 32, 34, 36, 39, 57, 66, 68) Automated collection, exchange and analysis of patient's objective data (body measurements, laboratory tests) (17, 33, 35, 36, 39, 46–48, 52, 53, 56, 68) Use of portable or wearable device to evaluate physiological parameters, including laboratory data (17, 35, 39, 46, 48, 53, 56, 68, 70)
2.	Insufficient productivity of the doctor: limited number of patients that he/she can follow simultaneously	Automated use of official clinical guidelines or standard programs to propose unified measures of risk reduction (32, 35, 46–48) Automated use of scientific publications to develop individualized recommendations (31, 33, 35, 37) Opening access for different doctors to patient's profile with information of health state and treatment schedule (67) Telemedicine-based interaction between patient and doctor (31, 39) The use of a digital model of physiology and machine learning-based artificial intelligence (68)
3.	Lack of infrastructure for patient education, information and motivation to behavior change	Modification of patient's behavior through information and lifestyle recommendations (17, 18, 31, 33, 34, 37, 39, 46–48, 68) Interactive representation of educational information to the patient depending on the feedback (51) The use of community to motivate patients to lifestyle changes (through gamification) (62) Graphical display of signs and symptoms; matching them with patient's behavior (36, 58) Estimation of expected life span and healthcare expenses as a motivation tool (52)
4.	High overall cost of health care, partially due to lack of prevention	Management of disease treatment (for diabetes) in home setting with complete cycle of data processing: collection, analysis, recommendations on patient's activities, control of compliance, evaluation of results (60) Keeping an analog of electronic medical record with individual planning and control of examinations and interventions (in a particular disease, diabetes) (61)
5.	Insufficient consideration of patient's life context, beliefs, sources of resistance and motivation, evaluation of his/her condition Overall insufficient individualization of lifestyle guidelines and recommendations	Individualized questionnaires (37) Evaluation of genetic polymorphisms for measuring NCD risks (32, 33) Consideration of patient's emotional state (stress, depression) (57) The use of integrative medicine (17, 21) Integration with third party data about patient's locations and behavior in social networks (18)
6.	Insufficient patient's autonomy in self-diagnosing and prevention	Teaching physical exercise with the use of telemonitoring and reference video (54, 55) The use of coaching (17, 31, 32, 39) Providing video instruction about necessary actions (based on individual goals) (51) Daily plan with reminding the patient about necessary measures (18, 56, 59)
7.	Gaps is continuum of care	Long-term follow-up in home setting (17, 18, 31, 39, 51)

Most of the existing medical information systems are designed to display individual medical data and don't allow the doctor to evaluate simultaneously medical data of numerous patients. Hence the doctor cannot correctly prioritize his efforts and consider different patients' needs within a group (51).

Success of treating NCD patients also depends on the ability of the treatment program to change patient's daily behavior affecting his/her health. This can apply to eating habits, physical exercise, smoking, etc. Patient's compliance is much influenced by subjective comprehension of his condition, education level, beliefs, incentives, etc. Design of treatment or follow-up plan should consider all these factors to provide maximum efficiency (47).

Patient's compliance is also connected with psychological resistance which can be due to temporary relief of symptoms or with too high demand that the treatment program imposes on habitual life style (and therefore, too much efforts that are required to change behavior). Consequently, the program should involve adequate feedback from the patient, detect resistance and correct the program to increase compliance (47).

In cases where the diagnosis is not quite clear, dynamic follow-up is necessary to better understand the patient's condition and to timely correct individual treatment plan.

The existing national and international clinical guidelines on NCD prevention provide very little individualization; they cannot motivate patients to change their life style—for example, by giving forecast of expected lifespan and medical costs (52).

Several patent applications underline the need in the instruments that would allow the patient to measure, register and analyze independently vital health indicators and risk factors,

TABLE 3 | Comparison of key parameters of diagnosis-centered and person-centered healthcare models relevant for design of AHMS.

Parameter	The "old, reactive," diagnosis-centered model	The "new, proactive," patient-centered model
The part of health continuum where major measures of health management take place	Acute disease or chronic disease with significant clinical representation (=a prerequisite for diagnosis)	Same as in the "old" model + patients with early premorbid health conditions and generally healthy people (with risk factors)
How the strategy of health management considers the root causes of NCD onset and progression	Almost fail to consider in everyday practice	Health is determined by factors that influence a person daily over a long term
Correlation with continuum of care	Fragmented care: 1. Emergency care 2. Hi-tech hospital care for complications of an NCD 3. Medical rehabilitation (short-term, hi-tech) 4. Outpatient follow-up for certain patient categories	Integrated care that is involved in addition to the fragments of the "old" model (pp. 1–4): - early premorbid prevention; - long-term rehabilitation in home setting; - long-term follow-up in lifestyle correction
The nature of interaction between patient and health professional	Usually one-time or occasional	Continuous and planned (regular)
Agents of health management	1. Patient 2. Doctor	1. Patient 2. Doctor 3. "Healthcare provider" who organizes interaction
Who initiates interaction and why	1. Patient, due to pain or discomfort 2. Planned check-ups (professional or annual)	Patient, due to pain or discomfort; planned reminders from "provider" Planned mandatory check-ups
Who makes decisions about goals and plan of health management	The doctor; the patient signs an "informed consent"	The patient him/herself with assistance and information support from the doctor
How decisions, goals, and action plan relate to medical diagnosis	Standards of examination and care are determined by medical diagnosis	Maximum personalization; adapted to individual physiology, psychology, social context, and lifestyle
Doctor's role	The key: decision making, drawing the plan of examination and treatment, legal liability	Expert, consultant, and coach in health management
The role of user (patient)	Passive: turn to the doctor in time; follow recommendations; pay for services; actual lack of responsibility for one's unhealthy behavior	The Key: goal setting, decision making, implementation of health management plan through behavior change; responsibility
Major instruments of health management	Medications; surgical procedures and operations	"Planning and control of following the therapeutic regimen and/or modifiable lifestyle factors": 1. Healthy food 2. Sufficient motion and exercise 3. Reducing toxin exposure 4. High quality sleep and rest 5. Effective stress management 6. Healthy relationships
Major sources of information about patient's health condition	Doctor (results of examination), laboratory and instrumental examinations	Patient: questionnaires, case monitoring with wearable devices; the "old" sources if necessary
Place where care is provided	Separate medical organizations not interacting with each other	An integrated information space (ecosystem), contributed by a "family" doctor and "provider" (supports the infrastructure)
Place where health information (health record) is stored	Medical organizations; generally isolated from the patient; access is usually closed for patient and other health professionals	The patient him/herself (through User Account); patient opens access to health professionals
Major mode of patient-doctor interaction	Physical contact in doctor's office	Continuous (planned) and remote, including telemedical instruments; personal contact if necessary
Automation instruments	"Traditional" MIS comprising CRM (customer relation management) and ERP (enterprise resource planning): 1. Electronic medical record; records of medical services 2. Auxiliary services (pharmacy, laboratory) 3. Accounting and finances	1. User accounts of patient (consumer), doctor (service supplier), and "provider" (responsible for infrastructure) 2. Accounts are integrated with "traditional" MIS and telemedical instruments

and also use them to monitor the efficacy of administered interventions (53).

Optimum health management in general is a complex problem that requires integration of data from multiple diverse sources. In particular, in addition to many types of health parameters, to continuously updated knowledge about human physiology and pathology, optimal management requires information about the best medical practices in various fields of medicine. The current health care system cannot provide patient-centered health management over the whole lifespan. Today's healthcare providers operate "on demand," and therefore can offer only a small part of the whole continuum of care that an individual may need. Today there is no system or single provider of integral, holistic health management encompassing the whole care continuum (68). Preventive measures to reduce NCD risks are recognized clinically and cost effective; however, their wide introduction is difficult due to problems in patients' comprehension of professional clinical guidelines and lack of individualization (47).

According to a 2012 study by the Bipartisan Policy Center, healthy behaviors are the main determinants of the health state of the average US citizen (50%), with environmental and genetics contributing another 20% each, and access to health care determines only 10%. However, medical services dominate the health-related spending of American people (88%), with spending aimed at promoting healthy behaviors only totaling 4% on average (68).

Evolution of Particular Technical Solutions in Health Management Systems: Disease-Centered Reactive Model vs. Person/Patient-Centered Preventive Model of Care

The evolution of proposed solutions and practices in automated health management systems over the last two decades can be attributed to the following factors: (1) development of digital and telecommunication technologies as tools necessary for scaling any medical technology; (2) better understanding of lifestyle-related factors as determinants of disease progression and health improvement, and emerging evidence that supports this idea; (3) global adoption of patient/person-centered instruments, interventions and models of care as a promising way to increase cost effectiveness. That is, in terms of effectiveness patient-centered health management systems have a significantly higher potential to improve the existing healthcare system, as can be seen from **Table 3**.

Patent literature reflects well this evolution; however, a major factor whether a particular technical solution would be put into practice or not, lies beyond technology: we have found that two most adequate solutions have not been commercialized.

Analysis of relevance of 36 patents and patent applications to criteria of self-contained ASHM is summarized in **Table 1**; each of the relevant inventions is further discussed in detail with comments.

The first relevant patent that we have found [(47), application filed in 2000] describes an interactive computerized method and system for determining the risk of developing a disease, and consequences of the disease with the use of questionnaires; it also enables monitoring of personal health state. The method involves identification and modification of risk factors, including nutrition, through patient education. The method is based on the use of official clinical guidelines, and therefore is able to identify only a small portion of lifestyle-related risks; it cannot be applied to many common functional problems, especially before an NCD diagnosis can be confirmed. The method is aimed at identifying the risks of particular diseases, whereas one lifestyle factor can increase the risk of multiple diseases, and one disease can be determined by multiple factors. From practical standpoint, the proposed method only partially covers certain cardiovascular diseases (coronary heart disease—CHD). It implies mandatory interaction with a doctor, since it contains no particular recommendations on lifestyle modification; that is, it cannot serve as a decision support system for an individual in health management. The proposed method doesn't enable early detection, monitoring and correction of not only common functional conditions, but also for CHD itself. In particular, it fails to provide a complete list of questions for questionnaire, and an algorithm of their analysis. Essentially, the proposed method is an algorithm of diagnosing CHD as an established condition; it fails to consider contemporary knowledge of the whole range of factors determining development and outcome of even CHD.

The next patent by Japanese authors [(52), priority of 2001, patent owner Hitachi, Japan] describes a system of health screening and data processing that provides an estimate of expected life span, future health care expenses, along with recommendations (a health management plan) for behavior modifications intended to extend the life span and reduce future expenses. In screening the system considers excessive weight, high blood pressure, dyslipidemia, high blood glucose, and uric acid. Out of all lifestyle factors the system considers smoking, alcohol consumption and physical exercise. Health management plan includes low calorie diet, quitting smoking, exercise (without any details), and repeated screening. The system is designed to inform the user how the proposed plan would extend the patient's life and reduce health care expenses; it is expected that this information should motivate the individual for behavior modification. The proposed system can be used in medical insurance, but in terms of patient-centered health management it only considers some of important lifestyle factors and relies on laboratory tests which are marginally sensitive to premorbid health conditions.

Patent authored by Pascucci and Pascucci (53) provides a health management kit that includes portable devices for evaluation of health risks (measuring blood pressure, blood glucose and cholesterol) combined with a PC to interpret test results and provide recommendations. Obviously, this solution cannot enable adequate health management.

Patent by Rao et al. (66) describes an automated system for distant collection of information about health state, functional problems (signs and symptoms), and lifestyle factors including diet. It is designed to help in occasional food choices that would consider individual health. However, the system doesn't contain any algorithms for analyzing causality between functional problems and lifestyle factors; it doesn't provide any individual advice. Therefore, it cannot provide a method of early detection, monitoring and correction of functional disturbances, nor it enables health management.

A similar application was filed in Korea (30): an Internet-based U-health care system using biometric and patient-reported data to enable remote specialist decision making. It provides only principles and very general description of the system, which makes it impossible to implement it directly. Its most probable primary utility is early detection and prevention of emergency health conditions.

In 2010, two patents were granted for methods of automated remote monitoring of health state and health management in patients with medical diagnosis (chronic disease like diabetes and coronary heart disease, CHD) with the use of stationary and wearable devices (46, 48). They are currently owned by Health Hero Network (USA, https://www.gohealthhero.com/). These methods can detect abnormality of physiological parameters and give recommendations on medication and correction of lifestyle factors that influence those parameters; recommendations are based on official clinical guidelines. The described systems improve patients' awareness of their conditions and of the ways to prevent disease complications, and also improve compliance. These methods have the following shortcomings: they cannot be applied until a medical diagnosis is established (i.e., they are useless in most people with early functional impairments); official guidelines fail to consider individual causal relations between lifestyle factors and functional impairments; they imply purchase of a device (which make them less affordable); they require a doctor.

Another patent of Health Hero Network (54) covers a virtual trainer system that can be considered a part of automated health management systems responsible for physical exercise. The trainer allows to improve skills in physical exercises by simulating a professional coach. The next patent of the same company (55) focuses on motivating the user to engage in physical exercise with a telemonitoring system and a digital assistant. The both systems can cover only a small part of functionality necessary in a complete health management system.

Another service was claimed as a health management system (67): it allows the patient to upload description of his/her complex pharmacotherapy on the web site profile and open access to it for different doctors for expertise and corrections. Obviously, this solution cannot be a complete health management system, since it solves a very narrow technical task for a small patient category exposed to polypharmacy and running a higher risk of undesirable drug interactions and adverse effects. In fact, this is rather a disease management than a health management system.

A patent by Rao and Rao (39) proposed an organizational solution for managing health of multiple users, especially in rural regions, with poor access to health care. The invention provides simple access to medical information, opinions of doctors and experts, without additional infrastructure costs. It involves the use of questionnaires and medical devices to remotely collect and transmit health data in automated mode (through mobile devices), a coaching module, and presentation of information content related to lifestyle. In essence, the patent describes telemedicine-based health management with the use of remote server accessed from mobile devices. This patent covers only organizational solution, and lacks substantial aspects necessary to design a complete health management system, including the method of screening, early detection and correction. It doesn't enable a method of health management.

In 2012–2014, Abbott Diabetes Care patented several technical solutions for automated collection and processing of blood glucose data from diabetic patients; one of them is presented as "a system for managing treatment of a particular health condition via a phone device" (56). The system involves a glucose measuring unit connected to a mobile PC or phone (including cordless connection); it enables automatic transfer of the readings to data base for storage and processing. The device can remind the patient to input data (including data on taken medications), can transfer both objective readings and subjective indices [for example, symptoms of stress and depression—(57)], and even information on daily activities (including nutrition, exercises, etc.) along with time mark when the data are read. The system can show correlation between symptoms, behavior indicators, intake of medications, and laboratory readings (58). Another technical solution (59) allows creating and storing in the mobile phone daily individual plan of daily regimen with reminders about necessary activities. Based on the all mentioned solutions, the authors present a principle of managing the treatment of a certain disease (60). The eventual system can integrate the functions of measuring, processing and transferring disease indicators and certain lifestyle indicators; it allows monitoring of signs and symptoms bound to treatment regimen and lifestyle. The proposed system can provide more effective monitoring of particular signs or symptoms and be useful to analyze dynamics and efficacy of treatment for an existing chronic disease. However, all mentioned patents provide only organization aspects and lack essential medical details. Such system doesn't allow health management in early premorbid conditions and fails to consider the whole range of factors relevant for health management.

Later, in 2015, an affiliated company, Abbott Laboratories, patented a system for managing healthcare of patients with chronic diseases (61). Their method involves creating and maintaining a register of patients (with patient profile, an analog of electronic medical record), where each patient undergo screening and planned regular examinations; then based on dynamics of the key disease progression indices, a plan of treatment or follow-up is proposed in agreement with professional guidelines. Patient profile can be updated, with corresponding update of individual treatment plan. The system is designed to coordinate medical care that the patient receives from different providers, to consolidate in one database all patient's medical records, and reduce overall healthcare costs. It doesn't suit personalized health management of patients with early premorbid health conditions (before chronic disease diagnosis is confirmed); as described, the system fail to consider the role of lifestyle factors in onset and progression of chronic disease; the patent covers only a system applied to diabetes.

Philips company (the Netherlands) received a patent on health management system designed for patients with chronic disease after discharge from the hospital. It allows remote long-term follow-up and support in home setting with the use of video content prepared beforehand to inform the patient about on-site rehabilitation program (51). The system allows individualized presentation of the content depending on specific rehabilitation goals for the particular patient. A separate content module with a set of sessions is prepared for a specific possible health management goal. The modules are offered to the patient depending on the current goals; the sessions are presented in interactive mode, with feedback from the patient. Each next session is selected depending on the feedback. The system in general provides an effective individualized information support for patients with chronic disease transitioning from hospital-provided care to self-care. However, it fails to describe planned continuous evaluation of patient's signs and symptoms, and lifestyle factors that determine the course of chronic disease. The more so, it doesn't fit for early premorbid health conditions. That is, the proposed technical solution can only be useful as a local element of a more complete health management system.

Keas (USA, https://www.welltok.com/), a consumer activation company and one of the leaders in promoting healthy lifestyle, patented in 2014 a method and a health management system with gamification elements (62). The system involves a community (social network) of people mastering specific healthy behaviors; a type of competition is set between community members, with assigning achievement score for completed tasks or mastered skills within a recommended plan. The described technical solution introduces gamification principles in transition to healthy lifestyle, but it fails to propose specific content for either evaluation of the user's needs (like screening, monitoring) or for proposing specific plans of behavior modification (correction of existing problems or risk factors). Therefore, the patent doesn't enable a complete health management system.

An application filed by Siemens Healthcare GmbH (68) proposes a sophisticated method and system for automated "holistic management of health." Medical data are fed through sensors, visualization instruments, laboratory tests, or examination; they form a base for individual computational physiology model; then a holistic health management plan for the individual is generated based on the current health state of the individual using a trained intelligent artificial agent. The key feature is a computational physiology model (a complex of models for particular body systems and processes) which is corrected and simulated based on actual patient's data, and is used to train the artificial intelligence (AI). By "holistic health management plan" the authors mean consultations with health professionals, non-prescription medications, individual nutrition advice, plan of exercise (standard or adapted individually), and also laboratory tests and prescription drugs as necessary. The application involves AI based on machine learning algorithms, deep learning architecture or deep neural network. A distinctive feature of the application is focus on a digital model of physiological processes and machine learning-based AI. However, these instruments *per se* cannot allow transition from reactive diagnosis-centered model to preventive person/patient-centered model of health management, if they don't focus on lifestyle factors and patient's key role in behavior modification. Therefore, this application's potential to solve the problems of health management can be estimated as very modest. Also, it fails to disclose many substantial features necessary to develop a complete health management system.

Taken together, all the above solutions are more in line with the model of reactive disease management than proactive health management; they suit for only individuals with established NCD diagnosis and generally follow formal clinical guidelines, without actual personalization. Therefore, their potential to solve the real problems of health management is very modest.

The first patent focused on a personalized lifestyle-related approach (20) was filed in 1997 and later turned into a very successful business project, www.sharecare.com (online test for 'real age' and related individual wellness programs). Although the patent doesn't directly claim a health management system, it describes its key elements: measuring of wellness, examination of its personal determinants, selection of the relevant lifestyle modifications, and motivation for behavior change.

An application by Japanese authors filed in 2004 (25) describes an automated HMS for lifestyle-related diseases and focused on evaluating lifestyle factors and giving the patient an opportunity to select from a plurality of possible changes in daily activities—that is, on involving the patient in managing his/her own health and improving the quality of life. The document lacks specific details of data acquisition and decision making algorithms which prevents its practical use.

Another attempt to base a health management system on daily lifestyle factors was made in application filed in 2005 by Bergantino (34). It describes a method of health management through analysis of individual's nutrition and development of an optimal nutrition plan. This method considers only one lifestyle factor, nutrition; it doesn't allow detection of functional problems, analysis of cause-effect relations between individual lifestyle factors (including nutrition) and functional problems; it doesn't support decision making in correction through lifestyle factors. Therefore, this application couldn't become a health management system.

The next application by Gerjets et al. (37) was filed in 2005 by Center U LLC. This is a physician directed method (and system) of computerized comprehensive health assessment and development of a science-based individual health improvement plan. In collecting information it uses a dynamically changing patient questionnaire reflecting functional scores and lifestyle factors, patient history, and laboratory tests, including genetic factors. Based on the questionnaire, the expert system draws conclusion on patient's functional impairments and develops an individual plan of nutrition and lifestyle. The expert system uses "PubMed" electronic database of the National Library of Medicine. The system is only useful to support decision making by physician. The authors didn't design it for automated screening or monitoring, evaluation of risks of the most common functional impairments, or support decision making by the patient in managing his/her personal health. Most importantly, the application fails to disclose specific algorithms of the expert system, which makes it useless in practice. Eight years later the same company made another attempt to patent a health management system (see below).

In 2005 medical diagnostic company Microlife (https://www.microlife.com/, Switzerland) filed an application covering a method and system for teaching and guiding an individual in changing the lifestyle (17). Its author was company founder, a citizen of Taiwan. The application is currently abandoned. The system's key elements are (1) collection of individual information about health, (2) informing the patient about causal relations between his/her signs and symptoms (markers of disease) and individual behaviors, and (3) teaching principles and algorithms of healthy lifestyle. The method involves remote monitoring of health, a school for healthier life (teaching healthy lifestyle), and holistic methods of treatment and health improvement. The application gives a broad overview of the system, with its basic principles and some particular details of diagnosing diseases. However, it lacks certain important technical details necessary to use this approach in modifying the lifestyle factors. In particular, information about functional impairments and lifestyle factors that should be fed to the system is given in a very general way; no clues are provided as to how to analyze this information and develop individual recommendations. Even with the mentioned shortcomings, this system can be considered as the most complete and adequate health management system out of all that were described in applications filed to the USPTO. Despite relative simplicity, this system has not been put into practice.

A patent filed in 2006 (26) describes a method of choosing lifestyle recommendations based on person's lifestyle and healthcare information obtained from a special aggregator. This is a sound biopsychosocial approach to health involving financial aspects, although the patent lacks details of data analysis, decision making algorithms and practical results, as well as consideration of some important factors like sleep and stress management.

More active patenting of systems focused on personalized and preventive health care through lifestyle modification started since about 2010.

In 2010 Pathway Genomics Corporation (https://www.pathway.com/) filed an application covering a health management system (apparatus) designed primarily to manage excessive weight (33). It is based on evaluation of individual inherited risks related to genetic markers, and on providing personalized plans of diet, nutrition and exercise. Today this system is marketed as a line of products that involves evaluation of dozens of genetic polymorphisms. In Russia a similar system is introduced by MyGenetics company (https://mygenetics.ru/) as a "genetic passport" with evaluation of 33 gene polymorphisms associated with chronic diseases. Essentially this system provides not health management but evaluation of risks of chronic diseases based on polymorphisms of genes implicated in NCDs. However, NCDs have multifactorial nature, with leading role of daily lifestyle factors, and genetics as a predisposing factor. Individual lifestyle factors interact to influence activity of multiple individual genes. Therefore, the proposed technical solution cannot be a self-contained health management system, but only supplement holistic patient-centered health management.

A patent was granted in 2017 to an application of 2010 that covers a method and computer program for remote automated personalized management of weight, lifestyle and/or disease (32). It claims integrated personalized "disease management and behavior modification" with the use of coaching. This method involves collection of information about functional impairments and patient's lifestyle with the use of questionnaires; it also evaluates person's readiness for behavior change and presence of health management skills. The system involves a platform for coaching: instruments to select a coach and communicate with him. Coaching is a method of consulting and training where in reaching a specific goal the coach instead of giving advice or firm recommendations is looking for a solution in cooperation with the client. The described method has a mandatory step of testing 3 genes related to obesity risk. The algorithm of health management according to the invention includes: (1) patient categorization based on information about personality attributes, nutrition, physical activity, and genetic profile; (2) selection (based on categorization) of one out of several unified programs to modify behavior (primarily, nutrition and physical exercise); (3) selection of a coach. Unified programs can be updated based on new scientific findings. The method allows storage of information about the patient and his progress in the selected program, and analysis of programs' and coaches' efficiency. Shortcomings of the method: it actually doesn't allow identification and evaluation of functional impairments, presence of risks of chronic diseases other than obesity. It fails to assess the whole range of all important lifestyle factors; it fails to provide automated design of recommendation on lifestyle correction; its functioning is dependent on personal coaches. As the result, the system doesn't provide automated health management and support of patient's decisions on managing personal health.

In 2015 Total Wellness Clinic (USA) filed an application covering a health management method based on the principles of integrative medicine [(21), application is abandoned]. It is based on an understanding that a person's functional state can be improved not only in an established disease but in any suboptimal health condition. This is possible with implementation of an integrative approach considering person's biochemical individuality and modified lifestyle factors. The application describes a method of health management (including conditions without an established disease) that combines Western medicine, Chinese medicine, Functional medicine, and bio-energy medicine. Based on initial evaluation of health, patient is offered treatment with various methods adapted to patient's individual circumstances. This method can only be practiced by a highly qualified professional. It doesn't fit for automated screening, monitoring and correction of functional disturbances in many patients.

In 2017, Better Therapeutics LLC (USA) filed patent application claiming a method and system for managing lifestyle and health interventions (31). It involves managing a lifestyle-related disease through remote interaction with a patient using digital interface. The method involves collection of information about patient's symptoms and lifestyle factors, and providing individual recommendations on lifestyle change to achieve a target condition for the patient's disease. This solution is implemented in a popular and effective online service promoting patient-centered concept of "lifestyle medicine" (https://www.bettertherapeutics.io/). It has certain limitations: it doesn't allow early detection of functional impairments since it covers only patients with already established diagnosis of a cardiometabolic disease. Description of the invention doesn't contain algorithm of revealing the causal relations between patient's symptoms and lifestyle factors. Therefore, it cannot enable an automated decision making support system for patient's health management.

In 2016, OutcomeMD Inc. claimed a method of automated determining a wellness score with the use of medical questionnaires (35). It enables evaluation of the user's current state (severity of functional impairments), changes over time, treatment effectiveness; it can also inform the patient about study results and give an interpretation. The application mentions numerous special medical questionnaires designed for hospital setting or under doctor's control. An online service based on the proposed method (https://www.outcomemd.com/) is claimed as an Outcome Management System designed for doctors of various specialties and using patient-reported outcomes. The method can considerably increase the effectiveness of health care. However, it doesn't imply the patient's leading role in managing his/her own health: it doesn't allow automated screening and early detection of functional impairments; the application doesn't describe analysis of the injected data. The method ignores analysis of lifestyle factors, therefore the user cannot identify the causes of functional impairments and cannot receive lifestyle-based recommendations how to correct the problems.

In 2013 Center U LLC made another attempt to patent a health management system in the format of a method for analysis (interpretation) of data received from the patient (36). The method involves filling health state and lifestyle questionnaires, automated calculation of functional scores (including their changes over time) and providing recommendations of lifestyle correction. Description contains very thoughtful ideas about insufficient use of lifestyle factors in the current doctors' practice and decision making. However, the application is focused in local formal algorithms of data analysis; it fails to propose a model of causal relations between the patient's symptoms and lifestyle factors that can be used in automated selection of recommendations on behavior change. There are no algorithms for practical implementation of the method. Therefore, the system either requires a doctor or cannot be implemented at all.

A patient-centered solution was proposed in two applications by Chinese authors. They involve the use of Traditional Chinese Medicine (TCM) to identify health problems, patient's constitution, and choose necessary preventive interventions (27, 28). TCM is an integrated self-sufficient system, however, the proposed solutions actually represent a tool for TCM doctor for data acquisition, decision making support, and patient follow-up; the set of data and algorithms of analysis and decision making are non-transparent. Another Chinese application (40) discloses a telemedicine system for automated data acquisition and involvement of patient's relatives and friends, without clear decision making algorithms and results.

Two patent documents by International Business Machines Corp disclose a personalized health care management system that pioneers with a focus on changing the user's behavior (18). The application discloses a method of processing the user's data on health and behavior patterns (lifestyle factors); the data can be obtained with any wearable sensors and behavior trackers, from electronic medical record, and also from questionnaires. User data also cover available resources and other details of life that determine the context for possible lifestyle correction; these data are obtained through analysis of patient's behavior in social networks, and also from locations associated from his/her daily lifestyle, information about environment quality of home and job, availability of local infrastructure relevant for health management, patient's membership in loyalty programs, the history of purchases and ordered services, etc. Through extensive analysis of information about patient's actual behavior patterns and lifestyle, it becomes possible to compare the actual and potential optimal patterns, identify deviations and propose advice in minimizing those deviations. For example, based on analysis of daily locations and available local sources of healthy food, places for physical exercises and recreation, the system could propose daily behavior patterns that would enable optimal lifestyle. Health management plan would actually represent a list of goals and specific behaviors to reach those goals. Personalization of the plan is due to maximum consideration of the user's lifestyle context and daily behavior patterns. The described system can enable very high personalization of health management. However, its significant shortcoming is complexity in receiving data from third-party sources and in integrating those data in a single system. For effective operation, this system would require an expensive hi-tech digital infrastructure; the system is very time- and resource-consuming. On the other hand, the system fails to duly consider certain important lifestyle factors which are less available for tracking: for example, the level of emotional stress and user's ability to manage stress. The application also ignores the aspects of lifestyle related to intrapersonal communications and spiritual dimensions of health. The second very close patent of the same assignee (19) implies that personalized patient care plan is based on both health record and any exogenous lifestyle-related data; the plan involves behavior modification to minimize the effects of exogenous conditions. The patent also involves machine learning and evaluation of patient's compliance. Limitations of this solution are similar to those of (18).

DISCUSSION

Above we have analyzed 17 non-patent sources and 36 patents and patent applications filed worldwide that claim and actually describe a personal health management system of different level of self-sufficiency and workability.

At least 10 of the mentioned applications have been implemented as commercial systems or services. Unfortunately, the two most sound (in our opinion) systems have not been put into practice, (17) and (18).

As a motivation to develop a health management system, most authors point at the problems and shortcomings of today's health care (health management) which are naturally inherent in the currently prevailing paradigm and model of medicine that can be termed as "reactive" and "diagnosis-centered." Some authors propose local improvement and modifications within the currently prevailing model, while others promote a new person/patient-centered model (70), more suitable for overcoming the epidemic of chronic diseases.

Conceptual Context

Below we would like to build a concept of an "ideal" workable ASHM based on analysis of the above-mentioned sources and on our understanding of what health management is and should be.

Management as a universal process deals with information in the first place, and therefore most authors take into account three major natural requirements for a health management system:

1) The system should encompass the complete cycle of processing information about patient's health and behavior (acquisition, analysis, storage, use for planning the interventions, and receiving the feedback on intervention results);
2) Operations with information should be automated as much as possible;
3) The system should be scalable.

In designing automated systems for personalized health management (ASHM), most authors proceed from the following three important prerequisites:

Prerequisite 1. The target audience that needs effective health management most of all is patients with NCDs and other chronic health conditions.

Prerequisite 2. Health management should consider continuity of care and represent a continuum of care. The latter term was introduced in the late 1980s (7) to describe the continuous range of all potential measures designed to meet all needs of an individual in recovery, support and improvement of health. Continuity includes three aspects (8):

(1) Informational continuity—The use of information on past events and personal circumstances to make current care appropriate for each individual
(2) Management continuity—A consistent and coherent approach to the management of a health condition that is responsive to a patient's changing needs
(3) Relational continuity—An ongoing therapeutic relationship between a patient and one or more providers

The overall goal of care continuum should be a tangible result for patient in the form of significant improvement of health.

Continuum of care can be described as the following series of measures [(8, 9), with modifications]:

At an early premorbid stage: (1) informing about the principles of healthy lifestyle and teaching algorithms of health management; (2) screening for early signs of health problems, detection and monitoring of premorbid conditions; (3) prevention of chronic diseases through correction of lifestyle factors.

At the stage of non-complicated chronic disease: (4) Examination in outpatient and hospital setting; (5) Planned interventions in outpatient and hospital settings; (6) Long-term follow-up at home to prevent disease complications, stop progression, and probably reverse the disease through correction of lifestyle.

At the stage of complicated chronic disease and disability: (7) Examination and interventions in out-patient and hospital settings, including states of emergency; (8) Rehabilitation by interdisciplinary team, in hospital and home settings; (9) Long-term follow-up at home, including the use of home care technologies.

At all stages of health and disease continuum: (10) informing about available lifestyle interventions and teaching health management algorithms.

Many inventors underline that today's healthcare model provides only a narrow range of services mentioned in the described continuum of care.

Prerequisite 3. Health management implies active patient's role and regular continuous interaction (follow-up) between patient and healthcare professional.

Ideally, care should be practiced as not only patient-centered but also person-centered care. This model implies collaboration between doctor and patient in development and implementation of personalized program; only collaboration can provide the patient with results he/she needs in the most cost-effective manner.

It is obvious that a health management system has to be automated with the use of a medical information system (MIS) on the one hand, and should be accessible from home or other place where the patient spends a major part of his/her time. A good review of problems and opportunities in the use of MIS in home setting can be found in a paper by Stolee et al. (71). Among other, this paper mentions the following barriers for automation with the use of Electronic Medical Records (EMR): the system is not focused on the client (the final consumer); the system doesn't collect information relevant for health management ("the right information"); the system is very labor consuming; one patient's data are scattered over MIS of different medical organizations.

The mentioned problems reflect the disadvantages of today's diagnosis-centered reactive model of healthcare: it features key role, burden and responsibility of the doctor (medical professional); it uses too little information about patient's lifestyle factors, and it uses too little patient's natural resources (time and attention). As the result, the healthcare systems struggles with shortage of resources (access to doctors), while the most potentially effective tools of health management (lifestyle interventions) appear the least used tools compared to pharmacotherapy and surgery.

These problems can be overcome through active introduction of patient-centered approaches; one of them could be a cloud-based MIS integrating data from different medical organization, where the patient him/herself would be involved in input of data relevant for decision making.

Integration of Common Technical Solutions Found in Literature: Design of AHMS and Different Healthcare Models

Common solutions and problems that they try to address are summarized earlier in **Table 2**. Here we would attempt to build on them an integral picture.

TABLE 4 | The needs of AHMS users (=results that they want) and possible measures that can be automated in AHMS to feed those needs.

The need (the objective)	The system of measures in AHMS
1. Recover from NCD complications, improve quality of life	Organize timely treatment of NCD complications Organize long-term rehabilitation and follow-up at home Organize supply of necessary medications, means of rehabilitation and health improvement Teach methods of self-care and self-help, and practices of healthy lifestyle
2. Avoid NCD complications (if NCD is present)	Detect and monitor signs and symptoms of NCD; identify lifestyle factors that promote NCD progression Help in selecting treatment to control NCD symptoms and complications (including analysis of treatment effectiveness) Assist in changing everyday behaviors to healthy lifestyle in order to prevent NCD complications
3. Avoid onset of NCD (if risk factors and early premorbid functional problems are present)	Detect and monitor early premorbid functional impairments; identify NCD risk factors and lifestyle factors that promote onset of NCD Inform about causality of NCD and ways to prevent NCD through correction of lifestyle Assist in transition to healthy lifestyle to prevent NCD
4. Improve health	Identify lifestyle factors that can affect health and cause NCDs Inform about causality of NCD in lifestyle and ways to improve health through correction of lifestyle Assist in transition to healthy lifestyle to improve health

TABLE 5 | Possible sequence of user's interactions with AHMS.

Event	Expected result(s)
1. The user registers in the system	Opportunities of the system are explained and instructions of its use are given User agreement is made; the user gives permission to store and process his/her data, and to send information, notifications and reminders
2. Identification of user's problems, needs, and risk factors	The user is informed and has a better awareness of his/her problems and needs Primary sorting is made in terms of user's need in a more thorough examination and/or intervention
3. Identification of potential sources of health problems in the user's lifestyle factors	The user is informed and has a better awareness of the most probable causes of health problems that he/she has Necessary information is collected to form a personalized health management program
4. A personal health management program is generated	Goals are set; available actions are chosen, with methods to implement them, timelines, necessary prerequisites (including resources) and participants (including health professionals)
5. Persona health management program is implemented	Exact steps are planned, and their implementation is controlled; necessary measures are taken to maintain motivation; current results are assessed
6. Evaluation of program effectiveness and goal setting for the next management cycle	Necessary feedback is received to adjust and fine tune health management strategy and tactics
7. Planned repeated evaluation of the current problems and needs	Continuity and integrity of health management is provided

Let's look how the proposed technical solutions correspond to patients' need in health management, with continuum of care, and the nature of management.

For this purpose we will have to abstract away from particular disease and health conditions to look at the general pattern how personal health is changing over time [(2), with modifications]:

(1) from complete health →
(2) to early (premorbid) functional impairments →
(3) to development of an NCD →
(4) to NCD complications →
(5) to death from NCD complications.

As a rule, today's "reactive," diagnosis-centered medicine comes into health management at stages (3) or (4); it primarily focuses on controlling the signs of NCD, and treats NCD complications in line with clinical standards (guidelines)—that is, actually without considering individual context and lifestyle factors that drive progression of NCD in a particular patient.

Here comes the first key conclusion about requirements for an AHMS that can be useful in NCD: it should be designed not within the framework of today's "reactive" diagnosis-centered healthcare model, but in line with proactive, person/patient-centered model. These two models are compared in **Table 3**.

Design of AHMS and Patient's Needs

Depending on the health state, the users of AHMS (patients and healthy people) can have a wide range of needs in health management; in turn, the needs determine the relevant personalized measures. **Table 4** sums up the needs of different user categories [based on common sense and continuum of care, see (8, 9)] and the corresponding functions of AHMS.

Each of the mentioned needs corresponds to different level of motivation: in general, people with more severe health problems ("more pain") are more motivated to change their behavior. Person-centered model of healthcare involves modification of behavior patterns and individual habits, and therefore in designing AHMS one should bear in mind the internal logic of behavior change. The cycle of individual changes and the instruments of managing this process are described in detail by Prochaska et al. (72), and Fogg (73). Important instruments in this process are informing and raising awareness and mindfulness. From the viewpoint of personal change, health management should look like cycles of communication and interaction closely connected with natural cycles of person's behavior change.

What functions should AHMS have to implement the mentioned measures? Which of them were not considered or disclosed in the patents and applications that we analyzed above?

To address these questions, let's reconstruct the most plausible "trajectory" of AHMS user, the possible sequence of user's interactions with the system. This sequence and expected results are summarized in **Table 5**.

After outlining the basic cycle of user interaction with AHMS, one can fill the system with the most relevant instruments and interventions for health management. Many of them are already present in current practices reviewed above, some remain to be developed and introduced.

Coming back to the descriptions of today's practices—health management systems given in the analyzed sources, there are three important points to add. None of the inventors has addressed at least the following key tasks of health management:

1. Consideration of all known significant lifestyle factors that may affect onset and progression of NCD in a particular patient (for example, combination of nutrition, chronic stress, lack of necessary physical exercise, lack of sleep, toxic burden, etc.).
2. Offering to the patient an algorithm of specific individualized recommendations how to change his/her lifestyle (for example, specific nutrition pattern, physical exercise pattern, stress management pattern, etc.).
3. Offering the patient an infrastructure supporting the proposed long-term monitoring and behavioral modifications (for example, in the form of tracking and/or coaching).

A lot of issues remain to be discussed about design of an optimum AHMS in line with person-centered healthcare model. This will be done in a separate paper. The authors feel that there are all prerequisites for creating an optimum AHMS already present in professional community and literature; it's time to bring them together like Lego bricks.

CONCLUSIONS AND RECOMMENDATIONS

Automated systems for personalized health management (AHMS) is a promising way to improve clinical and cost effectiveness of prevention and long-term follow-up of patients with NCDs.

Today's healthcare model focused on control of NCD symptoms can be defined as "reactive" and "diagnosis-centered"; its effectiveness is limited to acute diseases and emergencies, while AHMS is mostly required for prevention and long-term management of chronic health conditions.

Most technical solutions currently practiced or described in scientific and patent literature as AHMS only solve local tasks in health management; all diagnosis-centered AHMS have serious limitations and cannot provide effective and integrated solutions to most problems related to the global NCD epidemic.

To enable the best patient outcomes for chronic health conditions, an AHMS should be designed within the context of health continuum and continuum of care; it should consider the key role of lifestyle factors in the onset and progression of NCDs.

To be cost effective, an AHMS should be patient- or person-centered; it should imply patient's active role in managing one's own health: at least at the steps of collecting information, goal setting and implementation of lifestyle interventions.

To enable effective management of chronic health conditions, AHMS should consider all aspects of human health (physical, mental, and social), patient's needs and motivation; it should involve examination and modification of everyday behaviors.

Key prerequisites for developing and up-scaling an effective and ubiquitous (generally available) AHMS are: digital and telecommunication technologies based on Internet, mobile communication, portable and wearable devices and sensors; digital technologies should make major functions of AHMS available 24/7/365 and anywhere.

Automated algorithms of an effective AHMS should cover the following tasks: retrieving patient-centered data (questionnaires, wearable devices, etc.); evaluating self-reported symptoms, early predictors, risk factors and the need in detailed examination; providing decision support and individual advice on behavior modification; tracking the changes in behavior and symptoms of dysfunction.

Special focus in ASHM should be put on raising patient's awareness of cause-effect relations between everyday behavior and health problems, on informing him/her about available algorithms of lifestyle modification, and on patient's decision support system.

AUTHOR CONTRIBUTIONS

AM-P was responsible for the concept, data collection, analysis and interpretation, and drafting the article. DY contributed to the concept, data interpretation, critical revision of the article, and final approval of the version to be published. All authors contributed to the article and approved the submitted version.

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BRIEF RESEARCH REPORT
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Promoting Aspirin Use for Cardiovascular Disease Prevention Among an Adult Internet-Using Population: A Pilot Study

Niki C. Oldenburg[1*], *Keith J. Horvath*[2], *Jeremy Van't Hof*[1], *Jeffrey R. Misialek*[1] and *Alan T. Hirsch*[1†]

[1] *Lillehei Heart Institute and Cardiovascular Division, University of Minnesota Medical School, Minneapolis, MN, United States,* [2] *Division of Epidemiology and Community Health, School of Public Health, University of Minnesota, Minneapolis, MN, United States*

Cardiovascular disease prevention strategies include aspirin use as a preventive measure. The internet can be used to raise public awareness, promote healthy lifestyles, and improve disease management. This pilot study describes the feasibility of an educational website to recruit and follow adult internet users to examine whether they talked to their physician about aspirin and initiated aspirin use. As part of a statewide intervention promoting an aspirin regimen to prevent heart attacks and strokes in Minnesota, visitors to the website were encouraged to complete an aspirin candidacy tool. Between October, 2015 and February, 2016, men 45–79 and women 55–79 who identified as aspirin candidates were invited to participate in a 6-month study involving four, 5 min online surveys to examine physician discussions about aspirin, aspirin use, and mobile technology use. During the 5-month recruitment period, 234 adults enrolled in the study. Of the 174 who completed the baseline survey and at least one follow-up survey, 74 (43.5%) did not use aspirin at baseline. During follow-up, 12 (16.2%) talked to their doctor about aspirin and 31 (41.8%) initiated aspirin use. Internet, social media, and mobile technology use were high among this population. An educational website may have provided a cue to action for aspirin discussions with physicians and aspirin initiation. More research is needed to evaluate the utility of on-line tools to increase appropriate aspirin use among internet-using populations.

Keywords: health education, internet, aspirin, cardiovascular disease, prevention

Edited by:
Åsa Cajander,
Uppsala University, Sweden

Reviewed by:
Henry Blackburn,
University of Minnesota Twin Cities,
United States
Jonas Moll,
Örebro University, Sweden

****Correspondence:***
Niki C. Oldenburg
olden019@umn.edu

†Deceased

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INTRODUCTION

Cardiovascular disease (CVD) prevention strategies have utilized the internet to raise public awareness, promote healthy lifestyles, and improve disease management among the population of internet users that includes over 90% percent of U.S. adults (1). Much of the research surrounding internet-based CVD interventions has focused on individually tailored, interactive interventions among participants recruited primarily from work sites or medical clinics. The health outcomes measured have spanned risk reduction goals (smoking cessation, increased physical activity, and dietary control) to disease management goals (medical appointment adherence, medication compliance, and self-care strategies) (2–7).

WHAT CAUSES HEART ATTACKS?

Heart attacks are caused by a blood clot that blocks one of the coronary arteries. If blood flow to the arteries is blocked, the heart can't get oxygen and the heart cells die.

CARDIOVASCULAR DISEASE IS THE #1 KILLER. BUT IT DOESN'T HAVE TO BE.

Fighting heart attack and stroke could be as simple as taking one aspirin a day. That's an easy trade-off for a longer, healthier life. So talk to your doctor or a healthcare professional to determine if daily aspirin is right for you.

Ask About Aspirin is an initiative of the Minnesota Heart Health Program. To learn more click here.

ARE YOU A CANDIDATE?

Take this simple test to determine if daily aspirin may be right for you.

FIGURE 1 | Example of "Ask About Aspirin" advertisement and website.

Little is known about the impact internet-based CVD interventions may have on the behaviors of community-based internet users. In addition, it is unclear whether internet users who are middle-aged or older are willing to participate in online research.

As part of a large public health campaign promoting aspirin use to reduce heart attacks and strokes, an educational website and aspirin candidacy tool were created to prompt aspirin discussions with physicians and aspirin initiation when indicated. The aims of this study are to assess among those individuals identified as potential aspirin candidates from the online self-assessment the: (1) feasibility of recruiting and retaining a cohort of middle-aged to older internet users; (2) computer and mobile technology use of these individuals; and (3) proportion of these individuals who seek advice from their physician and who adopt a preventive aspirin regime.

METHOD

Community-Based Intervention

A multi-year, state-wide, media and health professional campaign was launched in 2012 in Minnesota to promote the 2009 U.S. Preventive Services Task Force (USPSTF) recommendations on aspirin use for the primary prevention of cardiovascular disease (8). The media campaign included radio spots, billboards, print and online advertisements (Facebook, Twitter, Pandora, Google Adwords), and brochures that encouraged individuals to talk to their doctor about a preventive aspirin regimen. Simultaneously, the media campaign directed individuals to visit the "Ask About Aspirin" educational website for more information about aspirin and to find out if they are an aspirin candidate (**Figure 1**). Adults in the 2009 USPSTF candidacy range (men 45–79 years; women 55–79 years) were encouraged to complete an aspirin candidacy tool that consisted of 9 questions addressing age, sex, CVD history, and contraindications to aspirin use. Those identified as potential aspirin candidates learned that aspirin may be beneficial for them and were advised to speak with their physicians about initiating a preventive aspirin regime.

Study Design

Between October, 2015 and February, 2016, adults who completed the aspirin candidacy tool, identified as aspirin candidates, and who were men 45–79 years and women 55–79 years old (**Figure 2**) were invited to participate in a 6-month online study about their aspirin-related behaviors and mobile technology use via a pop-up box on the website (**Figure 3**). To learn more about the study, interested individuals provided their first name and email address to facilitate a point of contact. Confidentiality was assured at the point of contact and was expanded upon in the on-line consent form. Once informed consent about the study was obtained from participants, they were asked to complete four, 5 min online surveys across a 6-month follow-up period (baseline and 1-, 3-, and 6-months).

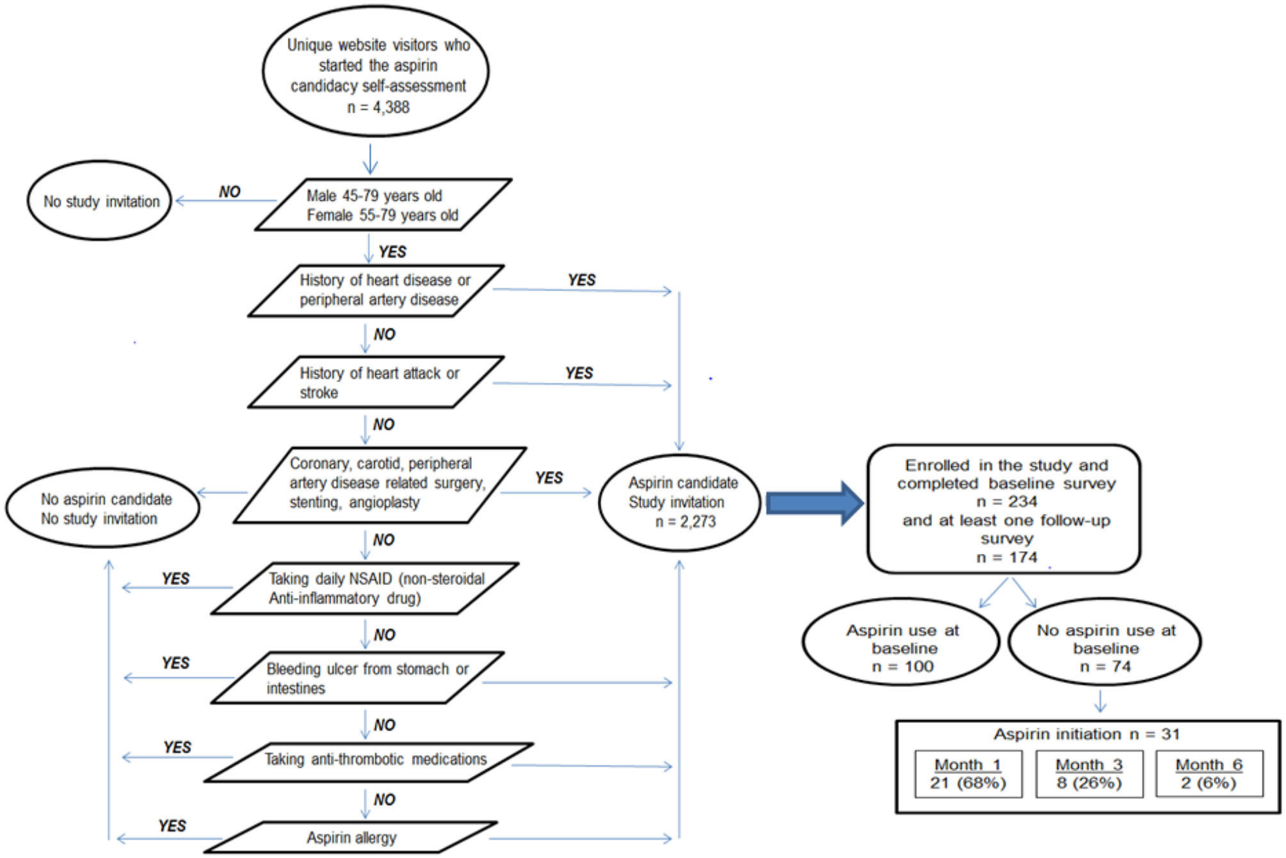


FIGURE 2 | Aspirin candidacy, study invitation, and aspirin initiation among visitors to the educational website.

Survey questions addressed sex (male/female), age (age reported in years at time of survey), aspirin discussions with physicians, aspirin use, and mobile technology and social media use. Aspirin discussions were determined by a "Yes/No" response to the baseline question "Have you ever talked with your doctor or other health professional about whether you should use aspirin as a means for preventing a heart attack or stroke?" In the follow-up surveys, this question began with the phrase "Since the last online survey you completed x month(s) ago…" to assess temporality. Aspirin use was determined by a "Yes/No" response to the question "Do you currently take aspirin to prevent a heart attack or stroke?"

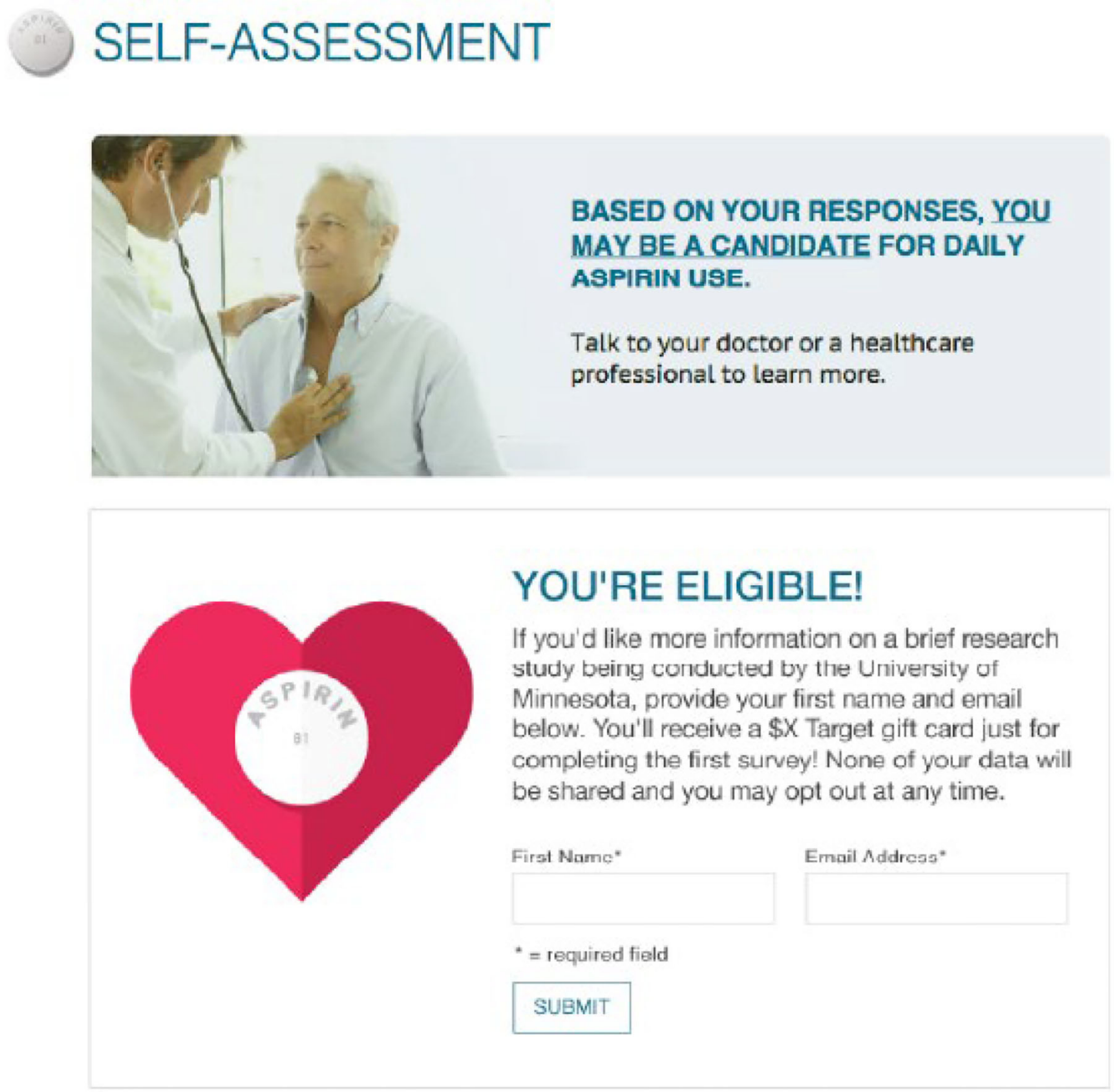
Participants received a $5 Amazon.com gift card via email for each survey they completed during the first 3-months, and a $10 Amazon.com gift card for the final survey at month 6. Links to the online surveys were emailed at each time point, followed by 2 reminder emails within a week if surveys had not been completed. Qualtrics (Qualtrics, Provo, UT) was used as the online survey management software. Data analyses included logistic regression (sex and baseline aspirin use), a two sample *t*-test (age and baseline aspirin use), and Pearson's chi-square tests (media use and baseline aspirin use) and were conducted using Stata version 12 (StataCorp LP, College Station, Texas). The University of Minnesota's Institutional Review Board, responsible for the ethical conduct of human research, approved the study.

RESULTS

During the 5-month enrollment period, there were 32,584 unique visits to the "Ask About Aspirin" website of which 4,388 visitors started the aspirin candidacy tool. Two thousand two hundred and seventy three completed the assessment and were identified as aspirin candidates which prompted a study invitation; 234 (10.2%) enrolled in the study and completed a baseline survey. Of these 234 participants, 149 (63.6%) completed the survey at month 1, 140 (59.8%) at month 3, and 123 (52.5%) at month 6. More women than men participated (58.0 and 41.9%, respectively) and the mean age was 61.9 years (range, 46–79 years).

When restricting analyses to the 233 participants who answered "Yes" or "No" to the aspirin use question, 59 (25.3%) completed only the baseline survey, 29 (12.4%) completed 2 surveys, 52 (22.3%) completed 3 surveys, and 93 (39.9%) completed all 4 surveys. At baseline, men were more likely to be aspirin users than women (OR = 2.73, 95% CI = 1.44, 5.18); age was not significantly different between aspirin users and non-users, 62.5 and 61.0 mean ages, respectively ($t = -1.4476$, $p = 0.15$).

One hundred and seventy four participants completed both the baseline survey and at least one follow-up survey, with 100 (57.4%) reporting current aspirin use on the baseline



SELF-ASSESSMENT

BASED ON YOUR RESPONSES, YOU MAY BE A CANDIDATE FOR DAILY ASPIRIN USE.

Talk to your doctor or a healthcare professional to learn more.

YOU'RE ELIGIBLE!

If you'd like more information on a brief research study being conducted by the University of Minnesota, provide your first name and email below. You'll receive a $X Target gift card just for completing the first survey! None of your data will be shared and you may opt out at any time.

First Name*

Email Address*

* = required field

SUBMIT

FIGURE 3 | Example of study invitation upon completing the aspirin candidacy tool. This image was updated when the study invitation went "live" on the website to include the exact dollar amounts and the type of gift card (amazon.com rather than Target gift cards were used).

survey. Of the 74 participants who did not use aspirin at baseline, 31 (41.8%) initiated aspirin use to prevent a heart attack or stroke and 12 (16.2%) talked to their doctor about aspirin use during the follow-up period. The majority of these 31 individuals started aspirin in the first month (**Figure 2**). When examining the 31 aspirin initiators further, 12 (38.7%) talked to their doctor about aspirin use during follow-up, 9 (29.0%) had discussed aspirin use with their doctor prior to baseline, 6 (19.3%) initiated aspirin use on their own, and 4 (12.9%) took aspirin previously, stopped, and then restarted during the study. Of the 100 participants who reported aspirin use at baseline, 96 (96.0%) continued using aspirin during follow-up.

The majority of participants accessed the internet and used social media sites several times a day. A majority also used laptops or tablets and used cell phones to access the internet. Eighty-three percent used cell phones to access the internet and 87% used social media. No difference in technology use existed between the baseline aspirin users and aspirin non-users (**Table 1**).

DISCUSSION

The study showed that it is feasible to recruit and retain a middle-aged to older, internet-using population in an online study. Participation rates for individuals recruited via the internet have ranged between <1% to approximately 15% among teenagers,

TABLE 1 | Computer or mobile technology use among participants by baseline aspirin use.

Survey questions regarding computer and mobile technology use	Total cohort ($n = 174$)	ASA non-users ($n = 74$) n (%)	ASA users ($n = 100$) n (%)	Chi-square
Which of the following devices do you use at least once a month?				
Desktop computer	107 (61.4%)	46 (62.1%)	61 (61.0%)	0.88
Laptop computer or notebook	116 (66.6%)	49 (66.2%)	67 (67.0%)	0.91
Tablet computer	117 (67.2%)	48 (64.8%)	69 (69.0%)	0.57
How often did you use Internet or email?*				
Several times a day	150 (86.2%)	62 (83.7%)	88 (88.0%)	0.44
About once a day or less	22 (12.6%)	11 (14.8%)	11 (11.0%)	
Which of the following types of social media have you ever used?				
Facebook	144 (82.7%)	61 (82.4%)	83 (83.0%)	0.92
LinkedIn	79 (45.4%)	36 (48.6%)	43 (43.0%)	0.46
Pinterest	76 (43.6%)	38 (51.3%)	38 (38.0%)	0.08
Instagram	29 (16.6%)	10 (13.5%)	19 (19.0%)	0.34
Twitter	37 (21.2%)	17 (22.9%)	20 (20.0%)	0.64
In the past month, about how often did you use any kind of social media, like Facebook, LinkedIn, Pinterest, Instagram, or Twitter?				
Several times a day	80 (45.9%)	33 (44.5%)	47 (47.0%)	0.57
About once a day	42 (24.1%)	17 (22.9%)	25 (25.0%)	
3–5 days a week or less	29 (16.6%)	15 (20.2%)	14 (14.0%)	
Have you ever used your cell phone to send or receive email?*				
Yes	136 (78.1%)	63 (85.1%)	73 (73.0%)	0.08
No	34 (19.5%)	10 (13.5%)	24 (24.0%)	
Have you ever used cell phone to send or receive text messages?*				
Yes	160 (91.9%)	70 (94.5%)	90 (90.0%)	0.39
No	10 (5.7%)	3 (4.0%)	7 (7.0%)	
On average, how many text messages do you send and receive in a month?*				
1–20	36 (20.6%)	14 (18.9%)	22 (22.0%)	0.62
21–50	41 (23.5%)	17 (22.9%)	24 (24.0%)	
51–100	39 (22.4%)	16 (21.6%)	23 (23.0%)	
>100	40 (22.9%)	21 (28.3%)	19 (19.0%)	
Have you ever used your cell phone to access the internet?*				
Yes	144 (82.7%)	65 (87.8%)	79 (79.0%)	0.22
No	25 (14.3%)	8 (10.8%)	17 (17.0%)	

**Percentages do not add up to 100% due to individuals who responded "Don't Know" or "Refused."*

and young to middle-aged adults (9–14). Study retention rates among internet-based interventions ranged widely, with follow-up rates of 13% to >80% (9, 10, 12, 15, 16). This study's participation rate of 10% and retention rate of 53% suggest that age may not be a barrier, as age-related differences in internet use are decreasing (17).

As may be expected among internet users, a higher percentage of the participants used smart phones and social media than the general adult population. Among U.S. adults, 79% of individuals ages 50–64 and 53% of those 65 years and older own a smartphone compared to 83% in the current study sample. In addition, 69% of 50–64 year olds and 40% of individuals 65 years and older use social media compared to 87% in this study (18, 19). Individuals recruited from the internet may be more frequent users of other mobile technology and social media platforms, and thus may be more responsive to health interventions that leverage varied mobile and social media tools or outlets.

A majority of the participants were already using aspirin to prevent a heart attack or stroke at the start of the study. Given the website's focus on the benefits of preventive aspirin use, such individuals may have been seeking online health information to confirm their current health behaviors. Among participants who did not use aspirin at baseline, aspirin initiation increased most dramatically during the first month of follow-up. This uptake in aspirin use is noteworthy given the minimal interaction the website provided its visitors and the short time span in which aspirin initiation was achieved. Individuals seeking online health information may be motivated to improve their health, and thus more responsive to behavior change and health maintenance messaging.

Approximately two thirds of the participants, who initiated aspirin use during follow-up, had had an aspirin discussion with their physician either prior to or during the study. This may suggest that the website prompted them to either act upon previous aspirin discussions with their physicians or to initiate new ones. Positive associations between aspirin discussions with a physician and aspirin initiation have been shown in other studies (8, 20).

An unique opportunity may exist for public health campaigns to promote community-wide behavior change among internet-users and to monitor its impact. With internet use among older adults becoming nearly universal (1, 17), internet-based campaigns focusing on CVD prevention are likely to see increases in reach and impact among this population.

Limitations

As a pilot study, the findings presented are primarily exploratory and hypothesis-generating. The lack of a control group and small numbers may limit the generalizability of the study findings to other middle-age to older internet users. Self-selection bias may be present since study participants may be more motivated to act upon internet-based health information than non-study participants. Aspirin initiation may be subject to self-report bias; however, this bias is likely minimal (21). It is not known whether aspirin initiators included individuals who should not be taking aspirin. The educational website and aspirin candidacy tool encouraged all individuals to ask their physician or health professional if a preventive aspirin regime was right for them.

CONCLUSION

This study provides preliminary evidence that it is feasible to recruit and maintain a middle- to older aged population of internet users in an online study. In addition, this study suggests that an educational website and aspirin candidacy tool may provide a promising CVD prevention strategy to increase aspirin physician discussions and aspirin use. The frequent and widespread use of mobile technology and social media platforms in this study suggest that older adult internet users may also be amenable to more varied digital interventions. More rigorous studies, such as randomized controlled trials, are needed to determine the utility of this approach to increasing appropriate aspirin use among older U.S. adults.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Minnesota (# 1201M08921). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

NO, KH, JV, and AH contributed to the study design, implementation, analysis, and manuscript writing. JM contributed to the statistical design and analysis and manuscript writing. All authors contributed to the article and approved the submitted version.

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ORIGINAL RESEARCH
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Mobile Pulmonary Rehabilitation: Feasibility of Delivery by a Mobile Phone-Based Program

Robyn Whittaker[1,2], Rosie Dobson[1], Sarah Candy[3], Taria Tane[1], Kelly Burrowes[4], Julie Reeve[5], Merryn Tawhai[4], Denise Taylor[5], Trina Robertson[2], Jeffrey Garrett[3], Gayl Humphrey[1], Tamzin Brott[2], Sabaoon Raza Khan[6], Feiyu Hu[6] and Jim Warren[6]*

[1]National Institute for Health Innovation, University of Auckland, Auckland, New Zealand, [2]Waitemata District Health Board, Auckland, New Zealand, [3]Counties-Manukau District Health Board, Auckland, New Zealand, [4]Auckland Bioengineering Institute, University of Auckland, Auckland, New Zealand, [5]Health and Rehabilitation Research Institute, Auckland University of Technology, Auckland, New Zealand, [6]School of Computer Science, University of Auckland, Auckland, New Zealand

Background: Pulmonary rehabilitation (PR) has been proven effective but is not well accessed due to transport, time, cost, and physical limitations of patients. We have developed a mobile phone-based PR program (mPR) that could be offered as an alternative for those unable to attend in-person. This was developed following formative research with patients, their families and clinicians. mPR has a core text message program plus an app that includes an action plan, exercise videos, lung visualization, symptom score questionnaire and 1-min sit-to-stand test.

Aims: To determine the feasibility of delivering pulmonary rehabilitation by mobile phone.

Methods: A 9-week non-randomized (1-arm) pilot study was conducted. Participants were 26 adults with chronic obstructive pulmonary disease plus four family members, who were offered participation at first assessment or during group PR sessions. Outcomes included satisfaction, engagement with the program, and perceived impacts.

Results: Eight people (31%) opted for text messages only, and 18 (69%) chose text messages plus the app. Three people stopped the program early, 20 said they would recommend it to others, 19 said it helped them to feel more supported, 17 said it helped them to change their behavior.

Conclusion: It is feasible to deliver PR support *via* mobile phone, including exercise prescription and support. Our mPR program was appreciated by a small number of people with chronic respiratory disorders and family members. Suggestions for improvements are being used to inform the further development of the program, which will then be tested for effectiveness. Registered with the Australia New Zealand Clinical Trials Registry ACTRN12619000884101 (www.anzctr.org.au).

Keywords: mHealth, pulmonary rehabilitation (PR), COPD, COPD—chronic obstructive pulmonary disease, digital health (eHealth), mobile phone

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Bridget T. Kane,
Karlstad University, Sweden

Reviewed by:
Jill Freyne,
Commonwealth Scientific and Industrial Research Organization, Australia
Björn Nordlund,
Karolinska Institutet, Sweden

****Correspondence:***
Robyn Whittaker
r.whittaker@auckland.ac.nz

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INTRODUCTION

Pulmonary rehabilitation (PR) has been shown to be effective in improving symptoms and quality of life in people with chronic respiratory disorders (McCarthy et al., 2015). PR is a structured program involving exercise training, education and behavior change, which is designed to improve a patient's physical and psychological health (Spruit et al., 2013). However only a very small proportion of those eligible access PR for reasons including transport, time off work, difficulty attending due to symptoms of their illness, lack of perceived benefit, and depression (Hayton et al., 2013; Guo and Bruce, 2014; Harrison et al., 2015). In recent times, those with long term respiratory disorders may be even more reluctant to attend group sessions, particularly those based in hospitals, due to the risk of COVID-19 infection. To increase the accessibility of PR (and consequently reduce the risk to this vulnerable population) we wanted to determine whether many of the aspects of PR could be delivered using mobile phones, in the same way other long-term condition self-management support programs have successfully been delivered (Chow et al., 2015; Dobson et al., 2018; Dobson et al., 2019b).

This project aims to develop a mobile phone-based PR support program using the steps outlined in the mHealth Development and Evaluation Framework (Whittaker et al., 2012). Formative work undertaken for this project found high interest in mPR from both patients and healthcare professionals (Dobson et al., 2019a). Both patients and healthcare professionals identified potential for an mPR program to overcome current barriers to traditional PR programs but had concerns regarding technology and the lack of a group environment within a digital program. Differing technology access, digital literacy and patient characteristics highlighted the need for a range of solutions to meet individual needs. There were differing views on how a potential mPR program should be accessed or how the program should sit in relation to current PR models of care. The findings from the formative work has led to the development of an mPR prototype intervention including a personally tailored text message program (mPR-SMS) and a personally tailored smartphone app (mPR-app).

The mPR prototype is an individually tailored and theoretically based PR intervention designed to support people with chronic respiratory conditions to: 1) Increase exercise capacity; 2) Increase health related quality of life; and 3) Decrease hospitalisations for acute exacerbations. The program is designed to support people (and their families) before, during, or after PR, or as an alternative for those not able to access traditional PR services. mPR consists of a core text message program with an optional mPR-app. In line with the findings from the formative work, a core text message program ensures that the intervention is accessible to everyone regardless of level of digital access and digital literacy.

The aim of this study was to pilot the prototype to assess the feasibility, acceptability and usability of a prototype mPR intervention, in order to inform the potential further development of a comprehensive integrated and adaptive mPR intervention.

METHODS

A nine-week, non-randomized one-arm pilot intervention study was conducted between July and November 2019. All study documents and procedures were approved by the Health and Disability Ethics Committee (19/NTA/74). It was registered with the Australia New Zealand Clinical Trials Registry (ACTRN12619000884101).

Intervention

The content for the mPR program was developed by a multidisciplinary team including physiotherapists, a respiratory physician, a health psychologist, a public health physician, mHealth behavior change experts, computer scientists, patients and engineers. The development of this program followed the mHealth Development and Evaluation framework (Whittaker et al., 2012), which provides a process to guide the development and testing of mHealth interventions with a focus on implementation, behavioral change theory, and involvement of the target population. The development of the content was informed by a review of current PR program content, literature, existing mHealth interventions, patient resources, and our formative research with the target audience (Dobson et al., 2019a). The program was informed by behavior change theories and incorporates behavior change techniques (BCTs) (Michie et al., 2013) including information about health consequences, social support, (practical) instructions on how to perform the behavior, and graded tasks.

Participants could stop the intervention and any of its components at any time by free texting back "STOP" and uninstalling the app.

mPR Text Messages

mPR consisted of a personally tailored package of text messages over a 9-week period. Different modules allowed content to be tailored to individual clinical characteristics, preferences and demographics. All participants received one mPR information/support message per day. In addition, smokers received a smoking module (encouraging consideration of quitting smoking) and an airway clearance module was available for participants who experienced increased respiratory secretions. All participants were also allocated an exercise prescription module based on their baseline exercise capacity and dyspnoea score as defined by the PR physiotherapist. Current smokers could opt to add a proven smoking cessation program (Bramley et al., 2005; Rodgers et al., 2005). **Table 1** provides more specific detail of the content of the modules. Family members who signed up for the program received core messages and could also receive the smoking module if a smoker. Messages across all modules were tailored and personalized by culture, the person's name, their motivations and the names of their support people.

Message delivery was managed by a specifically developed content management system, with messages sent and received through a gateway company to allow for participants to be registered with any New Zealand mobile network. The system maintained logs of all outgoing and incoming messages.

TABLE 1 | Description of the text message mPR modules.

Module name	Description	Who can receive this module
Core	One message per day includes motivation, support and information messages designed to encourage correct engagement with the program, healthy behaviors, and the healthcare system. Messages covered; general wellbeing, motivational messages, links to support services, general PR information/education, physical activity, breathing and healthy eating	All
Exercise prescription	Weekly exercise prescription based on exercise capacity including aerobic, resistance and balance exercises. There are 3 levels of exercise prescription	Patients only
Smoking	For those identified as smokers at baseline, one message every 2 weeks encouraging quitting smoking and offering a smoking cessation program	Current smokers
Smoking cessation	Those receiving the smoking module who reply text "quit" if they want support to quit to be enrolled in a smoking cessation program consisting of - Countdown to quit day (2 messages per day for a week), - Quit day (3 messages/day), - Main program (2 per day for 4 weeks) and - Relapse prevention (3 per week for the reminder of the time they receive mPR)	Current smokers who identify as wanting to quit
Airway clearance	One message per week including education and reminder messages regarding techniques for airway clearance	Patients who were productive of airway secretions only

TABLE 2 | Description of the mPR app components.

Component	Description
Tailored exercise prescription videos	Tailored exercise videos of people completing the prescribed exercises for people to follow Tailored to 3 levels based on baseline exercise capacity level
1-min sit-to-stand test	Instructions, timer, and ability to input number of repetitions completed. Reminder to complete this every 2 weeks
CAT[a] questionnaire	Questionnaire that could be completed in the app. Reminder to complete this every 2 weeks
Action plan	The standard action plan for respiratory disease exacerbations that could be completed in the app by the participant
Lung model visualization video	An educational tool to demonstrate to participants how their lungs work and changes that may have occurred related to their disease. This video was created using anatomically-realistic computational models, demonstrating the lungs and the airway structure, to provide visually appealing and accurate representations of the lungs [(Burroes et al., 2008). In addition, the users were referred to a web-based lung model app (https://sites.bioeng.auckland.ac.nz/medtech/lungs/) to provide further exploration of these models
Relaxation audio files	Freely available audio for participants to listen to and help them relax
Information for family	Brief information on how to support your loved one with their chronic respiratory disease

[a]CAT, COPD (Chronic Obstructive Pulmonary Disease) Assessment Test.

mPR app

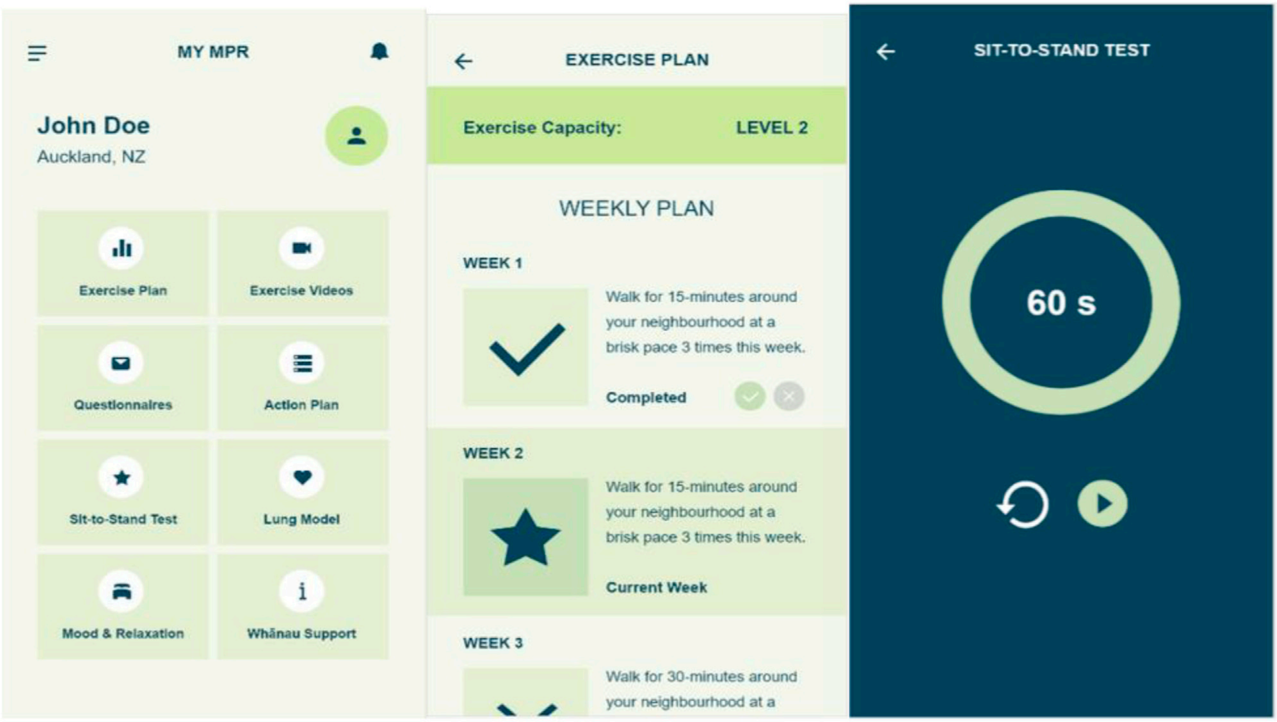
The mPR app was designed to complement the text message program and was developed by students and staff under the supervision of the study team (see **Table 2** for components and **Figure 1** for screenshots). It was loaded onto the Apple and Play app stores for download and was accessed using a study specific code. Each individual's profile was set up according to their baseline exercise prescription level.

Although no specific instructions were given to those choosing the app, participants may have been expected to use it approximately three times per week in order to view the exercise videos three times weekly and relaxation audio as needed. Other aspects of the app would expect to be used less frequently (for example, 1-min sit-to-stand test and CAT questionnaire every two weeks; lung model visualization and information for family only as desired).

Exercise Prescription

A key component of the mPR program is the exercise prescription. To ensure appropriateness, this was tailored to baseline exercise capacity. Participants were stratified to one of three exercise levels (1, 2, or 3). The exercise level was determined from their initial assessment findings, including; balance, dyspnoea score [MMRC Dyspnoea Scale Score (Bestall et al., 1999)] and functional exercise capacity [6-min walk test, 6 MWT (Holland et al., 2014)]. The exercise program included a generic warm up, walking program, and resistance training for upper and lower limbs using hand held weights. The level one program also included balance exercises. Participants were advised to exercise on five days of the week. The program was incremental - each week either the walking time, or the number of repetitions of strengthening exercises, increased. The progressed exercise prescription was sent to participants *via* SMS and updated on the mPR app. Participants were given instructions to use a scale of breathlessness (modified BORG scale) to guide the intensity of exercise. Participants were provided with instructions on how to complete each of the exercises as well as advice on when to stop exercise should they have pain or feel unwell.

The program was also adaptive to the patient's current health state utilizing assessment *via* free reply message. From week 2, each week the participant received a message asking for their current rating of their health on a Visual Analogue Scale (VAS)



John Doe
Auckland, NZ

Exercise Capacity: LEVEL 2

WEEK 1
Walk for 15-minutes around your neighbourhood at a brisk pace 3 times this week.
Completed

WEEK 2
Walk for 15-minutes around your neighbourhood at a brisk pace 3 times this week.
Current Week

WEEK 3
Walk for 30-minutes around your neighbourhood at a

FIGURE 1 | mPR app screenshots.

from 1 to 10. If their health was rated three or above, they received a reply message with the exercise prescription recommendation for the week corresponding to the level associated with their baseline exercise capacity (level 1, 2, or 3). If their current health was rated less than three then no exercise prescription was sent, and a general self-care message sent instead. If people did not respond or reported ratings of less than three for three weeks in a row, a tailored message was sent to encourage them to engage with their clinical team.

The program was also designed to monitor compliance with exercise prescription by 2-way messaging. At the end of each week a message was sent asking how many times they completed the exercise prescription for that week. An automated response was sent based on the number of times they had completed the prescription designed to congratulate them and encourage continued engagement with the program.

Participants and Recruitment

Eligibility criteria included adults aged 16 years and over with a chronic respiratory disease e.g., chronic obstructive pulmonary disease (COPD), being eligible for PR, having completed a PR initial assessment by a PR clinician, being able to read and understand English, being able to provide informed consent, and owning or with regular access to a mobile phone. The only reason for exclusion aside from the above criteria was not being available for the duration of the study. Recruitment was carried out in two secondary care hospitals in Auckland, New Zealand. Clinicians at each site identified potential participants and gave them information about the study. Informed consent was obtained before the participant was registered for the study and baseline assessment completed. The clinician then explained the exercise prescription, including providing demonstrations of each exercise and written instructions on how to perform them correctly.

Participants were asked about their intervention preferences (whether they wanted the mPR app alongside the core text message program) and intervention tailoring factors including cultural version, preferred message delivery time, names of support people and motivations. Participants were asked if a family member would be interested in also receiving the program, and if so, they were contacted separately to inform them about the study and complete informed consent.

The program was completely free to receive (no costs for text messaging or apps). Participants were given a voucher at the conclusion of the study to reimburse them for their time.

Safety

Participants were advised to contact the study physiotherapist (SC) if there were any issues arising from participation in the program. Multiple contact methods were provided.

Measures

Baseline measures were those routinely collected at assessment including demographics, exercise capacity and clinical measures [MMRC Dyspnea Scale Score (Bestall et al., 1999), 6-min walk test (6 MWT) (Holland et al., 2014), 1 min sit-to-stand test

TABLE 3 | Patient participant characteristics (n = 26).

	N	%
Gender: Male	13	50
Ethnicity		
Māori (indigenous NZ population)	4	15
NZ european	17	65
Other	5	19
Mean age	70 years	(Range 57–84)
Diagnosis		
COPD	20	77
Asthma	1	4
Bronchiectasis	1	4
Interstitial lung disease (ILD)	3	12
Other	1	4
Attendance at pulmonary rehabilitation (PR)		
PR attender (attended previously or currently attending)	20	77
PR non-attender	6	23
1 min sit-to-stand (mean)	16.65	(Range 0–31)
6 min walk test (6MWT) (mean)	374.58 m	(Range 98–570)
FEV1%		
GOLD 1-mild: FEV1≥ 80% predicted	1	4
GOLD 2-moderate: 50% ≤ FEV1 <80% predicted	14	54
GOLD 3-severe: 30% ≤ FEV1 <50% predicted	8	31
GOLD 4-very severe: FEV1 <30% predicted	2	8
Lowest SpO_2 (mean)	92%	(Range 73–100)
Secretion load: Does the patient have difficulty clearing phlegm? Yes	11	42
Smoking status: Non-smoker	26	100
COPD assessment test (CAT) score (mean)	17.08	SD = 7.05

(Vaidya et al., 2016)], plus symptom and quality of life measures [COPD Assessment Test, CAT (Jones et al., 2009)].

At the end of the nine-week program all participants (including those that stopped the intervention) were invited to complete questions about their satisfaction with the program, its usefulness and usability, and perceived impacts *via* a semi-structured telephone interview conducted by a research assistant. Engagement with the intervention was assessed using self-reports and system-recorded measures including text message responses and app data. In addition, participants were invited to repeat the exercise capacity and quality of life measures from baseline in person with the referring clinician for the purpose of assessing the feasibility of using these measures in the mPR context.

Statistical Analysis

Descriptive statistics were generated for baseline demographic and clinical characteristics, and measures of engagement with the system. Qualitative comments were analyzed using a simple, content analysis approach to identify common themes and meanings from the data.

RESULTS

A total of 30 people registered for the mPR pre-testing study with 26 patients recruited and four of their whānau (family members) invited and consenting to participate. **Table 3** presents characteristics of the patient participants only.

TABLE 4 | Mean ratings of usefulness from 1 (not at all useful) to 5 (extremely useful).

	N	Mean rating
Overall	20	4.00 (SD = 0.73; range 3–5)
Intervention type		
SMS only	11	4.09 (SD = 0.70; range 3–5)
SMS + app	9	3.89 (SD = 1.43; range 3–5)
PR attendance		
PR attender (past or current)	16	4.06 (SD = 0.68; range 3–5)
PR non-attender	4	3.75 (SD = 0.96; range 3–5)

Three of the 26 (10%) participants requested to stop the program early, one during the second week of messages due to the program being too simple for what he wanted, and two in the eighth week of messages, one of which went overseas and one whose health deteriorated significantly.

Of the 26 patient participants enrolled, six (23%) were lost to follow-up: one was too unwell, one had a family bereavement, one was overseas during the follow up period, two were unable to be contacted and one declined due to commitments. The 20 who provided follow-up interviews were representative of the full group (that is, there were no major differences in demographics or condition).

Seventeen (85%) of the 26 participants completed the 1-min sit-to-stand at follow-up, 19 (95%) completed the 6-min walk test and 16 (80%) the CAT questionnaire, indicating that it was feasible for these outcome measures to be used as part of the mPR program. Due to this being a small pilot study, not powered for testing significance in these outcomes, change in the outcomes was not assessed.

All participants (n = 20) reported that they would recommend the program to other people with chronic respiratory conditions. A total of 17 participants (85%) reported that the program had helped them to learn about their condition. Almost all reported the program made them feel more supported with their condition (19; 95%). All bar the participant who withdrew early due to the program being too simplistic, reported the program to be useful (19/20; 95%). Mean ratings of usefulness are shown in **Table 4**.

Participants were asked what they liked most about the program. The most common themes included that it was motivational and empowering (n = 8) and provided reminders and prompts (n = 8). Other themes included: that it was supportive (n = 3); it increased awareness and knowledge (n = 4); it increased confidence (n = 1); the exercise component and becoming more active (n = 2); and that you could do the program at your own pace (n = 1).

> "Liked it because it motivated me, mostly when I got the texts every day, it was like they were there with me, I found it really good" (Female, 65–74 years, ID#20)
>
> "Keeps it [exercising] in the front of your mind and you can't ignore" (Female, 65–74 years, ID#3)
>
> "Someone checking in on you." (Female, 65–74 years, ID#12)

When asked what they liked least about the program, themes included: nothing (n = 5); the exercises were too hard, progressing too quickly or exercise frequency unrealistic (n = 5); that the messages were not personalized enough (e.g., not specific to condition, irrelevant/inappropriate messages, n = 4); lack of feedback during the program (n = 1).

> "None. Should be compulsory with attending PR" (Male, 65–74 years, ID#10)

Exercise Prescription

There were three participants (12%) allocated to the level 1 exercise prescription, 20 (77%) level 2, and three (12%) level 3. Of the 26 patients receiving the program, there were four (15%) who did not respond to any of the question messages rating their health and therefore received no exercise prescriptions during the program, and eight (31%) who responded to all eight health ratings. There were two participants who rated their health at a level below the cut-off to get an exercise prescription for the week. On average participants received five exercise prescriptions (range 0–8).

At the end of each week that participants received an exercise prescription, they were asked to provide the number of times (0–5) they completed the prescription *via* reply message. Seven out of the 22 participants (32%) responded to all these questions, with participants responding on average to 64% of these question messages.

Participants stated that they liked the exercise program (n = 18, 2 did not answer this question) although 16 (80%) reported that there had been reasons that impacted their ability to perform the exercises. **Table 5** presents the frequencies of reported impacts.

TABLE 5 | Reasons impacting participants ability to do the exercises (n = 16).

Impact	Frequency
Health	13 (81%)
Personal circumstances	3 (19%)
Weather	3 (19%)
Motivation	2 (13%)
Exercise difficulty	2 (13%)
Time	1 (6%)
Energy level	1 (6%)

Engagement

At registration eight people (31%) opted for text messages only, and 18 (69%) chose to also download the mPR app. Participants reported that they read "all or nearly all of the messages" (19; 95%) or "most, more than half" of the messages (1; 5%). There were 12 (60%) participants who reported that they shared the messages with others. When asked about the dosage of messages, 12 (60%) felt that they received the right number of messages whereas seven (35%) reported that there were too many (one did not answer this question).

Of the 16 participants who selected to receive the app at registration, only 11 accessed the app (that is, completed app registration and logged in) according to system captured data. The mean number of days between users first logging into the app and their final visit was 39.2 (range 0–71). There was one user who only accessed the app on the day they first logged in. The mean number of unique days that a user accessed the app during this period was 13.3 (range 1–27).

The most viewed page in the app (excluding administration pages) was the Action Plan but only eight (73%) filled in their action plan. The individual exercise video pages were viewed a total of 88 times (11 people accessing these three times each week would mean an expected 297 times). All 11 participants who accessed the app completed the symptom score (CAT) questionnaire at least once with the average number of times completed per person being 3.1 (range 1–11; expected number of times would be at least 4). Four participants (36%) completed the 1-min sit-to-stand test through the app with the mean number of completions per participant for those that did complete it being 4.3 (range 2–6; expected number of times would be at least 4). Nearly all the participants (10, 91%) viewed the lung model visualization video page with a total of 25 views. Although nearly all of the participants viewed the mood and relaxation page (8; 82%) only three listened to one of the relaxation audio files.

In the follow up interview, participants who had not used the app stated their reasons, these included: forgetting (n = 2); difficulties downloading it or finding it on the app store (n = 3); that they did not feel it added anything above the messages so logged out (n = 1); and difficulties logging in (n = 1). Four participants felt that they needed more information on how to use the app. When asked for suggestions for how the app could be improved the following were suggested: warm up videos added; reminders to complete tasks; more consistency of information between app and text; adjustable plans and ability to go back into plans and edit; clearer instructions at the beginning; and more results reported back regularly to keep engaged.

Reported Impact

Seventeen (85%) participants reported that the program had impacted on how they managed their condition or helped them to change their behaviors.

> "how to live with it generally. I had a negative attitude before it, but after it (I now know) you can pretty much still do everything as long as you pace yourself and breath carefully, it helped me a lot" (Female, 65–74 years, ID#20)

Self-reported positive impacts included: improved breathing, increased physical activity or exercise, and reduced inhaler use. They also reported changes in sedentary behavior and physical activity with 11 (58%) reporting spending less time sitting down since taking part in the program, 16 (84%) reporting more time being up and about, 16 (84%) doing more walking and 17 (89%) exercising more.

Family members' feedback

All four patients who had family receiving the program reported that they found this beneficial and all reported that they felt it was beneficial to the family member.

> "Made him (husband) more aware of what I go through." (Female, 65–74 years, ID#9)

When interviewed, all four family members reported positive experiences with the program and that they appreciated being included. All said that it was useful to take part and would recommend it to other families.

> "(it taught me) how to encourage her and support her willpower... to support her to move . . . I've noticed a change in her exercise since and her mentally coping." (ID#23)

Safety

No adverse events were reported. Although alternatives were provided for anyone unable to comfortably complete the prescribed exercises, one participant did contact researchers about knee pain and was advised to stop lower limb exercises until the pain settled.

Suggestions for Improvement

Participants were asked to identify areas where mPR could be improved. Suggestions included: more condition specific information including more tailoring of the messages to conditions; and more details about the program and what it entails needs to be provided at registration including more information about what is included in the app and its functionality. It was suggested that the exercise component could be improved with more variability in exercises and more exercise options.

DISCUSSION

This study found that it is feasible to deliver a pulmonary rehabilitation program solely by smart phone. There are currently no existing mPR programs being delivered in this way in New Zealand. There has been considerable scepticism from clinicians that a program developed for in-person group sessions could be adapted to be delivered over mobile phones. However, the lessons learned from the global COVID-19 pandemic have included the importance of remote delivery of support and services for vulnerable populations who do not want to or are not able to attend in person (Houchen-Wolloff and Steiner, 2020). This work will help to inform all future remote patient support programs.

Issues with digital literacy and confidence in using digital tools appear to remain with some in this patient cohort. Offering a text message only program, as well as a more integrated smartphone-based program, is therefore still worthwhile. Some people may require more instructions on using an app, regardless of its simplicity. Offering a version to patients' family appears to be appreciated by both patients and their family members.

The exercise program was liked by participants, and they did report improvements in behaviors, however it seems that this may need further development. Future iterations of the mPR program will look to develop and strengthen the exercise component. This may include; increased feedback to the participant, resistance exercise prescription based on time rather than repetition, step counters and feedback loops, alternative exercises, and the possibility of a circuit option. We also intend to make the program more responsive and more tailored to the individual. More time is required to orientate participants to the program, especially the app, if they have low digital confidence.

Feedback from our participants aligns with our previous research in mHealth healthy behavior change (Bramley et al., 2005; Rodgers et al., 2005; Free et al., 2011), self-management support (Maddison et al., 2015; Dobson et al., 2018; Dobson et al., 2019b) and cardiac rehabilitation programs (Chow et al., 2015; Pfaeffli Dale et al., 2015). That is, that mHealth programs can be effective at improving health outcomes and that many people appreciate the motivation and support such programs are able to provide. Messages can provide timely reminders of desired behaviors and can align with existing in-person programs or act as an alternative where existing services are not accessible. To date, there has been less support for the effectiveness of smartphone apps than for mobile phone messaging in these areas (Whittaker et al., 2019). However, several current studies are investigating integrating the two forms of mHealth technology (Graham et al., 2016; Chen et al., 2020).

There is little other published research on mHealth pulmonary rehabilitation programs internationally. Bourne et al. (2017)

completed a randomized control trial comparing the effectiveness of an online pulmonary rehabilitation program with a center-based program for people living with COPD. The exercise prescription included in the online program was a generic program and not individually prescribed or monitored. The authors found comparable improvements in exercise capacity and quality of life measures achieved from both programs, although it had a small sample size and recruitment was limited to participants who had internet access in their own home.

Chaplin et al. (2017) examined whether an interactive online web-based PR program was a feasible alternative to center-based PR in a randomized controlled feasibility study. Their program was individually tailored and intensely monitored. The study found comparable results for both groups. The authors noted the challenges associated with recruitment to the web-based program and the declining adherence to both programs. Parks et al. (Park et al., 2020) compared a smart phone app-based self management program with a control group for people living with COPD. Both groups started with a four week center based group exercise and education program. The app-based group had significant improvements in physical activity time compared to the control. The duration of program was six months, much longer than the previous trials, and the study showed adherence remained consistent throughout the six-month trial (Park et al., 2020).

The visualization included in the mPR app is novel and requires further investigation. One example from a clinically focused study identified that using visual images of the effect of skipping doses of anti-retroviral medication for the management of HIV, improved adherence (Jones et al., 2018). Another similar example has demonstrated the impact of model-based animation to improve recovery from acute coronary syndrome (Jones et al., 2016). Active visualization includes the application of live demonstrations or animations to communicate information about the effects of medication or other aspects of how the body works in a more impactful way (Perera et al., 2014). When information that is intangible, such as how our lungs work and what can go wrong in this complicated system, is presented visually with the assistance of computational modeling and/or animation, it may be easier for many people to process than factual material provided in text format.

CONCLUSIONS

A prototype mPR program was appreciated by a small number of patients and family members. More work is required to develop the next version of the mPR program based on the feedback from participants. We intend to develop a more integrated program, with the text messaging and app working together. It will also be a more adaptive and responsive program, tailored to the individual, their disease and their current condition. This will undergo more rigorous testing of effectiveness.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Health and Disability Ethics Committee (19/NTA/74), New Zealand. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

The intervention was designed by RW, RD, SC, JW, KB, TT, JR, DT, GH, JG, MT, SK, and FH. The study was designed and conducted by TT, SC, RD, and RW. Data collection by TT, RD, SC, and TW. Data analysis and interpretation by RW, RD, SC, JR, and GH. Manuscript prepared by RW, RD, SC and reviewed and edited by all.

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BRIEF RESEARCH REPORT
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Machine Learning in Clinical Psychology and Psychotherapy Education: A Mixed Methods Pilot Survey of Postgraduate Students at a Swiss University

Charlotte Blease[1]*, Anna Kharko[2], Marco Annoni[3,4], Jens Gaab[5] and Cosima Locher[2,5,6]

[1] General Medicine and Primary Care, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, United States, [2] Faculty of Health, University of Plymouth, Plymouth, United Kingdom, [3] Interdepartmental Center for Research Ethics and Integrity CNR, Rome, Italy, [4] Fondazione Umberto Veronesi, Milan, Italy, [5] Department of Clinical Psychology and Psychotherapy, University of Basel, Basel, Switzerland, [6] Department of Consultation-Liaison Psychiatry and Psychosomatic Medicine, University Hospital Zurich, Zurich, Switzerland

Background: There is increasing use of psychotherapy apps in mental health care.

Objective: This mixed methods pilot study aimed to explore postgraduate clinical psychology students' familiarity and formal exposure to topics related to artificial intelligence and machine learning (AI/ML) during their studies.

Methods: In April-June 2020, we conducted a mixed-methods online survey using a convenience sample of 120 clinical psychology students enrolled in a two-year Masters' program at a Swiss University.

Results: In total 37 students responded (response rate: 37/120, 31%). Among respondents, 73% ($n = 27$) intended to enter a mental health profession, and 97% reported that they had heard of the term "machine learning." Students estimated 0.52% of their program would be spent on AI/ML education. Around half (46%) reported that they intended to learn about AI/ML as it pertained to mental health care. On 5-point Likert scale, students "moderately agreed" (median = 4) that AI/M should be part of clinical psychology/psychotherapy education. Qualitative analysis of students' comments resulted in four major themes on the impact of AI/ML on mental healthcare: (1) Changes in the quality and understanding of psychotherapy care; (2) Impact on patient-therapist interactions; (3) Impact on the psychotherapy profession; (4) Data management and ethical issues.

Conclusions: This pilot study found that postgraduate clinical psychology students held a wide range of opinions but had limited formal education on how AI/ML-enabled tools might impact psychotherapy. The survey raises questions about how curricula could be enhanced to educate clinical psychology/psychotherapy trainees about the scope of AI/ML in mental healthcare.

Keywords: artificial intelligence, machine learning, psychology students, attitudes, opinions, survey, ethics, medical education psychotherapy education

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University of Skövde, Sweden

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Tobias Weigl,
Psychology School, Germany
Isto Huvila,
Uppsala University, Sweden

****Correspondence:***
Charlotte Blease
cblease@bidmc.harvard.edu

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INTRODUCTION

Background

Digital services based on artificial intelligence and machine learning (AI/ML) are increasingly used in mental health care including the use of apps. Health apps encompass a range of proposed uses, including the monitoring and tracking of symptoms, as well as direct-to-consumer interventions designed to support, complement, or replace, psychotherapy (1, 2). Psychotherapy apps have been designed to include various techniques including cognitive behavioral therapy, acceptance commitment therapy, and eclectic therapy. The recent coronavirus crisis has further accelerated the shift toward a model in which therapeutic relationships are increasingly mediated by on-line platforms and digital services.

Considering these digital advances, educating future clinicians, including psychologists and psychotherapists, will be important to ensure optimal, safe use of AI/ML enabled tools and innovations. So far, a growing number of investigations have explored the views of clinicians including primary care physicians on the impact of AI/ML tools on their job (3–7). These studies, albeit limited, suggest that mental health clinicians expect AI/ML to influence or change their professional roles in the future. For example, in 2020, an international survey of 791 psychiatrists reported that 75% ($n = 593$) believed that AI/ML enabled tools would, at some point, be able to fully replace psychiatrists in documenting and updating clinical records (7). In the same survey, 54% ($n = 427$) of psychiatrists believed that AI/ML tools will be able to fully replace humans in synthesizing information to make diagnoses. In qualitative research, psychiatrists express divergent opinions on the benefits and harms of AI/ML in treating mental health patients with comments demonstrating scarce reflection of ethical and regulatory considerations for patient care (6). Similarly, in a recent survey of psychiatrists in France ($n = 515$) (8), respondents expressed "moderate acceptability" of disruptive technologies, such as wrist bands for monitoring symptoms, but concluded that this likely reflected lack of extensive knowledge about these technologies.

OBJECTIVES

In this study, our aim was to explore the opinions, openness, and familiarity of clinical psychology students on the impact of AI/ML on their job. In January 2020 we performed a scoping review of the literature using the terms "artificial intelligence," "psychotherapy," "education," and "training" in the search engines PubMed, PsychInfo, and Google Scholar. This revealed very limited research examining attitudes toward artificial intelligence among students. So far, only one study has explored the awareness, and formal education of medical students about AI (9). Our objective was to initiate research into psychotherapy and clinical psychology education by launching a pilot survey of students. Specifically, we aimed to explore whether clinical psychology students believed their career choice would be impacted by AI/ML, the benefits, and harms of any such impact, and their level of formal training on these topics. Using a convenience sample of clinical psychology students at a leading European University, we aimed to investigate whether more education may be required so that trainee clinical psychologists/psychotherapists might ethically harness and advise patients about AI/ML-enabled tools.

METHODS

Study Population

The single-center study was based at the Faculty of Psychology, University of Basel, Switzerland. The online survey was conducted from April to June 2020 with clinical psychology students (see **Supplementary File 1**). Students were 1st- and 2nd-year postgraduate students enrolled on a 2-year Masters' degree program in clinical psychology and psychotherapy (https://psychologie.unibas.ch/en/studies/master-program/).

Respondents enrolled in the Masters' program were invited via email to participate in the study. Three further reminder emails were sent, 1–2 weeks apart. Participation was voluntary and students were advised that the survey was not a test, that their responses would be pseudonymized, and that no sensitive information would be collected. There was no selection or exclusion in recruitment, and no reimbursement or compensation. Ethical approval for the study was granted by the Faculty of Psychology, University of Basel. The survey was administered in English, as students enrolled on the clinical psychology/psychotherapy Masters' program at the University of Basel are expected to be fluent English-speakers.

Survey Instrument

The online survey [see **Supplementary File 1**] was designed with the online software Jisc (https://www.jisc.ac.uk/). The survey instrument was devised with consultation from academic informaticians at Harvard Medical School, and with psychotherapists at the University of Basel the survey was pre-tested with psychology students from outside the University to ensure face validity and feasibility. The survey opened with a brief statement: "We are inviting you, as psychology students to give your opinions about technology and the future of mental health care." We also made it clear that the survey was aimed at assessing their personal opinions. We stated that we did not assume that participants have any expertise about AI/ML.

In the first section, respondents were asked to provide demographic information. Participants were also requested to state whether they intend to enter a mental health profession or not. The second section consisted of open comment questions on the future of psychotherapy (see **Table 1**, and **Supplementary File 1**). Respondents were requested to briefly describe way(s) in which AI/ML might change the care of patients with mental health conditions and psychotherapists' job in the next 25 years, as well as potential benefits and risks of AI/ML in the care of patients with mental health problems. The third section of the survey was intended to gauge participants' familiarity with artificial intelligence and machine learning. Participants were asked whether they were familiar with "machine learning" and "big data analytics" and whether they had read any academic journal articles relating to these

TABLE 1 | Open-ended questions.

In the next 25 years, please briefly describe the way(s) you believe artificial intelligence/machine learning might change the care of patients with mental health conditions.
In the next 25 years, please briefly describe the way(s) you believe artificial intelligence/machine learning might change the job of clinical psychologists and psychotherapists.
Please provide any brief comments you may have about the *potential benefits* of artificial intelligence/machine learning to the care of patients with mental health conditions.
Please provide any brief comments you may have about the *potential harms* of artificial intelligence/machine learning in the care of patients with mental health conditions.

topics ("no", "yes" answers). Students were also requested to estimate the amount time (a) already spent and (b) anticipated on these topics in their program of study. Finally, respondents were also asked to rate the importance of AI/ML for clinical psychology/psychotherapy education.

Data Management and Analysis

We used descriptive statistics to examine students' characteristics and opinions about the impact of AI/ML on the future of psychotherapy. The quantitative survey data was analyzed to extract summary statistics and 95% confidence intervals. Spearman's correlation coefficient was calculated for key variables describing students' experiences and attitudes toward including education about AI/ML in a clinical psychology program.

Survey responses were uploaded to the software QCAmap (coUnity Software Development GmbH) for analysis. Thematic content analysis was used to investigate students' responses. Transcripts were read several times by the two main coders (MA and CL) to achieve familiarization with the responses. Next, a process was employed in which brief descriptive labels ("code") were applied to comments by two main coders (MA and CL); multiple codes were applied if quotations presented multiple meanings. Comments and codes were reviewed alongside an independent coder (AK), and further revisions and refinements of codes were undertaken until consensus was reached. Afterward, first-order codes were grouped into second-order themes based on commonality of meaning. All authors met to review and refined the final themes.

RESULTS

Respondent Characteristics

Descriptive statistics and analysis were carried out using JASP (0.9.2). **Table 2** provides a summary of demographic characteristics. The final respondent sample comprised 37 students (response rate: 37/120, 31%). There was a homogeneous distribution of students in terms of their current study semester.

Participants' Opinions About, and Familiarity, With AI/ML

The vast majority of respondents (36 of 37, 97%) had heard of "machine learning" and were familiar with "big data analytics" (29 of 37, 78%) (see **Table 3**). Respondents reported an average (mean) of 6.18 h, so far, of AI/ML in their degree. They anticipated, on average (mean), a further 12.43 h of AI/ML education in their Masters' degree program. Almost half (46%) of surveyed participants reported their intention to learn more about AI/ML as it pertains to mental healthcare, the remaining respondents were either unsure (43%) or responded that they had no intention of doing so (11%).

TABLE 2 | Sample characteristics ($n = 37$).

	μ or n	(*SD*) or %
Gender (female)	30	81%
Age (n years)*	26.65	(5.21)
Year		
1st	24	65%
2nd	13	35%
n intend to enter a mental health profession		
Yes	27	73%
No	3	8%
Unsure	7	19%
Of those who said '*Yes*' (n = 27), n intend to enter…		
Clinical Psychology/Psychotherapy	23	85%
Counseling/Coaching	2	7%
Social Work	1	4%
Other: Neuropsychology	1	4%

μ, average value; n, count; SD, standard deviation; %, percentage.
Items, for which μ and SD were calculated.

Students who intended to learn more about the application of AI/ML in mental health reported more hours of relevant education (m = 9.24) than those who were uncertain (m = 4.44). Furthermore, students who intended to learn more stated that they will have more hours of such education in the future (m = 20.88) compared with those who were unsure (m = 6.53). Using a five-point agreement Likert scale, where *1) Strongly disagree, 2) Moderately disagree, 3) Neutral, 4) Moderately agree and 5) Strongly agree* students moderately agreed" that discussions about artificial intelligence/machine learning should be part of clinical psychology/psychotherapy education.

The only significant positive relationship was between respondents' attitudes about the inclusion of AI/ML in education, and hours spent receiving relevant education. Students who reported receiving more hours of AI/ML education gave a higher rating on the five-point Likert scale (r = 0.34, p = 0.038).

Results of Qualitative Findings

All 37 participants responded to the open questions, and left comments (544 words) which were typically brief (one phrase or one or two sentences). As a result of the iterative analysis, four major categories were identified in relation to

TABLE 3 | AI/ML education experience and interest.

	m* or *n	**(*SD*) or %**	**Range**
n have heard of machine learning	36	97%	–
n are familiar with big data analytics	29	78%	–
n have read AI/ML mental health journal articles	23	62%	–
AI/ML education during the degree (*n* h)*			
So far	6.18	(16.63)	0 – 100
Predicted	12.43	(16.39)	0 – 60
Intend to learn about AI/ML as it pertains to mental health care			
Yes	17	46%	-
No	4	11%	-
Unsure	16	43%	-
Discussion about AI/ML should be part of clinical psychology education.**	4 (Moderately agree)	(1.48)	

m, mean; n, count; SD, standard deviation; %, percentage.

**Items, for which m and SD were calculated.*

***Answer was a rating on a five-point agreement Likert scale, where 1) Strongly disagree, 2) Moderately disagree, 3) Neutral, 4) Moderately agree and 5) Strongly agree.*

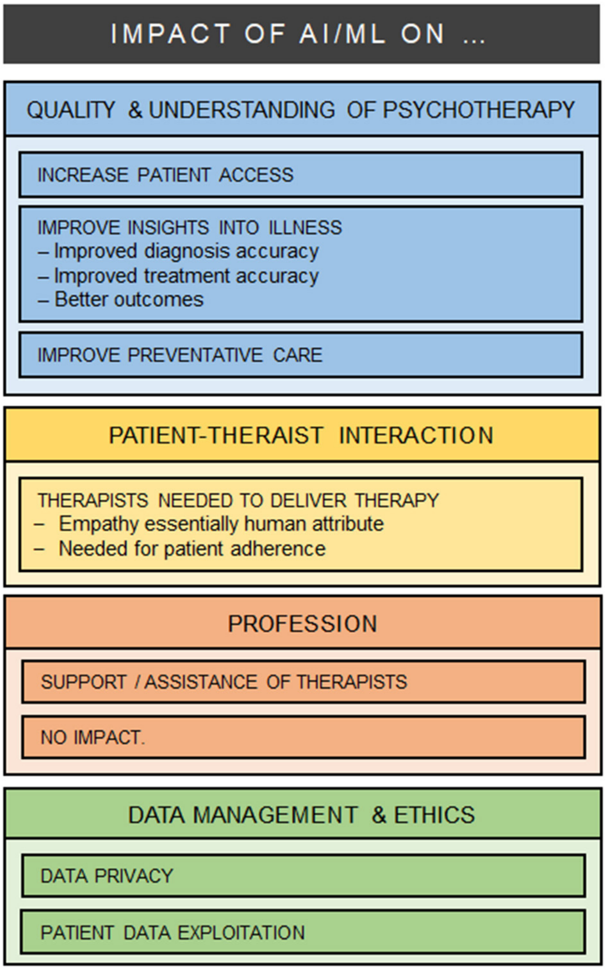

FIGURE 1 | Themes and Sub-Themes.

the impact of AI/ML on mental health care: (1) Changes in the quality and understanding of psychotherapy care; (2) Impact on patient-therapist interactions; (3) Impact on the psychotherapy profession; (4) Data management and ethical issues (see **Figure 1**).

Changes in the Quality and Understanding of Psychotherapy Care

Many comments reflected the view that AI/ML could facilitate and expand access to psychotherapy care and that this development would have a broad influence on public health; for example:

> *Facilitating access to mental health services for example by providing online psychotherapy programs* [Participant 08]
> *Machine learning can improve mental health care by adding more "knowledge"* [Participant 04]

Relatedly, many students believed that AI/ML will foster "*new patterns*" and research insights into mechanisms, and causes of mental illness; for example:

> *There could be a shift from treating disorders to treating symptom clusters/categories* [Participant 14]
> *Massively more data can be gained and analyzed which could lead to completely new insights into underlying mechanisms of mental health*

[Participant 17] Describing other benefits, some participants also predicted that AI/ML could lead to more accurate diagnoses, "*better outcomes*", and more targeted treatments; for example,

> *ML/AI may develop to help us in guiding our decision making in various health care situations, where a lot of information has to be taken into account and humans often lack to keep in mind all different outcomes or combinations (e.g., taking into account genetic variations, risk and protective factors, etc.)* [Participant 10]
> *Personalize the prescription of psychopharmacological drugs, specifically decide on which SSRI is the best suited for a patient* [Participant 15]

Preventative care, risk detection, and "closer monitoring" also received a considerable number of comments; for example:

> *AI will play a big role in the prevention of mental health conditions* [Participant 08]
> *I think in general AI may help detect people struggling with mental health disorders that would have otherwise not be detected* [Participant 08]
> *May become an additional guidance for treatment progression and predicting outcomes or identify high-risk patients.* [Participant 15]

However, not all participants agreed there might be broad benefits. Some students stressed that AI/ML-tools may be inaccurate or that the algorithms that power them are not humanly understandable. Others worried that innovations might induce a false sense of ease to access and get benefit from care; for example,

> *Not clear how the algorithms work and how categorization takes place.* [Participant 14]
> *I fear that patients will believe treatments via AI or machines will be easier and quicker and give them relief without much work* [Participant 03]
> *Every individual is different and I personally am not a bit fan of too much digitalization, so perhaps these algorithms and parameters are suitable for the majority of the population, but not the minority* [Participant 11]

Impact on Patient-Therapist Interactions

Respondents frequently commented on the potential consequences of AI/ML for the patient-clinician relationship. Many respondents emphasized that a core feature of psychotherapy is the patient-clinician relationship, and that therapists would always be necessary to deliver care:

> *I do not believe that machines will replace us as the client-therapist relationship is crucial to therapy.* [Participant 17]
> *People need people. Artificial intelligence/machine learning should give us more time to spend with other people not replace relationships.* [Participant 35]
> *As the current Covid-19 experience shows: many people are not happy with online therapy for a longer period of time since they miss the personal exchange with the therapist in the room (i.e. not in their own home nothing special anymore: like another business meeting on Zoom).* [Participant 26]
> *But I think the key in psychotherapy is the relationship between the patient and therapist. [It's] a work I think [which] is only effective when patients feel and experience real contact to the therapist a human being. I cannot imagine that AI can substitute us rather I think [it'll] be a support-tool for us.* [Participant19]

Multiple comments reflected concern that therapy depends on human attributes such as empathy (e.g., *"Computer can't give you empathy"*), and warmth (e.g., *"the social interaction warmth and real relationship will still be important"*). While a few participants suggested AI/ML might reduce the barriers to treatment participation and increased adherence, other comments proposed that human therapists would be necessary to ensure patient motivation and treatment adherence; for example:

> *Not sure how motivating apps can be when you know it is just an app and not a real person expecting you to do tasks etc.* [Participant 07]
> *[. . .] in the end they [the patients] will realize that it will not help them long-term, which could cause them even more suffering* [Participant 03]
> *If used too often, patient could feel abandoned and put away with a robot.* [Participant 16]

Notably, only one student foresaw positive scope for AI/ML in traditional patient-therapist relationship:

> *"A lot of therapists vary in many ways. And they make human mistakes a machine (virtual therapist) is less likely to have a bad day or feel [antipathy] for the patient... people can build a good relationship to a virtual therapist as well as long as they feel understood and accepted."* [Participant 24]

Finally, while the patient-clinician interaction was widely commented upon, consideration of particular patient populations was rare; one participant suggested that *"Patients (for example older patients) could hesitate about doing a test since they might not trust the AI."* [Participant 30]

Impact on the psychotherapy profession

Respondents' comments encompassed a number of predictions on the impact of AI/ML on therapists. Most respondents expressed the view that AI/ML-enabled tools will provide new ways to support, complement or assist therapists in carrying out their tasks; for example:

> *It can be a helpful tool, to complement the therapeutic work.* [Participant 16].
> *We can use AI as a tool to support our work.* [Participant 19]
> *Internet-based treatments as a "homework" for patients could facilitate the change process in order to make it clearer for patients what the psychologist is trying to communicate.* [Participant 33]

Numerous comments highlighted positive benefits to therapists of AI/ML tools with respect to more basic and routine tasks, or in delivering care for patients with less serious psychological problems; for example:

> *AI could [. . .] also be performing standardized tests with mental health patients and the results of these tests would be shown directly to the clinical psychologist and psychotherapist. Based on those results, the AI might also conclude what the next goal in the psychotherapy with mental health patients would be and therefore aid the clinical psychologist and psychotherapists to look what the next step is for the patient.* [Participant 30]
> *Minor issues will be treated via AI. Like chatbots. With minor issues I [mean] every day struggles or small psychological issues like a stressful life phase. AI will not take care of bigger problems and issues.* [Participant 16]

Some participants suggested that AI/ML-tools would help to relieve therapists of some workplace burdens, allowing them to devote more time to other important aspects of care by leaving the execution of bureaucratic work to technology; for example:

> *Would help clinicians to speed up a lengthy process.* [Participant 18]
> *I rather believe that it would help psychologists to have enough time in order to build good relationships with their clients.* [Participant 38]
> *[It will allow more focus on] what therapists really excel at, maybe bureaucratic work could be cut down with AI/ML.* [Participant 23]

Perhaps with this in mind, some comments emphasized the possible impact that AI/ML might have both for the education and the training of therapists; for example:

> *They will use more often computers and programs. Need to know more about programming and other technical knowledge.* [Participant 09]
> *Practitioners might need to learn to apply certain AI/ML applications that have been shown to help improve decision making.* [Participant 10]
> *I think clinical psychologists and psychotherapists will have to use artificial intelligence/machine learning. And therefore, have a certain knowhow in doing so* [Participant 35]

Finally, a number of participants expressed the view that AI/ML will have no significant impact on therapists in the short or long term; for example:

> *My job would probably stay similar.* [Participant 07]
> *I don't think related to this subject too much will change in 25 years.* [Participant 37]
> *I think that the job of clinical psychologists and psychotherapists won't change that much.* [Participant 20]
> *Artificial intelligence/machine learning can't replace psychotherapist/mental health professionals.* [Participant 09]

Data Management and Ethical Issues

Comments frequently described the "*massive amounts of data*" that can be accumulated through AI/ML-enabled tools, and many students expressed considerable concern about "*infringement of privacy*" with respect to data curation; for example:

> *How securely are the data stored?* [Participant 07]
> *To create trust, a transparent and secure way of data storage and protection would have to be provided.* [Participant 05]
> *Of course, security and data protection are a crucial issue in the field of AI especially when it comes to sensitive information like mental health.* [Participant 08]
> *Data security is probably the most important concern, where we really do lack the infrastructure for safe data collection and processing.* [Participant 23]

In respect of this, several students also identified the possibility of patient data exploitation as a problem; for example:

> *Who will have access to the personal information of patients?* [Participant 24]
> *Who will misuse them for commercial reasons… or will health insurance be able to track the patients' digital footprints – data protection?* [Participant 24]
> *Potential leakages of patient information on the internet to unwanted recipients or hackers. Thus, AI must have a tight security system, or it must automatically be able to recognize potential hazards and dangers.* [Participant 30]

Notably, some students raised broad ethical concerns about the impact of AI/ML on mental health care but did so in a vague or truncated manner; for example:

> *Autonomy or ethical problems.* [Participant 19]
> *The ethics are quite complex.* [Participant 15]
> *Is it ethical to monitor patients[?]* [Participant 31]

DISCUSSION

Summary of Major Findings

The opinions and experiences of trainee clinicians have been missing from the debate about the impact of AI/ML on clinical psychology and psychotherapy. This exploratory survey indicates that clinical psychology students express some awareness of AI/ML. Most postgraduate students in our sample intended to enter a mental health profession, and most had some familiarity with the terms "machine learning" and "big data." Around two thirds of respondents also reported reading a journal article on AI/ML. Around half (46%) the respondents reported their intention to learn more about AI/ML; remaining respondents were unsure, and around one in 10 reported no intention of doing so. Respondents also reported receiving an average of 6.18 h learning, so far, on the topic of AI/ML in their course and expected an average of a further 12.43 h of teaching on the topic in their degree program. Combining both reported and anticipated time on AI/ML education, this amounts to a perceived total of 18.61/3,600 h, or 0.52% of their total degree.

In light of limited course instruction, students demonstrated a wide range of views and some knowledge about AI/ML tools in psychotherapy. Participants commonly expressed the belief that AI/ML tools will help to expand access to care. Students frequently described the possibility of improving diagnostic and treatment insights, and preventative mental healthcare. While the term "digital phenotyping" (10, 11) was not used, students recognized the widely discussed potential of digital devices to gather moment-by-moment data that may be relevant to mental diagnosis and symptom monitoring (12, 13).

Students were divided about the impact of AI/ML on the future of their profession, findings that replicate a tension observed in other clinician surveys (4, 7). In line with these survey findings of practicing clinicians, students were skeptical that digital tools could replace human therapists in the delivery of care and considered empathy to be a quintessentially human attribute. Many students similarly forecast that digital technologies would be restricted to a supporting role, augmenting the role of the therapist or in undertaking automation of more routine tasks, though the specification of these tasks was often vague or unmentioned.

However, unlike other surveys on the future of the clinical professions (5, 6) students frequently expressed their ethical concerns about the impact of AI/ML on healthcare, especially in relation to patient privacy and data exploitation. Indeed, loss of privacy, and misuse of sensitive healthcare information remains a risk, with known cases of mobile technologies selling patient data to third parties (14–16). Mental health patients remain among the most vulnerable of patient populations and are especially at risk of privacy violations via the exploitation of their data, and it was clear that many of the students had reflected on this problem.

On the other hand, ethical considerations such as the "digital divide" in healthcare, patient digital literacy in using apps, and problems associated with algorithmic biases in the design of digital health tools received little or no attention (14). In addition, the regulation, approval, and evidence-base associated with currently available mental health apps received scarce commentary. These omissions may be viewed as concerning. As the digital app economy continues to boom there is considerable promise, but also the potential for harm. To date, it is estimated that there are more than 10,000 health apps available for download, yet most have never been subject to robust standards of evidence-based medicine (2, 17). While there is considerable scope for mobile health innovations in improving patient care (18, 19), there is also a pressing need to formulate clear recommendations for these apps among patients and clinicians.

Despite expressed ethical worries, it was also notable that some students believed that AI/ML would have no impact on psychotherapy in the short or long term, and around half of those surveyed suggested that they were unsure, or would not, follow up with more learning on AI/ML. We might cautiously infer from this that students did not consider it relevant to their job to provide advice to patients about the benefits and risks of currently available psychotherapy apps, for example or symptom monitoring. Again, this emerged as a concern. These tensions, and omissions may reflect lack of formal training about how AI/ML is already encroaching on mental health care. In addition, it is possible that students' current familiarity may be driven less by formal education than by outside sources, including the media.

Reflecting on these findings, the important question arises about whether teaching bodies and curricula should be adapted, not only for students but also for educators. In a recent survey, leading healthcare informaticians forecast that by 2029, AI/ML will incur workplace changes in primary care, with the need for increased training requirements in these fields (20). The present survey therefore raises questions about the preparedness of clinical psychology/psychotherapy students to fully engage in pressing debates about ethical and evidence-based issues pertaining to AI/ML tools, and in guiding patients on the use of psychotherapy and other mental health apps (21).

Strengths and Limitations

To our knowledge, this pilot survey is the first to investigate the exposure, and opinions of, clinical psychology/psychotherapy students to AI/ML. The average response rate for online surveys is 20–30% (22). While our response rate achieved 31%, the overall sample size was small. The survey was administered during the COVID-19 pandemic and this may have affected willingness to respond. Relatedly, it is not known how, or whether, contextual conditions influenced their responses to the survey. With the recent uptick in telemedicine, and considerable debate about digital health during the pandemic, it is conceivable that participants' answers may have been influenced by both global and local conditions. Response biases might also have affected findings: a high number of our participants (23 of 37, 62%) reported having read AI/ML mental health journal articles. It is unknown, however, whether the decision to complete the survey was influenced by students' prior knowledge or awareness of the topic of AI/ML. The convenience sample of students at a single academic center, also raises questions about representativeness.

Some items on the survey could be challenged on the grounds of vagueness. For example, "familiarity with big data analytics" might, justifiably, be considered semantically opaque. While we acknowledge that this survey item is coarse-grained, this preliminary study set out to explore general student awareness, level of personal inquiry, and formal educational exposure to the topic of AI/ML. We recommend that interviews, or focus groups would provide finer-grained analysis of student awareness and opinions of AI/ML. Further, we suggest that future research might usefully explore the views of specific groups of students (for example, only those who aim to work as psychotherapists), and on the views of clinical psychology/psychotherapy, and other mental health educators. In addition, it would be useful to evaluate course curricula across tertiary level colleges and universities to obtain a more objective assessment of topics and level of education about AI/ML in clinical psychology/psychotherapy training.

CONCLUSIONS

Clinical psychologists and psychotherapists entering the job-market will face new challenges posed by the emergence of new e-health tools based on artificial intelligence, machine learning and big data analytics. Although the majority of students in our survey had heard of "machine learning" and read about AI/ML in journal articles, only half of respondents planned to learn more about AI/ML as they pertain to mental health care. Importantly, most students agreed that discussions about AI/ML should be part of clinical psychology/psychotherapy education. Yet they estimated only 0.52% of their total degree (18.61/3,600 h) will be dedicated to these topics.These results seem to contrast with current trends. Clinical psychologists/psychotherapists—as well as patients/clients—can already access thousands of digital tools, online services and mobile apps based on AI/ML that have been specifically designed to integrate or substitute traditional mental healthcare services or consultations. The impact of these technologies on mental healthcare is set to rise as new and more advanced AI/ML tools and services are released.

We suggest that clinical psychology/psychotherapy curricula should embrace these new challenges in educating the clinicians of tomorrow. Courses might be usefully designed to train clinical psychologists and psychotherapists on how to guide and assist patents in being "digitally savvy" — and in making informed choices about available AI/ML tools and services. With this in mind, we envisage a need for interdisciplinary approaches to psychotherapy education. For example, psychotherapists with computer/informatics backgrounds, and psychotherapy ethicists with training on digital healthcare should devise relevant short courses for students and continuing professional development.Course curricula should encompass instruction on when patients might benefit from using apps, and/or when they should consult with therapists, in-person. Courses should therefore encompass discussion about the evidence-based effectiveness and safety of mental health apps, as well as about other delicate ethical and regulatory issues related to privacy, equality, and discrimination. Psychotherapy practitioners and students should feel empowered to keep abreast of new technological advances including what these developments mean for their profession and their patients.

DATA AVAILABILITY STATEMENT

Upon request, the raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Basel. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

CL, JG, MA, AK, and CB: administered survey, collected data, and revised the manuscript. AK, MA, and CL: data analysis. CB, CL, AK, and MA: wrote the first draft of paper. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.623088/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Understanding the Methodological Issues and Solutions in the Research Design of Stroke Caregiving Technology

Elton H. Lobo[1,2]*, **Anne Frølich**[2,3], **Lene J. Rasmussen**[4,5], **Patricia M. Livingston**[6], **John Grundy**[7], **Mohamed Abdelrazek**[1] and **Finn Kensing**[8]

[1] School of Information Technology, Faculty of Science, Engineering and Built Environment, Deakin University, Geelong, VIC, Australia, [2] Section of General Practice, Department of Public Health, University of Copenhagen, Copenhagen, Denmark, [3] Innovation and Research Centre for Multimorbidity, Slagelse Hospital, Region Zealand, Denmark, [4] Department of Cellular and Molecular Medicine, University of Copenhagen, Copenhagen, Denmark, [5] Center for Healthy Aging, University of Copenhagen, Copenhagen, Denmark, [6] Faculty of Health, Deakin University, Geelong, VIC, Australia, [7] Faculty of Information Technology, Monash University, Clayton, VIC, Australia, [8] Department of Computer Science, University of Copenhagen, Copenhagen, Denmark

Edited by:
Hanife Rexhepi,
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Sevilla University, Spain

***Correspondence:**
Elton H. Lobo
elobo@deakin.edu.au
orcid.org/0000-0003-0096-6318

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The rise in the number of cases of stroke has resulted in a significant burden on the healthcare system. As a result, the majority of care for the person living with stroke occurs within the community, resulting in caregivers being a central and challenged agent in care. To better support caregivers during the recovery trajectory poststroke, we investigated the role of health technologies to promote education and offer various kinds of support. However, the introduction of any new technology comes with challenges due to the growing need for more user-centric systems. The integration of user-centric systems in stroke caregiving has the potential to ensure long-term acceptance, success, and engagement with the technology, thereby ensuring better care for the person living with stroke. We first briefly characterize the affordances of available technologies for stroke caregiving. We then discuss key methodological issues related to the acceptance to such technologies. Finally, we suggest user-centered design strategies for mitigating such challenges.

Keywords: stroke, caregiver, design methodology, technology, issues, solutions, user-centered design

INTRODUCTION

The increase in healthcare costs has resulted in the transition of stroke care from inpatient to community-based services (1). As a result, caregivers are expected to take on the responsibility to provide essential support to people living with stroke (2). However, the lack of coordinated postdischarge care leaves the caregiver and the person living with stroke to often feel abandoned and unsupported (3). This leads to an increase in burden or strain on the caregiver (4). Research highlights that the burden of caregiving is a multidimensional concept that includes several adverse effects on the physical, psychological, social, and financial functioning of the caregiver (5). Because of this, the caregiver is at risk of impaired health, suboptimal cognitive functioning, poor mental health, disruption in household roles, reduced quality of life, and changes to important life goals and future plans (6). Therefore, there is a need to transform care support, increase access, improve quality of care, and reduce cost of care throughout the disease trajectory.

Recent advances in health information technologies have been gaining interest in supporting caregivers in stroke as they utilize a combination of information and communication technologies to provide a more practical, affordable, and user-friendly solution (7). Such technological solutions are unrestricted by the place or time and focus on empowering its user to improve participation, decision making, and commitment to treatment, thus improving overall health outcomes (8).

While health information technology solutions have the potential to better support caregivers, the process of providing such care within the community has proven to be a challenge (9) that needs to be considered in the design of any care support system. These challenges need to be addressed to ensure new technological solutions are acceptable to their target end users. However, to date, researchers do not fully understand the scope and complexity of including users in the design of the care support system (10). This leads to issues in adoption of the solutions proposed.

Our objective is to better inform future researchers on means to address this issue. To achieve this objective, we first characterize the potential of health technologies in stroke caregiving and issues faced by the user in accessing and using these technologies. We then review the methodological practices implemented to design these technologies. In doing so, we highlight the key methodological issues reported in the design of stroke caregiving technology. We also discuss various concerns addressed by the researchers during the development of such technological systems. Finally, we suggest user-centered design strategies that have proven instrumental for mitigating such challenges in the healthcare domain.

HEALTH TECHNOLOGIES IN STROKE CAREGIVING

Health technologies in stroke caregiving consist of different means to promote interaction using web (11–13), Information and Communication Technology (ICT) (14, 15), mHealth (16–24), and telehealth systems (22). Web-based systems are those that are delivered through a browser on different devices such as computer, television, or mobile, with the requirement for access to the internet to use the service (11–13). ICT systems rely on a communication technology to connect numerous different devices (14, 15), mHealth relies on mobile devices (16–24), and telehealth relies on telecommunication devices such as telephone to promote interaction and support (22). The intention of these systems is to promote healthcare delivery and exchange over a wider geographic distance, thereby ensuring more effective and efficient care to the person living with stroke (11–24).

Technologies for stroke caregiving highlight the potential of these interventions in providing the caregiver with education, communication, monitoring, and rehabilitation support tools to promote better care for the person living with stroke (11–24). These technologies are designed to address specific needs of the caregiver identified through the use of surveys (17–19), interview (14–18), focus groups (11, 14, 16, 17), observations (14, 15, 18), and/or best practices from evidence-based literature (12, 13, 20–24). Caregivers adopting these technologies are satisfied with the ability to use them at any given place or time, while being able to interact and share information with people having similar experiences (13, 17, 18). Moreover, they allow for the caregiver to be reassured about their practices and techniques during recovery (17). Overall, the literature reports that the technologies employed to date have been effective (11, 18, 19) and acceptable (13, 17–19) in helping to support and manage the person living with stroke.

METHODOLOGICAL ISSUES IN STROKE CAREGIVING TECHNOLOGY

Technology for stroke caregiving is a useful tool to improve efficiency and quality of rehabilitation care (25). Despite widespread agreement of the potential of stroke caregiving technology in care and recovery, several researchers rely mostly on evidence-based approaches for the design of stroke caregiving technology (12, 13, 20–24). The aim of such processes is to ensure conscientious, explicit, and judicious use of best evidence guidelines created by credible research or best-practice guidelines or through systematic reviews and/or meta-analysis to make critical decisions regarding the design of the system (26). While theoretical models can form a solid foundation in the design of new technologies, the lack of understanding and ability to provide direct attention to the user suggests that it may be less effective for people with different chronic conditions (27). Furthermore, there are numerous concerns regarding the level of use by stroke caregivers. As a result, several research-based stroke caregiving technologies are not yet fully realized in commercial markets for use by caregivers of those with stroke (28).

The lack of realization of stroke caregiving technology in the market raises concerns around the methods and evaluation procedures in their design. These are exacerbated by the structure and design of the system and means by which the user interacts with it (29). Issues surrounding the structure, design, and user interaction could be better addressed through a detailed understanding of the user capabilities. These need to be acquired from user responses that cannot be determined through evidence-based theories (29). Moreover, only a few studies focus on understanding the range of factors associated with the interaction of the user and the system in stroke caregiving technology literature (13, 14, 17, 18, 23, 30) and more focus on its ability to meet the caregivers' needs in recovery (13–18, 20–23, 31–35).

While stroke caregiving technology should be designed to support the caregivers' needs during recovery, it must also consider the range of factors toward implementing necessary functionalities. This is because it could create risk for not only the caregiver but also the patients and medical professionals (36). For example, providing general information regarding the disease and not specific information related to the patient's condition could impact the quality of care. Therefore, the system implemented needs to account for an easy-to-use design, while

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Abbreviations: mHealth, mobile health; App, application; PD, participatory design; CSCW, computer-supported cooperative work.

also ensuring the data presented to the user are effective, easy to comprehend, and free from errors (37). Moreover, information provided to the user should be based on their specific needs (38), thereby limiting any confusion during care and recovery. These factors are similar to the studies by Cameron et al. (2), Creasy et al. (39), and Krieger et al. (40), which all suggest the need of caregivers to have personalized information that are easy to comprehend (2, 40–42) and are delivered at appropriate times (2, 42–45). While technology has the potential to provide personalized information and support (such as medication delivery, self-monitoring, and so on) through the use of context-aware systems (46); it has not yet been realized for stroke caregiving technology. Hence, it is clear that there is a lack of understanding of the available technology and user needs, which results in issues during the design and implementation of such technologies.

USER-CENTERED DESIGN TO IMPROVE STROKE CAREGIVING TECHNOLOGY

The limitations of current and future stroke caregiving technologies can be reduced by better promoting user involvement in its design, development, and implementation (25). One such approach is user-centered design (47). The concept of user-centered design offers tangible, scalable, and reproducible methods to include relevant users in the healthcare process (48). Through the better inclusion of target end users during development, the developers can focus on observing and understanding the planning of care and recovery trajectories and tailor the technology to support the needs of the user during this process. This extends beyond traditional practices that tend to rely on evidence-based literature (13, 21–24) to develop and implement technologies to support stroke caregivers. However, it is important to note that the practices involved in user-centered design are not new to healthcare. For example, the development of medicines undergoes several modifications including understanding its effects and impact on the user prior to making it public and ensuring adoption. None of these medications is developed entirely based on evidence-based literature or personal experiences. This is similar to what user-centered design aims to achieve, but with technology solutions.

While some studies (13, 14, 17, 18, 23, 30, 35) have considered iterative user-centered design approaches and participatory design (PD) practices, the extent of implementation of these methods has not been fully described in the literature. For example, Sureshkumar et al. (18) focused on a user-centered design methodology for the design of an educational-based mobile application to support stroke caregivers; however, there is no explanation in the study of how they investigate users' needs and capabilities. Such knowledge could be used to conclude that educational support was the only need of stroke caregivers and that they are comfortable using a mobile-based application. These assumptions (i.e., education support delivered through mobile) are not always the case as highlighted in the studies involving the needs assessment (49) and technological capabilities (47) of caregivers in stroke. Similar assumptions were implemented in other user-centered design studies (14, 17, 23, 31), where the full breadth of caregivers' needs and capabilities were not investigated prior to designing the intervention. This led to issues in the initial design of the technology and a lack of integration of technology in the normal care practices during recovery as discussed in the previous section.

The lack of proper implementation of user-centered design practices could be due to three challenges: (i) understanding users' practices and needs, (ii) the codesign of innovative and sustainable solutions, and (iii) the technical and organizational implementation. These challenges were identified based on literature findings (50–53). This is important, as the success of any user-centered design study is dependent on a genuine user participation (54). Through the inclusion of users, it is possible to generate new insights and ideas that can embrace ambiguity and provide structured systematic innovation in public health. The healthcare literature has also highlighted the importance of user-centered design and the role of users in developing sustainable systems by creating actionable strategies to test, refine, and integrate the solution in the individual's daily activities (55). Hence, there is a need to suggest mitigation strategies in terms of guiding principles and tools and techniques that can support stroke caregivers, as shown in **Table 1**. These recommendations are based on our own and colleagues' experiences, some of which are gained in healthcare projects conducted to support different chronic conditions. However, these studies do not account for caregivers and would need to be studied further to gain greater insights to better support these individuals.

Challenge 1: Developing a Proper Understanding of Users' Practices and Needs

Stroke caregivers often demand to be involved in the decision-making process in care to ensure the practices implemented consider the survivors and their individual needs (39). While user-centered design allows for a clear understanding of user needs from different groups of users including primary, secondary, and some tertiary users (29), conducting research with older adults could be challenging (59) as the average age of stroke caregivers is expected to be >55 years (60). However, Wilkinson and Cornish (61) argue that user-centered design, especially PD approach, could be used to involve the real-world users in the design and development process as it ensures tools promote increased participation irrespective of the age.

PD draws from ethnographically inspired fieldwork (i.e., interviews, observations, workshops, thinking aloud, and so on) during a normal workday of the user (62) to gain firsthand experiences with current work practices (57). Through an understanding of current work practices, researchers can form design engagements according to local needs and respond to issues defined by the intended user within the community (63). A primary concern in PD is that it consists of the distribution of power, making it difficult to utilize technology to meet the needs of the intended user (56). Hence, much

TABLE 1 | Challenges, guiding principles, and tools and techniques in implementing user-centered design.

Strategy	Guiding principles	Primary tools and techniques
Developing a proper understanding of a diverse set of groups of users' practices and needs	Participatory design (PD) literature suggests genuine user participation (56) and getting firsthand experience with current work practices (57). Computer-supported cooperative work (CSCW) literature recommends, e.g., aligning concerns, focus on needs for awareness (10, 52), and being cautious expecting one group to deliver valuable data without getting valuable feedback (58)	Ethnographically inspired fieldwork: interviews, observations, workshops, thinking aloud, and so on
Codesign of innovative and sustainable solutions	PD literature recommend concurrent design of coherent visions for change (information technology systems, work organization, and mapping out the qualifications needed) and that special attention is given to anchoring visions with users, managers, and those responsible for the technical and organizational implementation (56)	Iterations of workshops, scenarios, and prototyping
Technical and organizational implementation	Respect or challenge existing technical and organizational infrastructures—and be prepared to take the consequences (56)	Move secure prototypes to a living laboratory (53) setting for further design, development, and test before rollout

of the existing body of research considers the inclusion of Computer-supported cooperative work to limit unforeseen tensions and ensure researchers shape the collaborative design engagements to align with a diverse group of users' needs and practices (63), while being cautious about expecting one group to deliver valuable data without getting valuable feedback (58).

Challenge 2: Codesign of Innovative and Sustainable Solutions

In user-centered design, once the user needs and requirements are identified, a process of design, evaluate, and reiterate is carried out. This iterative process refines a software prototype based on a collaboration between intended users and the researchers to eventually better support the intended user (i.e., caregiver) in their daily activities (64). Moreover, it allows for the researcher to identify possible usability errors that may impact the users' ability to interact with the system (65) during recovery and care of the person living with stroke.

The PD process during codesign relies on two principal values, participation and democracy, to involve a range of individuals with diversity in experiences and knowledge (66, 67). These principal values are expected to be maintained throughout the design process, thereby enabling trust and facilitating mutual learning and commitment toward developing a system that meets the needs of the intended user (50). One way to practice these values is by facilitating a variety of workshops, storyboards, mock-ups, probes, scenarios, walk-throughs, games, collaborative prototyping, etc. (66, 68, 69). These are to ensure equal collaboration in the design of innovative and sustainable solutions based on individual knowledge and perspectives (70).

Challenge 3: Technical and Organizational Implementation

The design of any technology in healthcare should focus both on technology and healthcare outcomes. Past healthcare literature focuses on only one aspect (i.e., health or technology) (55), which has raised some concerns in the past regarding its sustainability or adherence over extended periods. Hence, to create sustainable solutions for stroke caregivers, it is necessary for the system to meet the visions of the different stakeholders involved in the care (10), such as caregivers, survivors, medical professionals, rehabilitation specialists, etc. This is typically achieved through multiple iterations where the goals, needs, and potentials are constantly evaluated, leading to the formation of successful systems for recovery and care (71). According to Schuurman and De Marez (72) and Andersen et al. (73), it is possible to perform such practices through the use of living laboratories. The living laboratory is a concept that encompasses diverse concepts driven by local innovation activities stated by different stakeholders to improve their everyday lives (74). In general, living laboratories include codesign test beds, collaboration, and knowledge management tools to support interaction between multiple stakeholders, communities, and organizations (75) to create sustainable technological solutions that improve everyday life (74, 75), therefore allowing for the researcher to identify issues related to the technical and organizational implementation while being prepared to manage its consequences (56).

CONCLUSIONS AND FUTURE RESEARCH

In conclusion, there are several issues highlighted in the stroke caregiving technology literature that need to be addressed to promote better success, long-term acceptance, and engagement of the designed solutions. To achieve these goals, future research in stroke caregiving technology needs to focus more on improving user participation in the design and development through proper understanding of the user practices and needs, inclusion of codesign solutions, and technical and organizational implementation. These have been demonstrated in the literature considering PD and computer-supported collaborative work approaches.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

EL initiated this study to address the methodological issues in stroke caregiving technology through past literature studies in healthcare intervention design. EL performed this study under the supervision of FK, who provided critical comments that enabled a clear presentation of findings within the final manuscript. Further, EL drafted the manuscript that was revised by FK, MA, AF, LR, PL, and JG. All authors contributed to the article and approved the submitted version.

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Using Telemedicine During the COVID-19 Pandemic: Attitudes of Adult Health Care Consumers in Israel

Sima Reicher[1,2]*, Tal Sela*[3]* *and Orly Toren*[2,4]

[1] *Department of Nursing, Ariel University, Ariel, Israel,* [2] *Department of Nursing, Ono Academic College, Kiriat-Ono, Israel,*
[3] *Department of Behavioral Sciences, School of Social Sciences and Humanities, Kinneret College, Kinneret, Israel,*
[4] *Hadassah Medical Organization (HMO), Jerusalem, Israel*

Introduction: The COVID-19 pandemic has affected health care services worldwide due to lockdowns, prevention measures, and social distancing. During this period, patients, including older adults and those with chronic conditions, need ways to obtain medical attention other than going physically to the clinic, such as telemedicine services. The purpose of the present study was to evaluate attitudes toward telemedicine during the COVID-19 lockdown in Israel, assess willingness to use such services in the future, and evaluate the extent to which consumers have changed their minds regarding these services.

Method: A cross-sectional, descriptive, correlational study was conducted among adults (age 20–90) using social media networks ($N = 693$). Data were collected using an online questionnaire explicitly designed to measure attitudes toward telemedicine.

Results: Most of the participants had to use telemedicine during the lockdown and were satisfied therewith. The majority also stated that they would continue using telemedicine in the future. However, only a third stated that they had changed their minds regarding telemedicine. The main predictors of willingness to use telemedicine in the future were the necessity of using such services during lockdown, preference for going to a clinic, and satisfaction with telemedicine, alongside gender and having a chronic illness. Importantly, we found that a preference for visiting the clinic was negatively correlated with willingness to use telemedicine in the future. Education and being single were predictors of the change of mind regarding telemedicine. Participants with chronic conditions are more likely to use these services, and specific attention should be directed to their needs. A small portion of the study sample prefers live appointments with a physician.

Conclusions: Telemedicine use is rapidly changing. It is vital for health care providers to identify non-telemedicine users and their common characteristics. Monitoring patients' attitudes regarding telemedicine is essential in the future after the pandemic ends. Targeted outreach plans should be formulated. These plans should be directed at identifying barriers to using telemedicine, and they should generate specific, focused plans.

Keywords: telemedicine, attitudes, chronic illness, COVID-19 pandemic, health care policy, adults

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Åsa Cajander,
Uppsala University, Sweden

Reviewed by:
Kristina Eriksson-Backa,
Åbo Akademi University, Finland
Isto Huvila,
Uppsala University, Sweden

Correspondence:
Tal Sela
tal9.sela@gmail.com

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INTRODUCTION

The COVID-19 epidemic has affected millions worldwide, with enormous economic and medical implications. When the WHO Emergency Committee declared COVID-19 a pandemic (1), most countries, including Israel, imposed restrictions intended to address it. These restrictions were gradually increased to a point wherein most countries, including Israel, declared an overall lockdown. The spread of COVID-19 in Israel began at the end of February 2020.

While Israel has an effective health care system, hospitals are overburdened and crowded (2). A state comptroller's report published on March 23, 2020, concluded that the Israeli Ministry of Health (MoH) and the entire hospital system were not fully prepared for a pandemic influenza outbreak (3). This report cites the shortage of hospital beds, isolation rooms, health care workers, and medications, and fully equipped intensive care units.

From the beginning of the outbreak, the Israeli MoH operated on two primary levels: preventing the spread of the virus through the population, and preparing hospitals to treat patients with COVID-19. As a preventative measure, the MoH imposed a policy of quarantining those exposed to the virus, defined as either having been in proximity to a COVID-19 patient, or returning from abroad. The focus was to convert hospital beds (general and intensive care) to treat COVID-19 patients, decrease elective hospitalization, and reduce outpatient volume. Nearly all outpatient care was halted at the community level, then gradually resumed at the beginning of May 2020 (4).

These steps compelled the health care services both in hospitals and in the community to focus almost exclusively on coping with the pandemic. Failing to obtain an adequate response to their medical issues, patients, including the elderly and those suffering from chronic conditions, were often compelled to seek medical treatment in non-traditional ways. Consequently, medical services' quality in the community was affected, prompting patients to look for adequate medical care through digital means. The present study's main goal was to evaluate health care consumers' attitudes regarding telemedicine during the COVID-19 lockdown in Israel.

TELEMEDICINE

Many countries have begun assimilating remote medicine technologies into their health care services, a trend that was substantially accelerated with the COVID-19 pandemic. The WHO cited digital technology as one of the essential policy services to respond to the COVID-19 emergency. Such services can help caregivers communicate effectively with their patients during the pandemic and provide improved responses to their health concerns. Due to social distancing regulations, telemedicine's extent of care delivery has increased, providing an effective solution for safe communication (5).

Telemedicine enables digital technological improvements to provide lower cost yet still effective ways to extend medical consultation and treatment. Telemedicine's most significant advantages besides cost reduction are increasing medical service availability, enhancing physicians' efficacy, and extending patients' accessibility to care (6, 7). Studies have also advocated telemedicine as a promising solution to improve several chronic medical conditions, including hypertension, obesity, diabetes, depression, and cancer (8).

Telemedicine is defined as using medical data transferred from one source to another via electronic communication to improve clinical health. Telemedicine comprises a growing variety of applications and services such as two-way video, e-mail, smartphone, and other telecommunication technologies (9). These technologies enable communication between geographically remote patients and caregivers to provide care, consultation, follow-up, guidance and health education, medical intervention, monitoring, and remote hospitalization. They also enable inexpensive and effective ways to obtain medical care and overcome geographical distance (6), thereby reducing emergency room visits and hospitalization rates (10).

Digital caregiver–patient communication is divided into synchronous and asynchronous communication. The Office of the National Coordinator for Health Information Technology (ONC) defines synchronous telemedicine as "live video-conferencing," which is an "interactive video connection that transmits information in both directions during the same period“ [American Telemedicine Association—ATA; (11)]. The synchronous method's major advantage is the efficacies gained by eliciting relevant details during the session by seeking additional information or data, and in many cases providing a clinical diagnosis or advice within the session. The ATA defines asynchronous telemedicine as "store-and-forward transmission of medical images and/or data because the data transfer takes place over a period of time, and typically in separate time frames. The transmission typically does not take place simultaneously." This type of telemedicine is provided via a virtual clinic to which the patient does not need to come physically, but maintains communication with the health care provider in her own time through phone calls, video calls, and written correspondence.

Data from the US Department of Health show that the number of patients with government health insurance who used telemedicine rose from 11,000 users on March 7, 2020, to 1.3 million as of April 18, 2020 (5). According to Global Market Insights, Inc., telemedicine's market size is forecasted to exceed $175 billion by 2026, and the increasing prevalence of chronic diseases across the globe will bolster the demand therefor (12).

Following the policy of the Digital Israel project (13), the Israeli MoH has declared as its mission "to bring about a leap in the health system that will enable it to become sustainable, advanced, innovative, renewed, and constantly improving, by optimally leveraging the information, and communication technologies available to the entire Israeli population." In other words, the global acceleration in technological development

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Abbreviations: MoH, Israeli Ministry of Health; WHO, World Health Organization; ATA, American Telemedicine Association; HMO, Health Maintenance Organization; ONC, Office of the National Coordinator for Health Information Technology.

and the digital revolution creates an opportunity to implement further and develop diverse telemedicine options.

Studies show that interventions based on telemedicine may yield results similar to live appointments. For example, an Israeli study examined the effectiveness of reducing patients' sense of distress by using telemedicine. The study compared telephone, video, and face-to-face conversations between caregivers and patients. The findings suggest similar effects in reducing distress between face-to-face appointments and telemedicine (6). A literature review on the current state of telehealth shows that, generally, in most cases, telehealth appears to be equivalent to face-to-face care or, in some cases, has better outcomes than do services such as mental assessment and treatment, rehabilitation consultation, anti-coagulation management, and older adults' nutrition management (14).

Edwards et al. (15) showed that patients with chronic diseases are interested in using telemedicine, regardless of their health status and age. A study conducted in Italy's Veneto region revealed that chronic patients reported high satisfaction with telemedicine services in the short term and even higher satisfaction after 1 year. These findings indicate that the use of telemedicine likely requires an adjustment period. Interestingly, although patients have expressed high satisfaction with these services, they did not perceive telemedicine as a substitute for traditional medical care, but rather only as a supplement to help them manage their condition (16).

Studies on telemedicine use have focused on various adult age groups [18 and above; (7, 8, 17)] and found that telemedicine use varies by patient age. For example, Jaffe et al. (17) found that telemedicine use in the 18–44 age group was significantly higher than in the 45–64 age group and higher than adults aged 65 and over. Kruse et al. (7) reported that age-related barriers exist due to lack of exposure to the new technology and patients' lack of training, and claimed that the technology acceptance gap among older patients is consistent with the patients' preferences for face-to-face care.

An Israeli study conducted in 2017 (18) examined the use of telemedicine among adult members of a leading Health Maintenance Organization (HMO), Maccabi Healthcare Services. The study found that telemedicine use was negatively correlated with age: 69% of participants aged 45–54 reported using online services, and about 60–63% of participants aged 55–74 reported using these services. However, in the oldest age group (75 and above), only 43% reported using these services. Overall, around 60% of the study participants ($N = 331$) reported having used telemedicine. Jaffe et al. (16) noted that digital technology access and use has increased dramatically in the last decade among older adults. Therefore, despite the differences in the usage of various age groups, the fact that digitalization is becoming a part of regular life may eliminate the barrier to telemedicine use.

Another factor that may affect telemedicine use is gender, although findings regarding usage differences are mixed. For example, Hilbert suggested that women tend to be latecomers regarding digital applications (19). Hargittai and Shafer tested how gender and self-perceived abilities are related to online abilities (20). They found that women's lower self-assessment regarding their online skills affects the extent of their online behavior and the types of technology used. Guo et al. examined mobile-health use in China (21). They found that threat appraisal (i.e., how one assesses the severity of the situation) was more related to gender and age, whereas coping appraisal (i.e., how one responds to the situation) was better among men and youths. A recent cohort study in the US examined telemedicine vs. in-person encounters between March 2019 and March 2020. In this study, no difference was observed for gender, ethnicity, socioeconomic status, or health behavior (17).

The COVID-19 pandemic is a resounding reminder that chronic and adult patients need to be treated anywhere, anytime, taking into account the new restrictions, regulations, and changes in the consumption of health care services (12). As telemedicine was available to some extent in Israel pre-pandemic, the question is whether chronic and adult health care consumers are ready or willing to use this technology for any health care need. This question is crucial considering the trends of the Israeli MoH policy regarding the implementation of telemedicine as well as patient-centered care and personalized medicine in the national plan for digital health (22).

Given these trends, this study's main goal was to explore attitudes toward using telemedicine during Israel's COVID-19 lockdown. Specifically, we examined attitudes regarding the necessity of using telemedicine during the crisis, patients' preference for going to a clinic, and how satisfied patients were with the provided telemedicine services. We also aimed to assess the influence of attitudes toward telemedicine on willingness to use such services in the future and to evaluate to what extent patients have changed their attitudes toward telemedicine.

METHODS

Design and Data Collection

The study was a cross-sectional, descriptive, correlational study conducted as part of a more extensive study to build and validate a new, general-purpose questionnaire (not COVID-19 related) to measure attitudes toward telemedicine and map possible barriers that patients may face to using such services.

After obtaining institutional ethical approval, a pilot study was conducted to evaluate the questionnaire's reliability and validity. Data were collected online between April 21 and May 16, 2020. During this time, regulations in Israel changed from complete lockdown to activity restrictions (23). These restrictions included opening commercial services and industries under certain conditions (health declarations, body temperature measurement, social distancing, etc.). The number of people allowed in closed areas was limited. Quarantine was mandatory for those returning from abroad or exposed to a verified COVID-19 patient. During this time, a sharp decrease in hospitalization was recorded. On April 30, Israel adopted the WHO recommendations for considerations in adjusting public health and social measures in the context of COVID-19 (24).

Participants in this study were recruited through ads on websites aimed at general social media users, the elderly population, and patients with chronic diseases [Motke, an online portal and unique social network platform aiming to support

TABLE 1 | Descriptive statistics of the sample (*N* = 693).

Variable	Status	Frequency	%
Gender	Female	398	57.4
	Male	295	42.6
Education level	Academic education	408	58.9
	High school/vocational education	229	33.0
	Other education	56	8.1
Marital status	Partnered	412	59.5
	Single	67	9.7
	Divorced	124	17.9
	Widowed	72	10.4
	Other	18	2.6
Economic status	Poor	38	5.5
	Reasonable	281	40.5
	Good	314	45.3
	Excellent	60	8.7
Chronic illness	No (none diagnosed)	239	34.5
	Yes (one or more diagnosed)	454	65.5
Age	Mean (SD)	64.21	(12.89)
	Median (IQR)	67	(12.00)
	Minimum	20	
	Maximum	90	
	Skewness (SD)	−1.30	(0.09)
	Kurtosis (SD)	1.75	(0.18)

Age bracket	*N*	Mean (SD)	Median (IQR)
Below 40	50	30.78 (6.31)	31.5 (9)
40–49	42	45.55 (2.50)	45 (4)
50–59	74	55.61 (2.62)	56 (5)
60–69	301	66.00 (2.95)	66 (5)
70 and above	226	75.52 (4.14)	74 (6)

Total number of participants N = 693.

Israel's elderly population (25), and the Camoni portal, a social media site focusing on chronic health conditions (26)]. We also used chain referral sampling through social networks such as Facebook and WhatsApp. Of 944 participants who followed the questionnaire's link, 933 signed the consent form and agreed to participate in the research. Of those, 693 fully completed the survey. **Table 1** presents descriptive statistics of the sample.

Research Tool

A questionnaire was designed to assess 'participants' attitudes toward telemedicine services during the COVID-19 lockdown. The questionnaire includes five statements on a five-point Likert scale (1—"Strongly disagree" to 5—"Strongly agree"). Participants were asked to express the extent of their dis/agreement with each of the following statements:

1) **Item 1**: *Necessity* of using telemedicine—"Being isolated during the COVID-19 crisis required me to use telemedicine to receive health care/counseling."
2) **Item 2**: *Preference* for going to a clinic—"Despite the availability of telemedicine during the COVID-19 lockdown, I preferred going to the clinic."
3) **Item 3**: *Satisfaction* with telemedicine services—"In general, during the COVID-19 period, I am satisfied with the medical services provided through digital technology."
4) **Item 4**: *Willingness* to use telemedicine in the future—"I will continue to use telemedicine even after the COVID-19 pandemic ends."
5) **Item 5**: *Change of mind* about telemedicine—"Being isolated during the COVID-19 crisis has changed my mind about using telemedicine for my health needs."

In addition, a socio-demographic section was included, collecting age, gender, socioeconomic status, education, occupation, and the presence of chronic conditions. Descriptive statistics are presented in **Table 1**.

Statistical Analysis

First, we explored our results using descriptive analysis. Next, we calculated Spearman's rank correlations for the various telemedicine items. Then, we fitted ordered logistic regression (OLR) models to our dependent variables that included one of two items: *Willingness to use* telemedicine in the future (Item #4) and *Change of mind* regarding telemedicine (Item #5). We trichotomized these five-point Likert scales. For each item, we produced a three-point scale by collapsing responses 1 and 2 ("Strongly Disagree" and "Disagree," respectively) into one category and responses 4 and 5 ("Agree" and "Strongly agree", respectively) into another category, yielding an ordinal scale of 3 levels: 0 = "Disagree," 1 = "Neutral," and 2 = "Agree."

Independent variables included socio-demographic (gender, chronic illness, age bracket, personal status, economic status, and education level) alongside the three items from the questionnaire (necessity of using telemedicine, preference for going to a clinic, and satisfaction with telemedicine services; all entered as categorical variables, using Response 1—"Strongly disagree" as the baseline level).

For each dependent variable, we fitted several models. First, we examined the relationship between background variables and the dependent variable. Next, we added the telemedicine items. Finally, we used a forward-stepwise method as a variable selection method. We used various evaluation matrices to test model fit (e.g., Bayesian Information Criterion—BIC; McFadden Pseudo R^2). The Likelihood-ratio test (LR test) was used to test nested models. The Brant test and other regression diagnostics were used to evaluate model assumption. We present Average Adjusted Predictions (AAPs) and Adjusted Predictions at Representative values (APRs) for both dependent variables for ease of interpretation. All regression analyses employed robust cluster errors. The statistical significance was set at a *p*-value of 0.05. When needed, FDR correction was applied to address multiple comparisons. Data were analyzed using SPSS v.25 & Stata v.16.

TABLE 2 | Participants' responses (%) to the five-item questionnaire ($N = 693$).

	(1) Strongly disagree	(2) Disagree	(3) Undecided	(4) Agree	(5) Strongly agree
(1) Item 1: Necessity of using telemedicine during the COVID-19 crisis	12.1	14.2	9.5	36.4	27.8
(2) Item 2: Preference for going to a clinic during the COVID-19 crisis	36.7	27.1	10.6	16.8	8.8
(3) Item 3: Satisfaction with telemedicine services during the COVID-19 crisis	3.6	11.5	20.3	42.7	21.9
(4) Item 4: Willingness to use telemedicine in the future	3.9	4.9	14.0	44.3	32.9
(5) Item 5: Change of mind regarding telemedicine	22.9	28.9	17.0	23.0	8.2

TABLE 3 | Spearman's rank correlation between questionnaire items ($N = 693$).

	(1)	(2)	(3)	(4)	(5)
(1) Item 1 Necessity of using telemedicine during the COVID-19 crisis	1				
(2) Item 2 Preference for going to a clinic during the COVID-19 crisis	−0.198**	1			
(3) Item 3 Satisfaction with telemedicine services during the COVID-19 crisis	0.352**	−0.202**	1		
(4) Item 4 Willingness to use telemedicine in the future	0.320**	−0.404**	0.451**	1	
(5) Item 5 Change of mind regarding telemedicine	0.218**	0.062	0.060	−0.029	1

**$p < 0.001$.

RESULTS

Sixty-four percent of the participants agreed or strongly agreed that they had had to use telemedicine during the COVID-19 lockdown (**Table 2**). Around the same frequency (∼63%) disagreed or strongly disagreed with preferring to go to the clinic during the lockdown. Also, the same proportion of participants were satisfied with telemedicine services during the COVID-19 lockdown. Most of the participants (∼77%) agreed or strongly agreed that they would continue to use telemedicine in the future. However, only 31% agreed or strongly agreed that they had changed their minds regarding these services.

Table 3 presents the correlations between the various items. We found that the necessity of using telemedicine during the COVID-19 lockdown was positively correlated with both willing to use telemedicine in the future and with change of mind regarding telemedicine. That is, participants who agreed more strongly that they had had to use or receive telemedicine services during the COVID-19 lockdown were those who were more disposed to continue using these types of services in the future and are possibly more likely to change their minds regarding their use of this type of services.

Preference for going to a clinic during the COVID-19 lockdown was negatively correlated with willingness to use telemedicine in the future. That is, participants who preferred to go to the clinic during the COVID-19 lockdown were less likely to state that they would agree to continue using telemedicine in the future. Moreover, a positive correlation was found between participants' satisfaction with telemedicine services and their willingness to continue to use these services. Participants who reported a higher level of satisfaction with telemedicine services tended to state that they would agree to use telemedicine in the future.

Overall, the pattern of results that emerges from the correlation analysis points to only one item—necessity of use—being correlated with change of mind regarding telemedicine. However, necessity of use, preference for going to a clinic, and satisfaction with telemedicine services were correlated with willingness to use telemedicine in the future. Also, a preference for visiting the clinic was negatively correlated with willingness to use telemedicine in the future. Finally, the results' patterns were similar in a subpopulation analysis, wherein we restricted the age range to only those aged 60 and above ($N = 527$) or to only patients with chronic illness ($N = 454$) (see **Supplementary Tables 1–4** in **Supplementary Material**). That is, the correlations between the various items are stable.

Ordered Logistic Regression Models

Predicting Willingness to Use Telemedicine in the Future

We fitted various OLR models (as elaborated upon in **Supplementary Material**), and we present the best-fitted model for predicting willingness to use telemedicine in the future. As shown in **Table 4**, we found that gender, chronic illness, and Items 1–3 were associated with willingness to use telemedicine in the future. Specifically, most participants (77%) agreed that they would continue to use telemedicine in the future, nearly 14% are undecided, and nearly 9% disagreed with this statement. As presented in **Table 4**, we found a main effect for gender (OR = 2.16, 95% CI: 1.40, 3.32): Around 82% of the male participants agreed that they would continue to use telemedicine in the future; 11% were undecided, while 6% disagreed with this statement. For women, around 73% agreed that they would continue to use telemedicine in the future, 16% were undecided, and nearly 11% disagreed with this statement. In summary, while only 17% of males disagreed or did not strongly agree that they would continue to use telemedicine, nearly 27% of the women in the sample disagreed or did not strongly agree to use telemedicine in the future.

TABLE 4 | Results of OLR model predicting willingness to use telemedicine in the future (0 = "Disagree," 1 = "Neutral," and 2 = "Agree") (*N* = 693).

	OR	SE#	*z*	*P* > z	95% CI	
Gender (male = 1)	2.16	0.47	3.5	0	1.4	3.32
Chronic illness (yes = 1)	1.58	0.33	2.17	0.03	1.05	2.39
Item 1^						
2–"Disagree"	1.16	0.37	0.46	0.65	0.62	2.16
3–"Undecided"	1.57	0.58	1.23	0.22	0.76	3.25
4–"Agree"	2.19	0.68	2.53	0.01	1.19	4.01
5–"Strongly agree"	3.79	1.41	3.59	0	1.83	7.86
Item 2^						
2–"Disagree"	0.55	0.16	−2.05	0.04	0.31	0.97
3–"Undecided"	0.4	0.14	−2.69	0.01	0.21	0.78
4–"Agree"	0.17	0.05	−5.58	0	0.09	0.32
5–"Strongly agree"	0.09	0.03	−6.71	0	0.04	0.18
Item 3^						
2–"Disagree"	2.25	1.09	1.66	0.1	0.86	5.84
3–"Undecided"	1.73	0.83	1.15	0.25	0.68	4.42
4–"Agree"	6.76	3.25	3.98	0	2.64	17.35
5–"Strongly agree"	14.37	8.85	4.33	0	4.3	48.03
Cut point 1	−1.02	0.54			−2.08	0.04
Cut point 2	0.45	0.54			−0.61	1.5
Fit indices						
AIC	784.25					
BIC	856.91					
McFadden pseudo R^2	0.21					
Nagelkerke pseudo R^2	0.34					
Model df	14					

OR, Odds Ratio; SE#, Robust standard errors; ^, for items 1 to 3, response no. 1, "Strongly Disagree" serves as the baseline category; AIC, Akaike Information Criterion; BIC, Bayesian Information Criterion.

We also found a main effect for chronic illness (OR = 1.58, 95% CI: 1.05, 2.39): Around 80% of participants with any type of chronic illness agreed that they would continue to use telemedicine in the future; 13% were undecided, and 7% disagreed with this statement. For participants without chronic illness, around 73% agreed that they would continue to use telemedicine in the future, 16% were undecided, and 11% disagreed with this statement. In summary, while only 20% of participants with chronic illness disagreed or did not fully agree that they would continue to use telemedicine service in the future, 27% of non-chronic participants in the sample disagreed or did not fully agree to use telemedicine in the future.

Regarding both gender and chronic illness variables, the APRs for a man with a chronic illness agreeing to use telemedicine in the future were around 84.5% and those for a man without chronic illness were 75.5%, while the APRs for a woman with chronic illness agreeing to use telemedicine in the future was around 79.5% and those for a woman without chronic illness 69%.

Finally, as shown in **Table 4** and **Figure 1**, similar to the correlation analysis, all three items were significantly associated with willingness to use telemedicine in the future.

Predicting Change of Mind Regarding Telemedicine

We fitted various OLR models (as elaborated upon in **Supplementary Material**), and we present the best-fitted model for predicting change of mind regarding telemedicine. More than half of the participants (52%) disagreed that they had changed their mind toward telemedicine during the COVID-19 lockdown, nearly 17% were undecided, and nearly 32% agreed that they had changed their minds. As shown in **Table 5**, education level and being single are correlated with change of mind. Specifically, we found that high school/vocational education participants significantly differed from those with academic education (OR = 1.69, 95% CI 1.22, 2.34): While only 27% of participants with academic education agreed that they had changed their minds regarding telemedicine, around 37% of those with high school/vocational education reported that they had changed their minds. We also found that single participants differ from partnered ones (OR = 0.47, 95% CI 0.27, 0.79), i.e., nearly 20% of the single participants reported having changed their minds, while 34% of partnered participants reported having changed their minds regarding telemedicine.

Finally, consistent with the correlation analysis, *post-hoc* analyses (using FDR correction) revealed a linear trend for Item 1 only ($\chi_1^2 = 39.90$, $p < 0.001$; contrast = 0.097; 95% CI: 0.067,

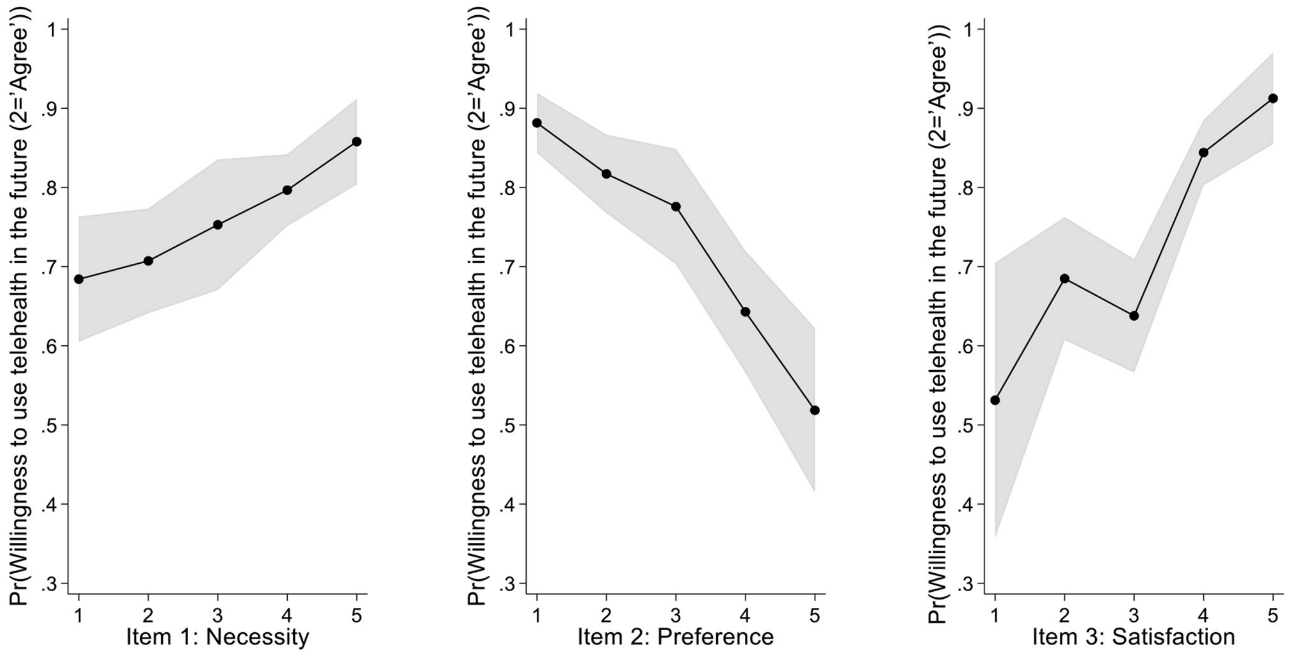

FIGURE 1 | Average Adjusted Predictions for Items 1 to 3. The *y*-axis represents the likelihood of agreeing with the statement "I will continue to use telemedicine in the future"; shaded gray represents 95% CI. *Post-hoc* analysis reveals a linear trend relating to the correlation between a given item and the likelihood of agreeing with the statement. Specifically, we found a linear trend for Item 1 ($\chi_1^2 = 16.54$, $p < 0.001$; contrast = 0.060; 95% CI: 0.031, 0.089), for Item 2 ($\chi_1^2 = 44.36$, $p < 0.001$; contrast = −0.113; 95% CI: −0.142, −0.084), and for Item 3 ($\chi_1^2 = 16.54$, $p < 0.001$; contrast = 0.104; 95% CI: 0.073, 0.134). Consistent with the correlation analysis, we found an association between each item and the intent to use telemedicine in the future.

0.127); i.e., we found a positive correlation between the necessity of using telemedicine during the COVID-19 crisis and having changed one's mind regarding telemedicine.

DISCUSSION

In Israel, as in other developed nations, the COVID-19 pandemic has accelerated the use of telemedicine. The current study examined the attitudes of adults toward the use of telemedicine during the COVID-19 lockdown. The results show that most participants preferred to use telemedicine and were satisfied with its use during this period. The health system needs to provide virtual medical care whenever possible to keep patients at home while still offering them access to necessary medical care (27). Various studies and surveys conducted during the lockdown found high satisfaction with the telecare provided (28). Our findings are consistent with these reports (18, 19), showing high satisfaction with telemedicine services.

In the current study, nearly 80% of the participants are willing to use telemedicine in 2020 and the future. We can assume that this finding is associated with an increase in the tendency to use these services, based on data from one HMO, in which 60% of the members surveyed reported having used them in the past (18). This trend is consistent with many countries reporting an increase in telemedicine use during lockdowns. This finding should be treated with caution, as other factors may have contributed to this phenomenon, such as technological progress and HMOs' efforts to encourage patients to use these services.

Our results suggest that most participants disagreed with going to the clinic during the outbreak, and those who did so found themselves using telemedicine to obtain medical treatment. Similarly, based on a survey of 2,700 patients in the US, Heat (28) stated that 4 in 10 patients began using a new app or digital technology to stay connected to their health care providers at the onset of the COVID-19 epidemic. Previous studies conducted in Israel showed that patients and physicians are willing to use digital technology instead of face-to-face appointments when their preferences are considered (29). Another study found that the high use of HMOs' mobile health apps across the socio-demographic spectrum indicates telemedicine's high perceived usefulness (30). The lockdown prompted many clinicians and patients to realize these tools' potential and compelled them—some for the first time—to utilize them when face-to-face appointments were precluded (31).

In the present study, participants rated their degree of willingness to use telemedicine in the future. Studies have found strong correlations between willingness, intent, and behavioral expectations (32). Our findings show that gender and chronic illness are correlated with participants' willingness to use telemedicine in the future. Specifically, around 82% of males and 73% of females agreed that they would continue to use telemedicine in the future. Our results also showed a correlation between chronic illness and willingness to use telemedicine in

TABLE 5 | Results of OLR model predicting change of mind regarding telemedicine (0 = "Disagree," 1 = "Neutral," and 2 = "Agree") ($N = 693$).

	OR	SE$^{\#}$	z	$P > z$	95% CI	
Personal status (partnered as baseline)						
Single	0.467	0.127	−2.810	0.005	0.274	0.795
Divorced	0.749	0.160	−1.350	0.175	0.493	1.138
Widowed	0.901	0.218	−.430	0.665	0.560	1.448
Other	0.829	0.414	−0.380	0.707	0.311	2.207
Education level (academic education as baseline)						
High school/vocational education	1.692	0.281	3.160	0.002	1.221	2.344
Other	1.322	0.356	1.040	0.299	0.781	2.240
Item 1^						
2–"Disagree"	0.897	0.295	−0.330	0.741	0.471	1.709
3–"Undecided"	1.587	0.482	1.520	0.128	0.875	2.879
4–"Agree"	3.154	0.857	4.230	0.000	1.852	5.373
5–"Strongly agree"	3.493	1.059	4.120	0.000	1.928	6.329
Item 2^						
2–"Disagree"	1.126	0.231	0.580	0.563	0.753	1.684
3–"Undecided"	1.931	0.474	2.680	0.007	1.194	3.123
4–"Agree"	1.588	0.375	1.950	0.051	0.999	2.524
5–"Strongly agree"	1.740	0.488	1.980	0.048	1.005	3.013
Item 3^						
2–"Disagree"	1.909	0.792	1.560	0.119	0.846	4.306
3–"Undecided"	3.295	1.311	3.000	0.003	1.511	7.185
4–"Agree"	2.014	0.787	1.790	0.073	0.936	4.332
5–"Strongly agree"	2.459	1.034	2.140	0.032	1.079	5.607
Cut point 1	1.977	0.463			1.069	2.885
Cut point 2	2.771	0.465			1.860	3.682
Fit indices						
AIC			1,353.771			
BIC			1,444.592			
McFadden Pseudo R^2			0.057			
Nagelkerke Pseudo R^2			0.126			
Model df			20			

OR, Odds Ratio; SE$^{\#}$, Robust standard errors; ^, for Items 1 to 3, response no. 1, Strongly Disagree" serves as the baseline category; AIC, Akaike Information Criterion; BIC, Bayesian Information Criterion.

the future. Around 80% of chronically ill participants agreed that they would continue to use telemedicine in the future vs. 73% of those not chronically ill, which is consistent with Edwards’s et al. (15) findings.

The necessity of using telemedicine and satisfaction therewith positively correlates with willingness to use them in the future, while going to a clinic was negatively correlated with this intention. One possible explanation for these results stems from the premise of planned behavior theory (33), according to which positive or negative attitudes toward a given action can predict one's intention and behavior. Accordingly, during the outbreak, some of the participants were already familiar with telemedicine. As a result, they expressed a high level of satisfaction with and willingness to use telemedicine in the future. The same reasoning can be applied to those participants who preferred to go to a clinic: Despite the lockdown, these participants were entrenched in their habit, were less satisfied with telemedicine services, and accordingly expressed no intention of using them in the future. However, this explanation cannot account for the possibility that some participants were compelled to use telemedicine during the outbreak and the positive correlation between the necessity of using such services and willingness to use them in the future.

In contrast to the attitude influence behavior framework, other accounts such as cognitive dissonance theory (34) and self-perception theory (35) have claimed that behavior can shape attitude in many situations. People have a strong need to maintain cognitive consistency (36), tend to act in a manner that is consistent with previous actions or behavior (37), and it has been found that past behavior can be a predictor of future behavior (38). Before the COVID-19 pandemic, telemedicine was often used as a secondary alternative to visiting a clinic. The lockdown rapidly changed the picture, as most participants were compelled to use telemedicine as a nearly exclusive alternative. We propose that this impelled behavioral change triggered a change in participants' attitudes toward telemedicine, thus increasing their willingness to use it in the future. The challenge, of course, is to continue the trend and establish the use of telemedicine as an equivalent alternative to face-to-face treatment in the clinical setting.

In the present study, we also found that only 32% of the participants agreed that telemedicine had changed their minds. One possible explanation for that may lie in the study sample: Some study participants are members of social network communities that include support groups and chronic patients. Therefore, it can be assumed that those participants are accustomed to using digital technology, have already formed their habits and opinions regarding telemedicine, and feel no need to change their intentions to use it. Likewise, in several studies, habits have been found to moderate the relationship between intentions and behavior (39). For example, behaviors that are engaged infrequently in stable contexts support the development of habits, and thus the impact of intention on behavior is attenuated (38).

Another central theme related to telemedicine use surrounded the patient–physician relationship. Several studies have linked participants' preferences for telemedicine to their familiarity with the physician. For example, in a study in South Carolina, patients expressed the importance of the patient–physician relationship, and it was the leading factor in choosing the type of service, i.e., face-to-face vs. telemedicine (40). However, Valikodath et al. found that among diabetic patients, only those who were unreceptive to telemedicine strongly valued their patient–physician relationship (41).

"No man is an island," as John Donne elegantly put it. Humans need to establish an emotional bond with a caregiver and want to be part of a relationship, while telemedicine may be perceived as indifferent to them, and thus they would avoid using it. Härtel and Russell-Bennett defined emotional loyalty as the psychological preference for a brand that consists of positive feelings and affective attachment that facilitates its purchase or use in the future (42). Such emotional loyalty is crucial to health care consumers; thus, policymakers need to be aware of how well-telemedicine meets the consumers' specific needs, emphasizing personal relationships. Consumers who still prefer a face-to-face meeting with the physician should not be ignored. The health care system should be prepared to meet these patients' needs, certainly in a pandemic or other national emergency.

Personal status and education were found to correlate with changing of mind. Being single decreased the probability of changing one's mind regarding telemedicine, while high school education increased it. A possible explanation for these findings could stem from the frequency with which digital technology is used. That is, the more the individual is accustomed to using telemedicine, the less likely he/she will be to change his/her mind regarding it. As the frequency of telemedicine use among those with a high school education is lower than for those with post-secondary education, the likelihood of the latter changing their minds is higher.

The current study has several limitations. Firstly, this study is a cross-sectional one based on a convenience sample and includes mainly older adults. Despite a large number of participants, the sample was not representative and was left-skewed in terms of participant age. Moreover, a sizable portion of the study sample was drawn from a digital list of people with e-mail addresses. It is possible that sample participants, having used at least some digital technology, were more likely to use other digital technology related to health. That is, digital recruitment may be one reason for the high number of telemedicine users among the current study participants. Using other sampling methodologies (postal or telephone survey) could have examined people's attitudes toward telemedicine among those who do not use the internet. Nonetheless, we note that although the sample is not representative, the results remained stable when we ran all the analyses on chronic patients only.

Secondly, patients' characteristic measures (other than demographics) were not part of the study. These variables should be incorporated into future research to better explain and understand the outcomes. Finally, the study employs single items to measure attitudes toward various aspects of telemedicine use. Single items may suffer from accuracy, content validity, and reliability problems (in particular, their internal consistency cannot be estimated). Nonetheless, many studies in various fields have been using a single-item scale to measure various constructs when time is constrained to obtain preliminary yet critical insight into important health and social phenomena.

CONCLUSIONS

The pandemic outbreak has created an opportunity at the state and institutional levels to promote telemedicine more vigorously and develop various services faster than planned. This rapid acceleration of telemedicine accords with the Israeli policy of promoting digital services and making them sustainable, advanced, innovative, and continuously improving. Although most participants were satisfied with current telemedicine and willing to use it in the future, monitoring patients' attitudes regarding telemedicine after the pandemic is essential. As a small yet still significant portion of participants prefers a live meeting with a physician, it is also essential for HMOs to facilitate specific encounters based on this expectation, alongside identifying barriers to patients' using telemedicine. As telemedicine's use is dramatically increasing, there is a need to disseminate information about each service's availability and its use, and its advantages over face-to-face appointments. Further research is needed on this topic to guide policymakers in formulating strategies that promote telemedicine implementation while addressing possible gender gaps therein, and to examine the study variables' causal influence on adopting telemedicine services.

IMPLICATIONS

It is essential to distinguish between groups of chronic patients and target telemedicine services accordingly. The HMOs should create targeted interventions to identify patients' preferences and maintain the patient–health care provider relationship for any given group of patients. Additionally, HMOs need to identify specific barriers and group characteristics to using telemedicine and, based thereon, to formulate targeted outreach plans. These plans should be directed at overcoming telemedicine barriers, such as initiating scheduled home visits and scheduled telephone inquiries for regular health assessment.

Plans should also include providing any health assistance needed (transportation to the clinic, home laboratory services, delivery of medicines, etc.). Policymakers need to address the extent to which consumers would enjoy the quality of care delivered via telemedicine and prefer it even post-COVID. As most countries have limited resources due to increased life expectancy and more chronic patients, it is incumbent upon policymakers and health care providers to learn about future consumer behavior.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethical approval was granted from the Ethical Committee at Ono Academic College. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

SR and OT: major contributor in designing the study, data collection, data interpretation, and writing the manuscript. TS: major contributor to data analysis, data interpretation, and writing the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.653553/full#supplementary-material

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Patient Safety Through Nursing Documentation: Barriers Identified by Healthcare Professionals and Students

Jorunn Bjerkan[1,2]*, *Victor Valderaune*[3,4] *and Rose Mari Olsen*[2,3]

[1]*Faculty of Nursing and Health Sciences, Nord University, Levanger, Norway,* [2]*Centre for Care Research Mid-Norway, Levanger, Norway,* [3]*Faculty of Nursing and Health Sciences, Nord University, Namsos, Norway,* [4]*Centre for Development of Institutional and Home Care Services, Municipality of Aafjord, Norway*

Background: Although access to accurate patient documentation is recognized as a prerequisite for delivering of safe and continuous municipal elderly care, healthcare professionals often fail to provide comprehensive clinical information in an accurate and timely manner. The aim of this study was to understand the perceptions of healthcare professionals and healthcare students regarding existing barriers to patient safety through the performance of documentation practices.

Methods: Using a qualitative, exploratory design, this study conducted six focus group interviews with nurses and social educators ($n = 12$) involved in primary care practice and nursing and social educator bachelor's degree students from a University College ($n = 11$). Data were analyzed using qualitative content analysis.

Results: Four themes emerged from the analysis, which described barriers to patient safety and quality in documentation practices: "Individual factors," "Social factors," "Organizational factors," and "Technological factors." Each theme also included several sub-themes.

Conclusion: According to the findings, several barriers negatively influenced documentation practices and information exchange, which may place primary care patients in a vulnerable and exposed situation. To achieve successful documentation, increased awareness and efforts by the individual professional are necessary. However, primary care services must facilitate the achievement of these goals by providing adequate resources, clear mission statements, and understandable policies.

Keywords: electronic patient record, nursing, patient safety, primary health care, documentation, focus group

Edited by:
Åsa Cajander,
Uppsala University, Sweden

Reviewed by:
Lex Van Velsen,
Roessingh Research and Development, Netherlands
Lina Nilsson,
Blekinge Institute of Technology, Sweden

****Correspondence:***
Jorunn Bjerkan
jorunn.bjerkan@nord.no

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INTRODUCTION

High-quality patient documentation in primary care is crucial for ensuring the quality of care, continuity of care, and patient safety. For many years, the quality of nursing documentation has been reported as inadequate (Hellesø and Ruland, 2001; Blair and Smith, 2012; Akhu-Zaheya et al., 2018). Thus, knowledge about primary care staff perceptions of barriers to documenting in electronic health records is necessary to ensure patient safety in the services.

The elderly population is expected to grow in both European and American countries in the near future, which will be accompanied by increased demand for elderly healthcare services. This growing patient population will require both complex medical treatment and nursing care (Ministry of Health and Care Services, 2012; Kulik et al., 2014). To ensure the effective use of healthcare resources and improve patient outcomes, many Western countries are attempting to transfer responsibilities from specialist care to primary care. This change has resulted in patients who are treated in municipalities being frailer and presenting with more advanced, complex, and treatment-demanding issues (Gautun and Syse, 2017; Næss et al., 2017). In Norway, we have enacted "the Coordination reform" (Ministry of Health and Care Services, 2009), a collaborative model for the provision of care services between hospital care and primary care, which is similar to the international concept of "integrated care" (Ahgren, 2014; Ferrer and Goodwin, 2014). The implementation of such increased and formalized coordination strategies represents a political focus as a potential tool for ensuring the efficacy and safety of elderly care.

This increased complexity in primary care nursing requires awareness and a focus on providing appropriate nursing-supportive tools, such as high-quality electronic patient records (EPRs) as a main tool for nursing documentation practices. The provision of sufficient documentation of healthcare associated with the patients' physical and mental health issues is particularly important among elderly patients because even minor changes in health status could be symptoms of severe or acute illnesses (Gray et al., 2002; Chong and Street, 2008; Cerejeira and Mukaetova-Ladinska, 2011). Any lapse in mental or physical health requires specific medical, nursing, and caring actions to be taken (Marengoni et al., 2011).

The implementation of EPR as a tool for documenting healthcare has resulted in major changes and increased requirements for nursing documentation (Ammenwerth et al., 2003). EPR implementation was intended to replace handwritten documentation practice and improve documentation structures to promote increased standardization (Hellesø and Ruland, 2001). In Norway, nursing homes and community care document care electronically use one of only three EPR systems (The Norwegian Directorate of eHealth, 2018). The EPR documentation practice consists typically of income notes, patient mapping, nursing actions, daily notes and -evaluation as well as discharge notes. E-messaging modules, medication, and collaboration with other professionals such as doctors and physiotherapists are included and used as well. In any case, to complete the documentation requirements, there seems to be a need for paper-based supportive systems, which tend to involve checklists, calendars, books, and post-it notes (Keenan et al., 2013). Nursing procedures and other supportive systems, such as tools for reporting adverse events, are either included in the chosen EPR system or solved in external systems. This study addresses this broad documentation practice.

Both legislation and practice for nursing documentation in healthcare services vary among countries; however, primary care nurses occupy a unique position within healthcare structures worldwide. Primary care nurses often work with few other nurses in primary care wards, or they meet patients alone at the patients' homes. Therefore, they are often required to assess and evaluate patients, acting independently of other colleagues. Home-health nurses might not have access to online EPRs, which would allow for them to consult previous nursing interventions and evaluations, and they must perform their own documentation, which they may be unable to do until they return to the home care center office (Olsen et al., 2013).

Even though EPR was implemented over a decade ago and is widely used in primary care in Norwegian municipalities, healthcare services continue to face documentation challenges that result in adverse events. Studies have shown that primary care employees often struggle to coordinate patient information in the EPRs (Gehring et al., 2012; Melby et al., 2018), and primary healthcare documentation continues to be both incomplete and inaccurate (Tuinman et al., 2017; Moldskred et al., 2020).

Patient safety and EPR documentation tasks are closely connected. Documentation in EPR is important to ensure continuity, quality, and safety of patient care. EPRs represent a communicative and collaborative tool, in addition to serving as the written record for which actions have been implemented.

Various definitions of patient safety have emerged over time (Mitchell, 2008), including:

> Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events (Emanuel et al., 2008, p. 16).

The World Health Organization (WHO) vision for patient safety is "A world where every patient receives safe healthcare, without risks and harm, every time, everywhere" (WHO, 2017, p. 4). In this vision, it is stated that, until recently, patient safety research has primarily focused on the hospital setting rather than primary care. The WHO strategy "Safer primary care" focuses on nine improvement areas: patient engagement, education and training, human factors, administrative errors, diagnostic errors, medication errors, multimorbidity, transitions of care, and electronic tools (WHO, 2012). These focus areas are all relevant to the context of patient safety and documentation.

Elderly patients often suffer from comorbidities, which require complex and tight regimes of treatment and care (Marengoni et al., 2011). Meeting this demand requires high-quality nursing homes and ambulant healthcare services capable of working among elderly patients outside of hospital settings. The coordination of treatment and care, documentation, and patient information exchange represent particular challenges, and these areas have been characterized as being of particular risk for adverse events (Olsen et al., 2012; Blais et al., 2013; Olsen et al., 2013; Gjevjon 2014; Wekre, 2014).

Patient safety can be evaluated by mapping adverse events that occur in healthcare units. Studies have shown that 1–24 adverse incidents occur during every 100 consultations in the primary care context (Panesar et al., 2015). A link between patient safety and inadequate documentation has previously been reported by studies examining documentation and adverse events in primary care. For example, Andersson et al. (2018) examined serious adverse events reports submitted by nurses in Swedish nursing homes to the Health and Social Care Inspectorate and found that a "lack of competence" and "incomplete or lack of documentation" were the two most common factors that contributed to adverse events.

This study has identified few articles focusing on the connection between patient safety and nursing documentation practices at home health nursing services or nursing homes. Additionally, there is a need observed for additional research projects that focus on students' experiences regarding the practice of patient documentation and the use of EPRs.

Social educators are employed in municipal care: in nursing homes and home healthcare units in Norway. They take part in a variety of nursing and caring tasks and activities, but their profession has more substantial knowledge in caring for people with various forms of disability than Registered Nurses. They have a deeper focus on rehabilitation and habilitation for disabled patients. On the other hand, Registered Nurses have a deeper awareness of the medical issues of nursing, as understanding of all kind of illness and its consequences, as well as medical treatment and medication (Grung, 2016). Nevertheless, when social educators are employed within the healthcare domain in Norway they are obligated to act under the same legislation guidelines regarding documentation as Registered Nurses. Understanding the experiences and perceptions of these staff members can also influence their contributions to collaboration in healthcare services. Therefore, the aim of this study was to better understand the perceptions of healthcare professionals and healthcare students regarding existing barriers to patient safety through the performance of documentation practices.

METHODS

A descriptive, exploratory design (Polit and Beck, 2012) with a focus group methodology was applied to provide insights into the perceptions of nurses, social educators, and students and to understand their experiences in terms of patient safety and their documentation practices. To secure accurate and complete reporting of the study, the COREQ checklist (Tong et al., 2007) was used as a guideline.

Sample and Setting

The study was conducted between March 2015 and June 2015 at three3 primary care agencies and one University College located in central Norway. In the chosen region, all municipalities use the same EPR system—one of three main systems used in primary care in Norway—and similar to all other systems being used this one responds to the legislation requirements for digital documentation of healthcare information in Norway as well as GDPR regulations which Norway joined in 2018 (Ministry of Health and Care Services, 2012; The Norweigian Directorate of eHealth, 2019). This particular EPR solution, as is the case for the other two EPR systems, offers an enlarged EPR solution where the EPR module is connected to other relevant modules; for example, basic personal information, billing, and medication order modules.

Purposive sampling was used to recruit participants. The inclusion criteria for the nurses and social educators included that they were employed in primary healthcare (nursing homes or home nursing care) and that they were involved in direct patient care. The inclusion criteria for students included regular enrollment as a nursing or social educator student (at the bachelor-degree level) and previous practice in nursing homes and/or in-home healthcare settings as part of their education. Whereas the professionals were recruited by their ward managers, the students were recruited by contact persons at the University College. Both professionals and students were forwarded written information about the study, and all signed a consent form prior to participating in the study.

In total, 12 nurses and social educators and 11 students (22 women and one man) volunteered for this study. The mean working experience among the nurses and social educators was 13°years (ranging from 1 to 25 years), and their mean age was 40.5°years (ranging from 23 to 51°years). The students' mean age was 23°years (ranging from 22 to 28°years). six of the students were in their final semester of a 3 years degree program, and five were in their penultimate year. The participants were interviewed in six focus groups; three groups of nurses and social educators ("staff informants") and three groups of students. The sizes of the groups ranged from 3–5 participants, which is considered an optimal size for focus groups (Kitzinger 1995).

Data Collection

Focus group interviews were used to study perceptions among the group participants (Polit and Beck, 2012). In the focus groups, the participants were invited to reflect upon and compare each other's views and experiences to contribute to a broader understanding of patient safety and documentation practices (Kitzinger, 1995).

The study applied an interview guide, which was developed based on performing a literature search and including previous clinical experiences and knowledge among the researchers. The interview guide included these areas:

(1) Descriptions of patient information exchanges, collaborative procedures, and documentation practices applied during patient transfer.
(2) Descriptions of daily nursing and care planning, communications, and documentation processes.
(3) Uncovering whether EPR solutions meet professional needs with regard to patient information.
(4) Descriptions of communications or EPR documentations that have caused or could cause adverse events.

As described by Krueger and Casey (2009), the focus group interviews were performed by two researchers: a moderator and an assistant. The moderator guided the discussion while the assistant kept track of the tape recording, made notes, and summarized the

TABLE 1 | Themes and sub-themes describing barriers for patient documentation.

Themes	Sub-themes
Technological barriers	Unstable system access Deficient system usability and user interface Lack of technical support
Organizational barriers	Inappropriate documenting routines Fragmented documentation structure
Social barriers	Documentation had lower priority Avoidance regarding documentation practice
Individual barriers	Lack of motivation to comply with routines and policies Inadequacy, insecurity and lack of knowledge

discussion. The focus group interviews lasted from 90 to 120 min, and all audio was recorded and transcribed verbatim.

Data Analysis

Data were analyzed using qualitative content analysis (Krippendorff, 2018). The authors listened to each recorded interview and simultaneously read the transcribed text to obtain an overall view of the data. The texts were re-read several times to allow reflection on barriers to patient safety through the documentation practices for healthcare professionals and healthcare students. Then, the text was broken down into meaning units (i.e., words, phrases and sentences that relate to the same central meaning), which were condensed and labeled with a code. Based on similarities and differences, the codes were compared and sorted into nine sub-themes and four main themes. All authors participated in the data analysis and jointly discussed possible approaches to each theme until a consensus was reached (Patton, 2012).

By following Lincoln and Guba (1985) criteria, several strategies were used to enhance the trustworthiness of the study. Credibility was supported by including an adequate number of professional and student informants, encouraging dialogue in the focus group sessions, and by discussing the interpretation of data until a consensus on themes and sub-themes was reached. Providing descriptions of informants, data collection, analysis, and quotes from the focus group interviews enabled each individual reader to assess the transferability of the study findings to other contexts. Dependability and confirmability were achieved by using audio-recording during the interviews and transcribing all interviews verbatim and by having all authors discussing the data interpretations together.

Ethical Considerations

The study was implemented in accordance with the Declaration of Helsinki (World Medical Association, 2001). Formal permission to perform data collection was obtained from the authorities at all municipalities and the University College. All nurses, social educators, and students were written-informed of the study and provided informed consent to participate. They were made aware of their rights to withdraw from the study at any time without consequence. The project was conferred with the Norwegian Center for Research Data (NSD), which concluded it not being notifiable.

RESULTS

The focus group analysis resulted in the identification of four main themes to describe the perceptions held by healthcare professionals and healthcare students regarding existing barriers to patient safety through the performance of documentation practices in primary care: 1) Technological barriers, 2) Organizational barriers, 3) Social barriers, and 4) Individual barriers. As shown in **Table 1**, each of these themes included several sub-themes. All participants responded based on experiences using the same EPR system to perform documentation tasks. In the presentation of results, the municipal nurses and social educators are described as a single group, referred to as “staff” or “nurse”. Quotes from the focus group sessions are used to elucidate the themes and sub-themes.

Technological Barriers

This theme included three sub-themes and refers to the technological obstacles that the nursing staff and students were required to overcome when documenting patient care. The informants of this study described *unstable system access* as one of the main technological challenges. All participants described experiencing time-consuming log-in procedures, lasting more than 5 min each time, and not particularly connected to the EPR system itself but to the municipal server setup system requiring several levels of log-on procedures. Encountering this barrier would result in participants leaving the computer without logging off as expected, or they would ask a colleague to perform documentation on their behalf to avoid using their time for waiting for system access. They admitted that both practices were against security rules. Another example was unannounced system downtime caused by random and unforeseen internet issues, which could occur in the middle of documentation or while using the EPR system for shift reports or doctor’s visits. These experiences prevented the informants from using the system completely. Nursing staff and students had described experiencing the loss of system access due to planned, unannounced technical maintenance. These episodes resulted in a lack of trust in the EPR system, and respondents reported the regular use of paper-based backups for the most important patient information, such as patient personalia, patient contacts, and medication lists.

Further, the respondents presented the EPR system as incomplete, with *deficient system usability and user interface* that did not support their needs and requirements for daily nursing documentation routines, resulting in the use of a paper-based documentation system as a supplement to secure documentation, information exchange, and patient safety. One example was a staff informant group who still used the previous manual documentation system as a back-up:

> When we need to find information about a patient, we must first go to the EPR system to see if we can find it there. If it is not there, we must look in the ‘Kardex’. It can take some time, then, if you are unsure where to find it.

Deficient system usability and user interface were found to be risk factors for adverse events. Multiple areas could be used to document the same information within the EPR system, which made documentation fragmented and difficult to rediscover when the nursing staff required the information. The EPR system did not follow the logical nursing planning structure that the informants expected and were trained for, which also increased the potential for adverse events. One staff informant stated:

> . . .and it is a bit scary in everyday life because we are actually responsible for what we do, and when the system is designed so that you are tricked into making mistakes, as we do our job.

Usability and interface problems also included small fonts and compressed text that made information difficult to read and was another possible risk for adverse events.

The final technological barrier was the *lack of technical support*. When informants experienced problems, such as the system being down or log-on problems, these issues could only be addressed during a normal working day between 08:00–16:00, with no support offered during night shifts, weekends, or holidays. This lack of support was another reason many of the staff informants relied on paper-based backups and handwritten notes that would later be added to the EPR system. Paper-based backup routines were viewed as a necessary workaround; however, all participants admitted that paper backups were a safety risk because documentation became fragmented and paper notes could be lost.

Organizational Barriers

This theme includes two sub-themes and refers to barriers within the organizational system, which made informants struggle when documenting patient information. Even though the informants of this study had experience using the same EPR system, each municipality was able to some extent to technically adjust the system setup according to their existing or desired organizational routines. This ability resulted in some variety in documentation routines. Thus, informants reported both shared and unique organizational documentation challenges and barriers between the focus groups.

Many of the organizational barriers were ascribed to *inappropriate documentation routines* in the unit. The EPR system was implemented many years ago, and it included areas suitable for registrations. However, some units maintained old routines, using notes, lists, and notebooks to document care. Some focus groups reported the reduced use of paper-based documentation, even though some paper-based routines were maintained due to technical issues, as described above. Other routines were maintained despite an awareness of the possibility of causing adverse events. The complete and expected reorganization of documentation routines was simply never initiated after implementing the EPR. In one of the student groups having experiences from a variety of municipalities, this frustration was shared:

> A big source of error is that you always have to remember where to look for things; where to check the patch, the medications, where to find time appointments, and there, and there, and there and in addition you have to take care of the patients and keep them in mind, and then you have to keep in mind if there is any wound procedure, and then you have to keep in mind inhalation and the eye drop form in the closet, and. -You have to constantly go and keep in mind!

This inappropriate routine was confirmed by the student informant groups, who faced even more substantial challenges when attempting to retrieve information from multiple sources.

Furthermore, this theme also addressed a severe barrier to patient safety: inappropriate routines that included a lack of patient information. A lack of patient information either caused adverse events, or these adverse events were avoided by the clinical skills of the nursing staff or, as described by study informants, pure luck. Nursing staff had experienced rigid organizational EPR routines, in which only a few persons were permitted to add or change basic patient information. One example provided was an acute situation in which no family information could be found. The nurse involved traced the phone number of the patient's daughter on the internet because she knew her name, but this informant said, '*It was a bit hectic to find the daughters phone number, and simultaneously trying to save the patient`s life while waiting for the ambulance to come*'. Lack of such information could lead to phone calls to the wrong individuals and a breach of confidentiality.

Staff informants had experienced not being allowed to add medical diagnoses to the EPR system because this task was reserved for the patient's doctor. However, if the doctor did not perform this task diligently, the nurses had to guess which underlying illness the patient suffered to complete their nursing observations and actions. Lacking blood sample results was a recurring problem that was reported by multiple groups of informants. These results did exist, but sample information was not found. Partly, the results were not sent as e-messages and thereby not found within the EPR system as expected, or results were not inserted into the EPR system when received through a letter or phone call. Much time and effort were spent tracking answers to determine the correct administration of medications, potentially causing harm to the patients. In a staff focus group, one informant told:

> Yes, we can wait for several days for answers for blood samples (. . .), and quite a few nurses get frustrated. We take a test on Monday and do not receive a response from the doctor before Thursday. So, then you should be happy that the nurse knows the users and give them what they think is right. It's a big problem in the rural areas. It takes time.

One result of the different documentation practices in the various units was a *fragmented documentation structure*, which led to confusing patient information. This barrier was viewed as an organizational reinforcement of the technological barrier due to the organization allowing so much confusion in the structure of the EPR system. In the focus group sessions, the informants discussed the lack of overview of patient information in their documentation practice. In all of the focus group meetings, the informants discussed the time spent searching for patient information within the fragmented patient information structure. "*There is a lot of paper lying all around.*"

Both within the EPR system and between the EPR system and the paper-based supplementation systems, time was spent searching for, checking, and double-checking information. Both students and nursing staff experienced the documentation structure as a risk for patient safety. Furthermore, variations were found in the structure of care planning within the EPR system. Our informants reported the availability of both firm templates for documenting nursing actions and evaluations in addition to day-to-day reporting practices. Day-to-day reporting did not provide a broad overview and represented a risk of losing important follow-up areas for each patient. In contrast, a care-planning template with too much detail could overly fragment patient information and increase the risk of adverse events.

Another identified risk area was patient transfer reports. Our groups discussed the lack of a transfer documenting template and the various shapes of the reports. The following quote from one staff informant was representative for concerns expressed among all groups interviewed:

> It is not specified what to write in the transfer report, so it is left to each person to decide and what she emphasizes of observations.

Poor reports increased the risks for adverse events, which could often only be prevented by making phone calls to verify the necessary information required for medical treatments and nursing follow-up.

Social Barriers

This theme included two sub-themes associated with barriers to patient documentation that were not recognized as being caused by the organizational structures of the units. The main social barrier associated with an increased risk of adverse events was that *documentation had lower priority* compared with other tasks in the caring unit. Practical, daily tasks and patient-oriented work had higher priority and were more accepted among the nursing staff than spending time on the computer. During hectic shifts, our informants would rather relieve their colleagues than update the EPR. Thus, documentation tasks were postponed. This finding was confirmed by some student informants, who had received negative feedback if they spent too much time reading or updating the EPR instead of participating in direct patient-related activities. Our informants provided multiple examples in which they did not spend time learning how to use the EPR system or did not know where to document their nursing actions, and they described the dilemma. One staff informant said:

> It is the issue of closeness to the patient. It is central in our caring to spend time with the patient. Documentation becomes a secondary issue, which I feel have to get into the heads of nurses: they must understand the importance of documentation! Why should you read? To stay updated.

A reoccurring issue that appeared in the focus group discussions was obvious *avoidance regarding documentation practices* in some units. The study found unequal attitudes towards the documentation of adverse events, even if the informants all agreed that the public strategy in their working units was to welcome such registration. However, the social attitude was that documenting an adverse event could be viewed as a form of self-punishment rather than as an opportunity for common learning and improvement. One of the focus groups consisting of staff participants discussed their proactive system developed to report and address adverse events, which was accepted and followed by staff members. The unit maintained a quality system known to everyone, and deviations from procedures were marked and reported as an adverse event and was followed up by leaders, as the procedure required. But even here:

> We have had many plenary discussions now about the positivity of documenting deviations (. . .), but we think there is a lot below the surface that is not registered and reported.

This response revealed a developing culture for the handling of adverse events, which continued to face cultural challenges. The staff informants discussed their experiences with social change, moving towards a more pro-active attitude regarding the documentation and learning from the mistakes that led to adverse event registrations.

Individual Barriers

This theme includes two sub-themes and refers to the barriers associated with personal characteristics that may influence a staff member's documentation practices. The barrier *lack of motivation to comply with routines and policies* was neither a result of the organizational regime nor a social structure within the units. When documenting nursing actions, the units had routines and procedures designating where in the EPR system nursing assessments and measures should be documented, but these guidelines were not always followed. Some staff informants admitted that they did not want to use the available tablet personal computer (PC) to document the EPR.

> We act so different. Some of us document and take it very seriously. Document everything (. . .) everything done in a day, while others are better at documenting what is relevant for the patient care (. . .) And some do not write at all.

The staff informants stated that they and their colleagues did not always read the EPR when they began their shifts or did not thoroughly examine the documentation, such as when administering medications. Important information could be missed, leading to adverse events of varying degrees of severity. Time shortage or not sharing the same sense of responsibility for documentation were the explanations given for not accomplishing documentation tasks, either in a standardized way or at all. However, not having complete and sufficient patient information is a risk factor for adverse events and was also a stress factor for our informants in their daily work.

Our focus group informants discussed their common experiences of *inadequacy, insecurity, and lack of knowledge* regarding the ability to document patient information properly. In particular, staff informants experienced a lack of confidence, skills, and knowledge necessary for documentation tasks, even if they had have received both an education and formal training on the topic.

> It's easier not to do it, when you are insecure, than to do it. It is about they don't exactly know how to do it . . . and then they do not; not document at all, leaving it to someone who can. And then there are a few who are very good at it, and the days they are not here, then it will not be done.

Basic information and communications technology (ICT) skills varied among the participants and strengthened the sense of insecurity described above. Our student groups did not address such insecurity in the same manner as our staff informants did. The challenge included where to search for or document patient care.

> It feels safer to document it all under "general information" because you have not analyzed so much yourself then, on your own.

They reported low confidence in their own and their colleagues' ability to place documentation elements correctly in the EPR system, resulting in a fundamental concern regarding the quality of patient documentation and a constant fear that adverse events will occur. To overcome these barriers, they searched for, checked, and double-checked available patient information sources within and outside the EPR system to secure the quality of care. They had to rely on oral handover for adequate patient information.

> You must ask the nurses you work with; maybe they know, but it is not certain you get the right answer.

Individual use of phrases in documentation practice was also discussed in the focus groups. The student groups, in particular, felt unsafe when nurses used phrases and words not familiar to them; however, staff informants also expressed problems with individual approaches toward documenting language, subsequently making it difficult to contextualize follow-up activities.

Our informants worried about their ability to remember all messages and tasks and their ability to accomplish their documenting duties correctly, particularly during busy periods. The documentation of drug administration was a major challenge reported for individual documentation practices among our informants. Most adverse event reports were associated with the area of medication. One student representative had the following experience:

> One of our patients had anti-constipation treatment without being constipated: His elimination status was just not recorded anywhere.

Another example was not being aware of a missing blood sampling that was necessary to perform medication adjustments, resulting in incorrect medication; this error was recognized as a potential patient safety risk.

Uncertainty among the nursing staff was observed by the student groups, making them insecure during their practical study periods. Students also experienced expectations among the nurse staff, who expected them to know without being taught:

> It is not documented anywhere! (. . .) and then they just said that I will learn this as I am working here more permanently.

This expectation of tacit knowledge frustrated them and made them anxious about potentially harming the patients due to a lack of patient information.

DISCUSSION

This study aimed to better understand the perceptions of healthcare professionals and healthcare students regarding the barriers to patient safety through the performance of documentation practices. The results demonstrated that technological, organizational, social, and individual barriers to nursing documentation pose potential risks to patient safety. Our results could be associated with seven of the nine areas outlined in the WHO strategy "Safer primary care" (2012). Follow-up thematic reports (WHO, 2016) underpin the study's results by many converging elements that involve safety risks.

Technological barriers were a basic challenge reported by our participants. Unstable system access, deficient EPR usability, and poor user interfaces, together with scarce technical support, did not support their nursing practice needs. The respondents struggled to document and access sufficient information to perform daily care. Similar findings were reported in Priestman et al. (2018) and in a review by Stevenson et al. (2010) and followed up by a study in 2012 where nurses reported that the EPR does not support their nursing practice (Stevenson and Nilsson, 2012). WHO (2016) also emphasized the increased use of technical devices in primary care to improve patient safety. The report admitted that poorly designed EPR systems might create more work and frustration among staff, similar to our findings. A literature review by Gesulga et al. (2017) also recognized barriers, such as user resistance arising from data security concerns. Technological tools, such as EPRs aim for but do not necessarily achieve the prevention of human errors and the improvement of information exchange. Such tools can also create additional human work or new ways of working. Thus, the nursing staff became dependent on technological usability and stability to provide nursing and care and secure patient safety (Dekker, 2016).

One of this study's four main themes was organizational barriers, also identified as a main patient safety area by WHO (2012); WHO (2016). Barriers were identified in this study, such as incomplete or inaccurate documentation routines and fragmented documentation structures. Kutney-Lee et al. (2019) also found correlations between organizational issues, such as work environment, patient safety and EPR system usability. Many documentation errors by use of the EPR systems can be caused by deficiencies in the organizational structure in a care unit, such as patient transfers, something many participants also described in the study, including "poorly written or illegible discharge summaries" (WHO, 2016). "Transitions of care" is also emphasized as a focus area by WHO (2016) as well as in other studies (Graabæk et al., 2019; Patel and Landrigan, 2019). This topic identifies several risk areas related to patient safety that were also discussed by our informants: increased adverse events, delays in receiving appropriate treatment, and lost tests or blood sample results. Studies suggest interventions to prevent safety risks such as standardization of documentation and discharge information (Törnvall and Jansson, 2017; De Groot et al., 2019), all of which were supported by our informants: for both transition situations and to improve the documentation structure in general.

Two sub-themes were regarded as social barriers to documentation in the EPR. The study found that spending time documenting had a lower priority than other tasks and that in some units, the staff groups showed avoidance behavior toward documenting practices. Similar negative attitudes toward documentation have been reported previously, such as in Bøgeskov and Grimshaw-Aagaard (2018) research, in which nurses in hospitals perceived documentation as being a meaningless burden that hindered them from focusing on the patient. When the safety culture within staff groups undermines documentation tasks, identifying whether the underlying reasons for these attitudes and behaviors are associated with the priority of direct patient care or whether other causalities exist is imperative (Barkhordari-Sharifabad et al., 2017).

Individual barriers to documentation practices included both a lack of motivation for documenting practices and the informant's sense of *inadequacy, insecurity, and lack of knowledge* regarding correct documentation procedures. Designing systems that better support the nursing staff can contribute to their motivation to comply with the established routines and policies for documenting tasks (Stevenson et al., 2010). Improved system usability may reduce the occurrence of potential adverse events and increase patient safety (Williams, 2019). One area associated with severe patient risk that was reported in our work was nursing staff not correctly updating or carefully reading the EPR when handling medication. WHO (2016) confirmed, in line with our results, "workload and time pressure" and "lack of accuracy in the patient record" as factors that increased the risk of patient safety harm. This is also found by other studies (Al-Jumaili and Doucette 2018; Dunn Lopez et al., 2021). There appears to be a need for a more systematic approach to handling medication information, such as computerized decision support systems (Marasinghe, 2015).

Reasons for not using the tablet PC for documentation were not provided in our result. However, tablets may reduce the time spent on documentation, as reported in the reviews by Dall'ora et al. (2020) and Blair and Smith (2012). Lack of time was discussed by the healthcare staff as a reason for not documenting or postponing documentation tasks during their shift, as also noted by Söderberg et al. (2009): therefore, it is necessary to cross this barrier to patient safety by providing an understanding of the use of the EPR as an efficient way of documentation time in contrast to time spent walking around, collecting necessary information among colleagues in the unit.

Lack of training, which was also emphasized by our informants, in our view, was regarded as an individual issue rather than an organizational problem. Our participants indicated *inadequacy, insecurity, and lack of knowledge* among their individual challenges but did not necessarily describe these issues as part of the organizational strategy because they had all received training sessions within their units. Bing-Jonsson et al. (2016) investigated the sufficiency of nursing staff competence in Norwegian community elderly care and found that documentation is one of the areas where nurses, auxiliary nurses, and assistants may have insufficient competence. The authors concluded that education and training alone appeared to have a limited impact on competence, potentially due to health professionals having unclear roles and inadequate standards for judging their own competence; they perform many of the same tasks, regardless of formal competence based on education (Bing-Jonsson et al., 2016).

The student informants in our study described nursing staff who sometimes omitted the documentation of patient information and expected the students to know without being taught (i.e., tacit knowledge). Staff members in long-term elderly care often know their patients quite well and, therefore, may find documentation redundant because they maintain a lot of information "in their heads" (Østensen et al., 2019).

Strengths and Limitations

One strength of this study is that the sample included a combination of healthcare professionals with considerable experience and bachelor-degree students with an outside view of the workplace. The students had experience from health services in several municipalities during their practical studies and contributed with useful reflections on similarities and differences between these areas in the focus group interviews. Only one man attended the study, which could be considered a limitation. However, this skewed gender distribution is reflective of the large proportion of women employed in elderly care.

The student informants were recruited from the University College where all authors were employed, but none of the authors were involved in assessing these participants' academic elements of their studies. All students were made aware that participating in the research would have no impact on their progression through their bachelor's program.

The use of a topic-based interview guide, instead of narrow questions, contributed to data-rich discussions in the focus groups. The authors experienced an open and trusting atmosphere during the sessions, where all informants shared honest reflections and described real challenges from practice.

Lively discussions, both in the staff focus groups and the student focus groups, contributed to rich qualitative data. The years between data collection and publication may be seen as a limitation in the study, but we have also learned that changes due to digitalization in healthcare take many years to implement and adopt, as described by Morris et al. (2011). Thus, we suggest that the experiences will still be relevant for healthcare organizations preparing for the implementation of ICT tools. The fact that the study involved one EPR solution may be regarded as a limitation. On the other hand, one may also consider this as a strength, because all informants reported on their experiences from a common starting point when describing their challenges. Involving municipalities with other EPR solutions could have expanded the picture of challenge. On the other hand it could have given responses based on more unequal prerequisites referring to various EPR systems. This could further have drawn attention away from challenges described in the result of this study, and more toward variations between EPR systems as such.

The fact that all 3 authors were involved in the analysis process was also an advantage. Due to the qualitative design, the results cannot be generalized. However, because the documentation of patient information is an important part of any healthcare professional's practice, the study results could be transformed and applied to several other contexts in healthcare.

CONCLUSION AND IMPLICATIONS

In this study, our results identified several barriers that negatively influenced patient documentation practices, exposing patients in primary care to increased safety risks and potentially harmful situations. To enhance and secure patient safety, increased individual, social, organizational, and technological support is necessary to overcome these barriers to ensure that optimal patient information is available when required for nursing care. To achieve this aim, primary care services must facilitate the necessary improvements by prioritizing technical, economic, and human resources for system development, training, and the definition of clear mission statements and policies.

The study results may inform various stakeholders in designing, implementing, using, and teaching EPR systems:

- System vendors may gain more knowledge of the complexity in nursing staff's everyday lives, and to what extent implemented EPR systems still fail to meet the needs for documentation and information exchange continuing to risks of adverse events.
- Health service leaders and ICT leaders should pay close attention to system implementation and adoption phases paving the path for their staff members, not underestimating the complexity in documentation and information exchange in their caring units, all in order to secure and improve patient safety.
- Staff members and healthcare students may learn how colleagues and co-students experience their EPR documentation practice, reflecting upon their own situation regarding patient safety and EPR use.
- Teaching organizations at high school and university level may become more effectively supported in their focus on teaching their students documentation in both theory and practice as well as the connectivity between structured EPR use for documentation and an improved level of patient safety.
- System vendors may gain more knowledge of the complexity of nursing staff practices and the fact that implemented EPR systems still do not meet the needs for documentation and information exchange but continue to pose risks of adverse events.
- Health service leaders and ICT leaders should pay close attention to system implementation and adoption phases: This study shows the need for these leaders to pave the path for their staff members and not to underestimate the complexity in documentation and information exchange in their caring units: all in order to secure and improve patient safety.
- Staff members and healthcare students may learn how colleagues and co-students experience their EPR documentation practice, engaging in reflection about their own situation regarding patient safety and EPR use.
- Teaching organizations at high school and university level may be better supported in their focus on teaching their students documentation in both theory and practice: This study could also deepen the understanding of the connectivity between structured EPR use for documentation and the necessary level of patient safety.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

Ethical review and the approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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Factors Influencing Development and Implementation of Patients' Access to Electronic Health Records—A Comparative Study of Sweden and the Netherlands

Charlotte D. Cijvat[1], *Ronald Cornet*[1] *and Maria Hägglund*[2]*

[1] Amsterdam Public Health, Medical Informatics, Amsterdam Universitair Medische Centra, University of Amsterdam, Amsterdam, Netherlands, [2] Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden

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Arnold Bosman,
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****Correspondence:***
Maria Hägglund
maria.hagglund@kbh.uu.se

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Background: Patient-accessible electronic health records (PAEHRs) and associated national policies have increasingly been set up over the past two decades. Still little is known about the most effective strategy for developing and implementing PAEHRs. There are many stakeholders to take into account, and previous research focuses on the viewpoints of patients and healthcare professionals. Many known barriers and challenges could be solved by involving end-users in the development and implementation process. This study therefore compares barriers and facilitators for PAEHR development and implementation, both general and specific for patient involvement, that were present in Sweden and the Netherlands.

Methods: There were a total of 14 semi-structured interviews with 16 key informants from both countries, on which content analysis was performed. The Consolidated Framework for Implementation Research was used to guide both the construction of the interview guides and the content analysis.

Outcomes: The main barriers present in both countries are resistance from healthcare professionals and technical barriers regarding electronic health record systems and vendors. Facilitators varied across the two contexts, where the national infrastructure and program management were highlighted as facilitators in Sweden and stakeholder engagement (including patients and healthcare professionals) was described as a facilitator in both contexts. Strong leadership was also described as a critical success factor, especially when faced with healthcare professional resistance.

Conclusion: Most of the major barriers and facilitators from both countries are covered in existing literature. This study, however, identified factors that can be seen as more practical and that would not have arisen from interviews with patients or physicians. Recommendations for policymakers include keeping the mentioned barriers in mind from the start of development and paving the way for facilitators, mainly strict policies, learning from peer implementers, and patient involvement, when possible. Implementers should focus on strong decision-making and project management and on preparing the healthcare organization for the PAEHR.

Keywords: patient accessible electronic health record, open notes, patient portal, implementation, consolidated framework for implementation research

INTRODUCTION

Over the past two decades, advancements in law, technology, and policy have stimulated the implementation of patient-accessible electronic health records (PAEHRs) (1). These systems, set up by either healthcare providers or governments, allow patients to access their medical data whenever they want. PAEHRs can be designed and implemented in different ways, including logging in to a web-accessible portal to read the EHR information and potentially downloading this information into a personal health record (PHR). In the USA, a distinction is often made between access to, e.g., lab results and access to the actual notes in the record, with the latter referred to as *open notes* (2, 3). The concept PAEHR, on the other hand, refers to patients' access to all the content in the electronic health record (EHR) (1), including, but not limited to, clinical notes. Providing access to medical data potentially improves patient empowerment, leading to less consultations and more efficient healthcare provision, thus lowering healthcare expenditure and resulting in better health outcomes (4). Since these benefits can occur not only on an individual healthcare provider level but also for the whole healthcare system, many countries take a national approach to either developing national PAEHRs or creating national policies for implementation (5).

Even though more and more PAEHRs have been implemented, still little is known about the most effective strategy for developing and implementing PAEHRs and associated policy. Implementation can be defined as "the constellation of processes intended to get an intervention into use within an organization; it is the means by which an intervention is assimilated into an organization" (6). In the case of PAEHRs, there are many human, organizational, and technological factors that can complicate these processes (7). There are, for example, many different stakeholders affected by PAEHRs, all with different and sometimes contradictory concerns, incentives, or demands (8, 9). Existing literature mainly focuses on individual cases and on the viewpoints of patients (10, 11) or healthcare professionals (HCPs) (12) rather than the people responsible for developing or implementing PAEHR policy (13). Progress, internationally, has been slow due to legal constraints, technical challenges, and concerns or resistance among HCPs (14). Low rates of adoption among patients have also been a problem in some areas (14). Nonetheless, research evidence reports positive outcomes among patients accessing their records (3, 10), and the concerns expressed by HCPs have not been realized. Patients who read their notes report understanding their care plans better (3), feeling more in control of their care (3, 10), doing a better job taking their medications (15), improved communication with and trust in their clinicians (10, 15), and improved patient safety (16). Studies focusing on implementation barriers stress the importance of involving end-users' viewpoints—in this case, the patients—in the development and implementation (4, 17, 18). For example, patient-reported barriers for PAEHR adoption include lack of healthcare provider acceptance, endorsement, and promotion of the PAEHR, poor user health literacy, and perceived usability and utility problems (e.g., usefulness of the available information and personalization of the PAEHR).

It has been hypothesized that countries developing PAEHRs and associated policies face similar barriers and facilitators, both general and specific, for patient involvement and can improve their existing policies by comparing these factors and learning from each other (19). We have chosen Sweden and the Netherlands as two contexts to explore and compare in this study. It is expected that the outcomes of this study can help Sweden, the Netherlands, and potentially other countries with similar strategies to improve their policies and strategies regarding PAEHR development and implementation. This study aims to:

1. describe and compare barriers and facilitators to implementing PAEHRs in Sweden and the Netherlands, and
2. describe and compare different aspects of patient involvement in PAEHR development and implementation processes in Sweden and the Netherlands.

METHODS

To compare the implementation of PAEHRs in Sweden and the Netherlands, we performed semi-structured interviews with key informants in the respective contexts, focusing on barriers and facilitators in the implementation process, as well as on issues specifically related to patient involvement.

Study Settings

The study settings presented in **Table 1** were used as a guide for identifying the different stakeholders and key informants. Implementation of PAEHRs may consist of several parts; both PAEHR policy and the practical (often both technical and organizational) implementation, which will likely need to take place on both national and local (healthcare provider) levels (**Figure 1**).

Depending on the context, activities may vary between the national and local levels, both with respect to policy and practical implementation. The difference between Sweden and the Netherlands will be highlighted below.

The Netherlands

We chose to focus on the "Versnellingsprogramma Informatieuitwisseling Patiënt en Professional" (VIPP program) in the Netherlands. At the time of data collection, the program

TABLE 1 | Overview of healthcare system structures, regulations concerning access to medical data, and existing patient-accessible electronic health record (PAEHR) policies in Sweden and the Netherlands.

	Sweden	**The Netherlands**
Number of inhabitants	10 million	17 million
Healthcare system structure	Tax-funded; decentralized: regional governments, 21 regions are responsible for provision of care and may contract both public and private providers	Mandatory private insurance; private care providers deliver care
Laws regarding (digital) access to medical records	All citizens aged 16 and over have a right to directly access different types of health documentation[a]	Patients aged 12 and over have a right to a digital copy of all information included in the record when the data is processed digitally (from July 2020)[b]
PAEHR policy	One PAEHR for all citizens: Journalen, which was developed by Region Uppsala in several projects since 1997 (5). All regions agreed to implement Journalen as part of the national 1177 Healthcare Guide patient portal. It collects data from different EHR systems through a Health Information Exchange (HIE) infrastructure. There are national guidelines, the National Regulatory Framework (NRF), but it is not mandatory to follow	From December 2016 to December 2019, the "Versnellingsprogramma Informatieuitwisseling Patiënt en Professional" (VIPP program) is in operation. It aims to promote general hospitals and other specialist care institutions to provide digital access and improve medication safety. Participation is not mandatory, but a financial incentive is awarded when specific goals are met
Choices in implementation	The first version of the NRF included both mandatory and electable paragraphs. The main decisions for regions were regarding displaying record entries with or without signing by the physician and with or without a 14-day delay (20). In 2016, a new version of the NRF was published with the intention to provide patients with access to all health and dental care information by 2020	Hospitals can choose which goals regarding patients' access, standardized data capture, and medication verification they want to implement[c]. Providing access is allowed by implementing a patient portal or an upload of EHR information into a PHR. Besides VIPP's goals, choices can be made regarding the history of displayed data, whether information is displayed with or without delay, and the potential functionalities of the portal
Responsible organizations	Inera AB manages the national patient portal 1177.se, including the PAEHR Journalen. It is a company owned by the Swedish regional governments. Regions are responsible for connecting their EHR systems to the national HIE	The Ministry of Health, Welfare, and Sports and the Dutch Hospital Association (NVZ) developed the subsidy program Individual hospitals carry out the implementation by making arrangements with their EHR system supplier
State of the art	As of March 2018, all regions have connected to the HIE and implemented the PAEHR Journalen. However, some private healthcare providers are still not connected	66 out of 70 non-academic hospitals are participating in VIPP[d]. In December 2017, 30 out of 78 Dutch hospitals had a patient portal with access to medical data[e]

[a] *https://inera.atlassian.net/wiki/spaces/OIJ/pages/438700782/Nationellt%2Bramverk%2Bf%2Br%2BJournalen.*

[b] *https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/brochures/2017/06/01/elektronische-gegevensuitwisseling-in-de-zorg/Wet+elektronische+verwerking+van+gegevens+20170620.pdf.*

[c] *https://www.vipp-programma.nl/over-vipp/doelstellingen.*

[d] *VIPP 1 Resultatentabel meting maart 2018: https://drive.google.com/file/d/1qe_owm3U0I2D-osz4Fw413ZlFlXDdxDw/view.*

[e] *nictiz.siw-ontwikkeling.nl/blog/online-inzage-groeit-door/#.*

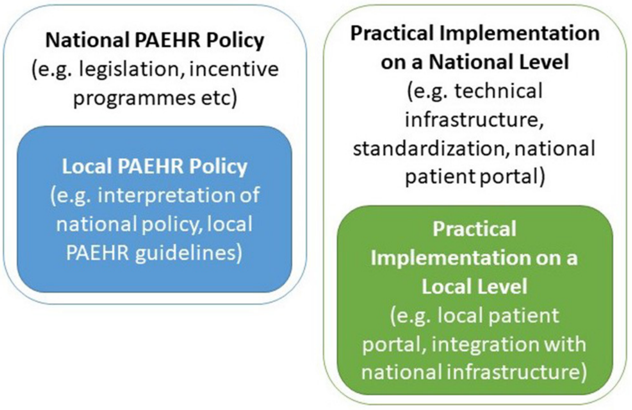

FIGURE 1 | Components of patient-accessible electronic health record implementation.

was in its first phase, which lasted until 2019. It aimed at promoting general hospitals to ensure patients' digital access to medical data and improve medication safety. Participation was not mandatory, but a financial incentive was awarded when hospitals met specific goals of their own selection. Since then, the program has progressed to include other types of healthcare providers and to focus on standardized registration of medical information. Currently, the program is in its fifth phase, which will run until July 2023. Each local healthcare provider is responsible for developing and implementing their online patient portals, and therefore describing them in more detail is difficult.

The VIPP program mainly includes policy on the national level, whereas both policy adaptions, e.g., choice of goals to focus on, and practical implementations, e.g., setting up an online patient portal, occur on the local (hospital/healthcare provider) level.

Sweden

In Sweden, 21 regions are responsible for providing healthcare. Although the regions are autonomous and can prioritize which eHealth services to focus on, the national eHealth strategy stipulates that there should be only one online healthcare access point for patients (21). Therefore, a national patient portal, "1177.se," has been implemented (5). The portal runs on a national health information exchange (HIE) platform (22, 23), and through this infrastructure, data stored in any of the EHR systems used in the 21 regions can be accessed. Authentication with an e-ID gives patients access to a number of administrative services as well as the PAEHR Journalen.

In Sweden, policy is important both on the national and local levels, with a national regulatory framework (NRF) for PAEHR (20, 24), which is adapted on the local/regional level. In contrast to the Netherlands, practical implementation, however, also takes place on both the national and the local level, with the bulk being on the national level with the national HIE platform, the national patient portal, and the national PAEHR. On the local level, practical implementation in Sweden is limited to connecting the local EHR system with the national HIE platform.

Similar to the Swedish context, national patient portals are implemented throughout the Nordic countries, whereas healthcare-provider-specific portals are common beyond the Nordic context, such as in the Netherlands. The Swedish and Dutch cases in this study therefore represent two different approaches that countries take to ensure that citizens have access to their health information. **Table 1** gives an overview of the two contexts.

It is important to note that the Dutch VIPP only covers general hospitals and other specialist care institutions, while the Swedish PAEHR "Journalen" can display EHR data from all levels of healthcare. We distinguish developers of national PAEHR policies and solutions from local or regional healthcare providers that implement those.

Study Participants

We purposefully chose key informants in both contexts that could provide insights into the research questions. Personal and professional networks were used in Sweden, and in the Netherlands, the participants were recruited through the VIPP organization. An element of snowball sampling was also applied, where the initially identified key informants recommended others. In total, 16 key informants chose to participate in the study (see **Table 2** for a description of the respondents' roles).

In Sweden, the original developers of the PAEHR Journalen from Region Uppsala, the current responsible organization Inera AB, and other regions and healthcare providers that have implemented the PAEHR Journalen were approached. In the Netherlands, we interviewed the decision-makers of the VIPP program and experienced experts of implementing PAEHRs according to VIPP. In this study, we focused on the project managers' and implementers' perspective, not those of patients and HCPs which have been covered more extensively in the literature already.

Data Collection

Semi-structured interviews were conducted between March and May 2018 *via* Skype or phone, where possible. All interviews with Dutch respondents were conducted in Dutch. All interviews were performed by the first author, who speaks Dutch but not Swedish. Some Swedish respondents were reluctant to conduct the interviews in English and were offered to (iteratively) answer questions via email in Swedish. Their answers were translated into English with the help of a native Swedish speaker. The remainder of the Swedish respondents participated in English. This applied to interview numbers 4–6 (marked in **Table 2**) with five respondents.

TABLE 2 | Overview of the interview respondents.

Interview	Respondent	Organization	Role related to patient-accessible electronic health record
Sweden			
1	1	Inera	Head of Journalen
2	2	Region Uppsala	Project manager/coordinator in several projects of Journalen development and implementation
3	3	Region Uppsala	Medical expert involved in several projects of Journalen development and implementation
4[a]	4	Region 2	Project leader of Journalen implementation
5[a]	5	Region 2 Private caregiver	Member of steering committee for Journalen implementation Chief medical informatics officer
6[a]	6, 7, 8	Region 2	Participant in central work of Journalen implementation
7	9	Region 3	Project leader for healthcare IT implementation
8	10	University	Researcher
The Netherlands			
9	11	IT advising company Hospital 1	Senior advisor Project leader
10	12	Hospital 2	Project manager
11	13	Hospital 3	Project leader/advisor
12	14	Hospital 4	Project leader
13	15	VIPP program Dutch hospital organization	Project leader Senior policy advisor
14	16	Patient federation	Policy advisor

[a] *The interview was performed via email.*

Semi-structured interview guides were established for each respondent separately based on their role and the context they practice in. The interview guide revolved around the following topics:

- factors affecting the implementation: perceived barriers and facilitators, and
- patient involvement: necessity, ideal execution, execution in reality, outcomes, and consequences

The interview guides were based on the Consolidated Framework for Implementation Research (CFIR), which identifies five dimensions that are essential to implement an intervention (6). An overview of the CFIR dimensions and sub-constructs is given in **Figure 2**.

The framework further provides sub-constructs and related questions for each of the dimensions (6). The structure of the

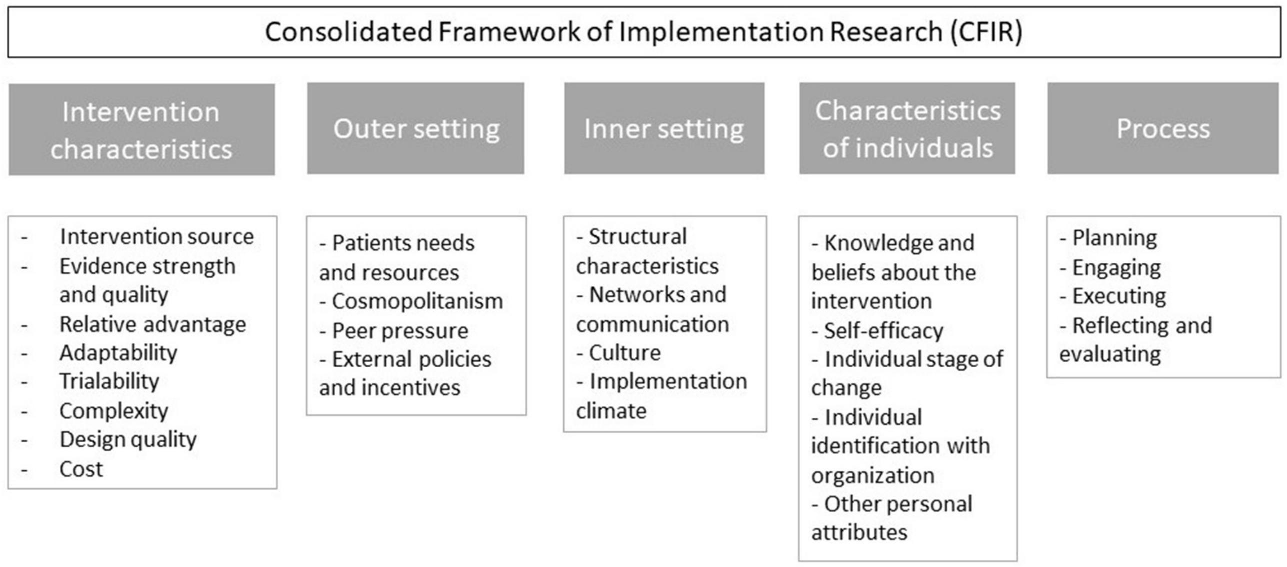

FIGURE 2 | Overview of the consolidated framework for implementation research.

TABLE 3 | Barriers on the national level.

Category	Sweden	The Netherlands
Systems and suppliers	Authentication methods	Difficulties in measuring hospitals' progress
Social and organizational	Resistance and fears from physicians	–
Resources	Financing the development of Journalen	–
	Too little time to take precautions for physicians' resistance	
Policies, laws, and regulations	Include electable rules to make progress	Challenging to define goals adequately for desired outcomes
	Electable rules caused confusion and inequality for users	Challenging to estimate reasonable usage percentages
	Giving patients direct online access to the record was illegal when the PAEHR Journalen was first introduced in 2002	Slow development of other national programs
Effects of barriers	Delays	Delays
	Restrictions on information that is displayed	

interview guides was determined by the sub-constructs that were deemed relevant for each type of respondent, i.e., respondents on the national or local level for both Sweden and the Netherlands.

To inquire about the factors affecting PAEHR implementation, the following selection of (sub)constructs was used: the strength and quality of evidence for the intervention, the external policies and incentives, the implementation climate, and all stages of the process (planning, engaging, executing, reflecting, and evaluating). The constructs that patient needs and resources and tension for change were used to assess the involvement of patients.

In addition, several other sub-constructs were selected for specific respondent types, such as peer pressure among Swedish regions. The questions proposed by the CFIR framework were adapted to each individual respondent's specific context. The interview guides were further improved iteratively after each interview to ensure that all relevant aspects were covered.

All participants were informed about the goals and risks of the study. If applicable, audio was recorded, and notes were kept. The interviews were transcribed as soon as possible using intelligent verbatim transcription. While listening to the recordings, transcripts were shortened and edited for the sake of clarity before analysis.

Analysis

The interviews were analyzed by means of content analysis according to Taylor-Powell and Renner (25). The selected CFIR constructs and sub-constructs formed the basis of the codes with which relevant passages from the edited transcripts were categorized. All passages were provided with a condensed meaning unit in English. Related passages and condensed meaning units were collected, compared, grouped, and provided with a description.

RESULTS

The results of our analysis are presented in two sections;

1. analysis of barriers and facilitators to implementation of PAEHRs, and

2. the level and impact of user involvement in the respective setting.

Factors Affecting the Implementation of PAEHRs

We have identified the main barriers and facilitators to developing and implementing national PAEHR policy as described by the respondents from both countries. Barriers exist both on the national level (**Table 3**) and on the local implementation level (**Table 4**). One of the main barriers has been resistance from HCPs on both levels in Sweden and on the local implementation level in the Netherlands. This resistance is very much in line with concerns that have previously been described in the literature; concern that patients will misunderstand, take offense or worry unnecessarily, concern that the workload will increase with patients asking questions, and concern that the records' value will be reduced as it can no longer be used as a tool for professional communication.

TABLE 4 | Barriers on the local implementation level.

Category	Sweden	The Netherlands
Systems and suppliers	Technical limitations of systems	Limitations in choice and possibilities of systems
	High costs for connecting small EHR systems	Large dependency on software suppliers
	Testing prior to implementation necessary	Alignment of systems necessary but difficult
	Difficult requisites for connecting to the HIE	Systems and suppliers determine achievement of VIPP
Social and organizational	Resistance and fears from physicians	Physicians' reluctancy, resistance, and fears
	Changing HCPs' routines, workflows and attitudes	Changing HCPs' political status and workflow
		Effects on hospitals' culture and work processes
		Fears for patients' confusion, questions, fears
		Gradual implementation necessary to keep physicians on board
Resources	High costs for connecting to the HIE	VIPP requires a lot of human work
	Time-consuming decision making due to flexibility in NRF	Human work leads to high costs
		Too little time to make VIPP's deadlines
Policies, laws, and regulations		Some VIPP goals are difficult to accomplish
		Strict privacy regulations not in patients' interests
		Strict security rules impede user-friendliness
Governance	Gradual approach necessary to get all stakeholders on board	Gradual implementation to keep physicians on board
	Flexibility in choosing EHR systems in some counties but only one supported	VIPP has no or low priority
		Cooperation between stakeholders necessary
Effects of barriers	Delays	Delays
	Restrictions on information that is displayed	High costs for implementing systems and VIPP
		Too little time to create support from staff
		Low user-friendliness and usage
		VIPP has low priority

> "[…] one of the barriers was the healthcare professionals, especially the physicians' professional organization/union. The professional organization was more reluctant to expose it to the patient than the average doctor, is my opinion. Because they wanted to be in control of what the patient read. The legislation says it should not be hidden to the patient, with two exceptions: if someone else is mentioned in the record or if it is proven that the result of a treatment will be worse if the patient is aware of it, then the record can be closed. More or less, I have not found any doctor that has used any of those two reasons for not sending a copy on request of the patient." (Sweden, local level)

Regarding policy, both countries had some challenges on the national level. In Sweden, it was difficult to agree on a NRF, and the first version had several "electable rules," i.e., rules where each region or local healthcare provider had to choose how to implement (20). One could, e.g., choose which types of information to release to patients (notes, lab results, referrals, *etc.*), also whether to give immediate access or have a 2-week waiting period, and whether to release only signed/validated information or not. This, of course, led to a fragmentation of the otherwise national PAEHR, where it was difficult for patients to understand why they could see lab results from Region A but not from Region B. In the Netherlands, all practical implementation took place at the local level, but the VIPP program provided an important incentive. Here it was, however, difficult to both define goals and measure the hospitals' progress toward these goals.

> "So, at the very last moment we thought, oh, something with an auditor and a manual is also still necessary. You can see that hospitals want to know everything down to the decimal point: what is meant with this, what do you want to achieve with that? […] You see that such a manual in auditor language is difficult to interpret for hospitals." (the Netherlands, national level)
>
> "I wonder whether the VIPP program actually delivers what it aims to deliver. This is mainly due to the audit questions, which are very technically structured: is this available, do you offer this…? I think that the reality in the workplace has not been looked at very carefully, whether these audit standards match reality. And there is a lot of confusion." (the Netherlands, local level)

Implementers from both countries faced technical barriers when implementing PAEHRs. In Sweden, the first pilot projects

TABLE 5 | Facilitators on the national level.

Category	Sweden	The Netherlands
Systems and suppliers	Use of national HIE created by another project	
	Previous experience and knowledge	
Policies, laws, and regulations	Stricter policy	
Governance	Decision-making on a political level	

TABLE 6 | Facilitators on the local implementation level.

Category	Sweden	The Netherlands
Systems and suppliers	Use of national protocols and standards	Large EHR system suppliers address security issues
	Reusable contracts and protocols	Portal functionalities existed outside of healthcare
		Think about future development from the start
Social and organizational	Involve HCPs' perspective in decision making	Involve both patients and professionals
	Communicate with stakeholders	NVZ published an analysis of impact on hospitals' work processes
	Gradual implementation	
	Patients can change physicians' behavior if no one else will	
	Ambassadors in healthcare organizations	
Resources	Learn from peers' implementation processes	
	Previous experience and knowledge	
Policies, laws, and regulations	Involve HCPs' perspective in decision making	
Governance	Implementing gradually	Involve both patients and professionals
	Dare to try despite fears from professionals	Strong decision makers
	Central program management	Involve different stakeholders: IT and communication departments, IT suppliers

struggled to find secure authentication methods, but in later implementations, the technical challenges related mainly to connecting the EHR systems to the national HIE platform:

"The first barriers were strictly technical, making sure that we had the right protocols from the supplier of the EHR and making sure that everything worked fine in that integration." (Sweden, local level)

Connecting to the national HIE platform was not only described as a technical challenge; it could also be quite costly, which kept smaller private healthcare providers from connecting:

"[…] healthcare providers in our region can use whatever EHR system they want. It is expensive to make changes in the systems unless they are big. That's why there are healthcare providers who are still not connected. All hospitals and most health centers are connected." (Sweden, local level)

Dutch implementers were dependent on their IT suppliers for implementing a successful PAEHR and achieving the VIPP goals:

> "At the moment, we have a technological status in hospitals in the Netherlands; we have two suppliers who, kind of, wield the scepter, and we are therefore largely dependent on the speed at which they develop [the patient portals]. We have limited influence on that." (the Netherlands, local level)

The Dutch interviews revealed no facilitators on the national level, likely due to the fact that all practical implementations took place at the local hospital level. In Sweden, the National HIE platform as well as the updated, more strict version of the national regulatory framework (24) was described as facilitator (**Table 5**).

On the local implementation level (**Table 6**), the national infrastructure was also described as a facilitator in Sweden, with the use of national protocols and contracts making it easier for regions and private healthcare providers to integrate. Social aspects were also important Swedish facilitators, where involvement of different stakeholders, learning from peers who were also implementing, and a gradual implementation process were described as beneficial:

> "It hasn't been so complicated to implement Journalen because our region was among the last to do it in Sweden. That means we could learn a lot from the experiences of those who had already implemented." (Sweden, local level)

Involvement of HCPs in the implementation process was described as a facilitator, but there were also some respondents who highlighted the importance of daring to proceed despite resistance from HCPs, indicating that this may be a double-edged sword.

Strong decision-makers and involvement of different stakeholders (including patients and HCPs) were highlighted as facilitators in the Dutch context, too (**Table 6**):

> "Involving HCPs very early and closely in decision-making is extremely important, so you want to treat them very nicely and carefully and never feel like you are making choices over their heads. There is still resistance to portals, and you can take that away by treating them properly. You can never take it away completely, so you have to be persistent. You also need a strong board of directors that make choices or someone else making choices and saying, we are going to do this, even if people are against it. You need that, too; it is also a critical success factor." (the Netherlands, local level)
>
> "I think the success of this also depends on who gets involved, so if the board of directors finds this very important and gives it a lot of 'bravado', then it is more likely to lead to success. […] I think that is a success factor that you do not have [at this hospital], which means that the project is also running less than it could.

> […] Because when the board of directors says: this is what we are going to do—then the specialists and medical managers and business managers will often listen much more carefully. Now, it is me who is always peddling. A hospital is quite hierarchical, which means that it is sometimes necessary for someone to say: this is what we are going to do." (the Netherlands, local level)

In the Dutch interviews, the EHR vendors' role was more prominent, and their contribution to addressing, e.g., security issues was considered a facilitator:

> "Security is often addressed relatively late, like—oh, [the portal] also needs to be safe. That problem is somewhat smaller since we work with the large EHR suppliers because they already have their own ideas on that; they simply offer it in the safest possible way." (the Netherlands, local level)

Some facilitators and barriers were considered critical. In the Swedish context, the central management of the patient portal and HIE was seen as essential. In the Netherlands, involvement of end-users (both patients and HCPs), implementing toward a clear future goal, involvement of vendors and IT departments, and strong leadership were considered critical success factors. In the Dutch context, the dependence on collaboration with system vendors was also seen as a critical weakness.

Patient Involvement

The different aspects of patient involvement in PAEHR policy development and implementation in Sweden and the Netherlands are displayed in **Table 7** (national level) and **Table 8** (local implementation level). In Sweden, patients' wishes and preferences regarding digital access to the EHR were analyzed during the early deployment of the PAEHR Journalen. Regions implementing Journalen also attempted to do so but used fewer means to explore the patients' preferences. In addition, as most decisions relating to the national patient portal and the PAEHR were centralized to the national organization, there was a sense of loss of control on the local/regional level, making the incentives for engaging patients in decision-making limited. In the Netherlands, patient involvement mainly took place at the implementation level, even though hospitals face multiple barriers when doing so. Little to no patient involvement was carried out when developing VIPP.

DISCUSSION

Principal Findings

Swedish and Dutch developers and implementers of national PAEHR policy have reported on many different barriers, facilitators, critical success factors, and aspects of patient involvement. These outcomes are compared and linked to existing literature in order to interpret them and give recommendations.

Barriers, Facilitators, and Critical Success Factors

The main barrier that both countries face is resistance from HCPs, which is confirmed in many other studies (4, 9, 12, 14, 26). Even though the resistance presents itself on different levels in Sweden and the Netherlands, the approaches for dealing with it are similar. Both countries felt the need to involve the professionals' viewpoint in decision-making. Even if this compromised the patients' preferences, it was a necessary step to make progress. Multiple Dutch stakeholders perceive involving both the patient and professional perspective as a critical success factor because it is not likely that professionals will be enthusiastic about and use a tool that is created for patients alone and *vice versa*.

TABLE 7 | Patient involvement on the national level.

Category	Sweden	The Netherlands
National policy's intended benefits	Improve patient empowerment	Improve medication safety
	Improve efficiency of medical services	Provide information access for patients
	Digital "self-service" for patients	
Patient-centeredness of national policy	NRF version 1 and 2 have the same goals	VIPP is developed for patients
	Access needs to be improved for persons aged 13–15	
Methods/tools for patient involvement	Workshops with patients and caregivers	
	User surveys	
	Collecting feedback	
Gained understanding and insights	Users want direct access to signed and unsigned notes, preferably in the professionals' language	
	Users want to make their own decision about viewing the information with or without delay	
	Less negative outcomes for patients than expected	
Challenges	Make compromises between patients' and HCPs' wishes	

The importance of involving patients' (17, 27–29) and HCPs' perspectives (26, 28) in the implementation processes is supported by many studies. Besides stakeholder involvement, the necessity for strong leadership and a gradual approach in implementing were expressed in both countries. Strong leadership is recognized as an important factor for implementation success (27, 30), while a gradual implementation strategy can be seen as a way of reducing the HCPs' resistance, for instance, by implementing functionalities or types of information one at a time. However, gradual implementation was viewed as both a barrier and facilitator in Sweden, whereas the delays it caused in the implementation process was only seen as a barrier for Dutch respondents. Another potential solution to HCP resistance that was mentioned in both countries was enforcing stricter rules or regulations regarding the PAEHR. This is being done, e.g., in the USA, where from April 5, 2021, new federal laws will mandate that providers must extend open notes to all patients, with a few permitted exemptions (31).

TABLE 8 | Patient involvement on the local implementation level.

Category	Sweden	The Netherlands
Importance or necessity	Leads to better care provision	Added value for patients and their treatment
		To accomplish VIPP
Patient-centeredness of national policy	NRF version 2 is more transparent and supporting to patients than version 1	VIPP is developed for professionals
		Patients will benefit from the information that is displayed
Methods/tools for patient involvement	User surveys	(Online) panels, focus groups
	Collecting feedback	User surveys
	Patient advisory board	Collecting feedback
	Research	Client council members
	Assumptions from HCPs	Research and publications
Gained understanding and insights		Wishes, needs, complaints and questions
		Insights into desired future functionalities
		Debates between client council members and medical staff, which sometimes lead to more support from staff for the patients' wishes
Challenges	Make compromises between patients' and HCPs' wishes	Not possible to combine with VIPP and its technical focus
	Few decisions to involve patients in	Find enough users that are willing and able to participate, have the right mindset and are representative for the hospital's patient population
		Did not get enough feedback from patients
Lack of resources	Patients had too little knowledge or experience to involve in the development process	Not enough time or other resources for patient involvement
		Technically not possible to meet the patients' wishes and requirements
		Too many different wishes and requirements to take into account

In Sweden, this could have reduced the inequality in access between regions and let the PAEHR Journalen meet citizens' preferences better. Even though providing digital access is mandatory in the Netherlands from 2020, stricter regulations could have saved time and money that is now needed for convincing HCPs.

Even though technical barriers are reported less often in literature (32, 33), they are present on the implementation level in both countries. In the Netherlands, hospitals are dependent on their software vendors for implementing a successful PAEHR and achieving the VIPP goals. Swedish healthcare providers are faced with high integration costs when connecting EHR systems to the HIE. In addition, it is not always possible to show all types of information that are desired due to technical limitations of the EHR systems that are connected to the HIE. Swedish implementers, however, mentioned that sometimes the reuse of protocols and contracts from other regions or healthcare providers is possible, which facilitates the integration. Regions also have the possibility to take note of and learn from social aspects of implementing the PAEHR Journalen in other regions. Dutch hospitals sometimes do the latter as well, whereas technical collaboration appears limited. Even though the majority of Dutch hospitals use one of two large EHR systems and their corresponding patient portal, the implementation of VIPP in practice is dependent on more factors such as the pharmacy's medication system. Learning from peers' implementations seems to be very valuable, but has not been mentioned in literature, as a factor playing a role in the implementation process. Concerns about privacy, security, and authentication are recurrent barriers in literature (4, 14, 17, 27, 29), which are surprisingly not mentioned by the respondents in this study. The only barriers related to this domain were about the existing regulations or solutions being too strict and therefore impeding user-friendliness and PAEHR usage.

Patient Involvement

The most prominent difference in patient involvement between the two countries is not the reasons for or means of doing it but rather the level on which it is performed. The wishes and preferences of Swedish citizens have been studied and known from the beginning of the PAEHR Journalen's development. Until the new version of the NRF came into place, these preferences had, however, not been taken into account. This is due to the compromises that had to be made between patients' and HCPs' preferences in the development of both the national NRF and regional adaptations of the NRF. The new NRF that was agreed upon in 2016 stipulated that the regions should make all information available without delay by 2020, in accordance with the patients' preferences (34). This is, however, still not the case, and there are so far no consequences for not complying nor incentives to comply. There was little to no patient involvement in developing the Dutch national PAEHR policy, VIPP. Individual hospitals, however, make large efforts in involving users in the development and implementation of their patient portals and even perceive this as a prerequisite for accomplishing VIPP's goals. When doing this, hospitals face different barriers that can be roughly divided into two categories. The first is related to finding the right number of users that are not just willing to participate but also have the right mindset and can together represent the hospital's patient population. The second encompasses barriers that are related to the project itself. These include not having enough time or other resources for patient involvement or not being able to meet the patients' wishes and requirements from either a technical perspective or because there are just too many different wishes and requirements to take into account. Another barrier that cannot be categorized in the previous two groups but that is unforeseen enough to mention is

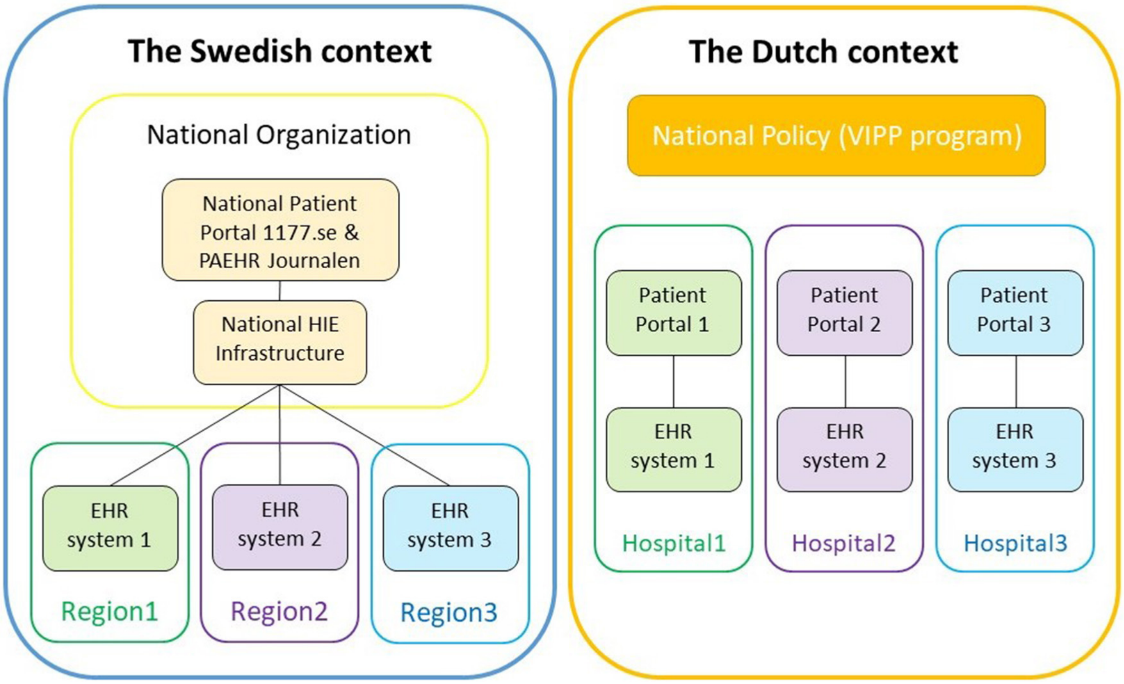

FIGURE 3 | Difference between Sweden's centralized solution and the Netherlands' decentralized.

VIPP itself. The program was set up as an incentive to implement (valuable) PAEHRs, but hospitals report that its technical focus leaves no space for patient involvement.

Centralized vs. Local Implementation in Practice

One of the most important differences between the Swedish and the Dutch contexts is the centralized approach to PAEHR implementation taken in Sweden *vs*. the local implementation in the Netherlands. **Figure 3** gives an overview of the difference.

The centralized solution requires, of course, an agreement from all local healthcare providers (in Sweden, the 21 regions and private healthcare providers) to be integrated with the same infrastructure. It has the added benefit for patients in that they only have one access point; even if they move between regions, their data will be in the same patient portal. The distance between the local implementers and the developers of the national patient portal and PAEHR is, however, quite vast, and it is not easy to make local adaptations or pilot new innovative solutions locally.

The decentralized solution, on the other hand, puts all the responsibility of the development of new patient portals and PAEHRs on the local healthcare providers (hospitals in the Netherlands) and requires quite a commitment on their behalf to actually go through with the implementation. As a patient, you may also have to use different portals if receiving care from different healthcare providers. On the other hand, having a closer distance between the local organizations (the hospital and EHR vendor) may facilitate more rapid development and testing of useful functionality, and a variation in PAEHRs could allow for competition and improvements.

Strengths and Limitations

The strength of this study is that policymakers and implementers were chosen as respondents, while previous studies have mainly focused on the viewpoints of patients and/or HCPs.

Limitations include the sampling method and conduct of the interviews. Even though attempts were made to interview as many respondents as possible, the respondents were sampled though convenience sampling, and it was not investigated how well the implementers represented the whole implementation level in both countries, yet a limited number of people have deeper insights into the implementation process and the individuals interviewed in each context can be considered experts. It is important to note also that the respondents from the implementation levels from both countries were implementing PAEHRs in different settings within healthcare. The interview respondents that implement VIPP all represent hospitals, while Swedish county councils that implement Journalen are responsible for all levels of healthcare. This may, of course, influence the experienced barriers and facilitators, similar to the way other contextual differences do. Some Swedish respondents were offered to answer the interview questions *via* email in Swedish, even though the researcher responsible for data collection was not proficient in this language. The answers were translated together with the last author (who is a native Swedish speaker), yet the email interview format led to less detailed questions and answers than in other interviews. However, the respondents' expertise was considered important, and their answers confirmed results from the more in-depth in-person interviews.

CONCLUSION AND RECOMMENDATIONS

Most of the major barriers and facilitators that have been mentioned by the PAEHR policy developers and implementers are covered in existing literature, even though previous research generally looked at the viewpoints of patients or HCPs. Our research identified factors that can be seen as more practical and that would not have arisen from interviews with patients or physicians. These include barriers from IT systems and vendors of these systems and the facilitating effect of learning from peers' implementation experiences. While previous literature often mentions concerns about privacy and security as a barrier, this has not been reported by the respondents in this study. We therefore conclude that the factors that affect the PAEHR development and implementation process can differ from the factors that are reported in literature.

We would recommend anyone preparing to implement PAEHRs on a national level or locally in a healthcare organization to consider the factors described in this study when developing and implementing both policy and patient portal/PAEHR. Policy developers can keep the barriers in mind and pave the way for the mentioned facilitators. More specifically, they can consider attaching incentives or penalties to the policy or capturing it in law in order to save resources needed to convince HCPs during implementation. In addition, thoughts can be put into facilitating peer learning among implementers and leaving both room and resources for patient involvement. Implementers should mainly focus on strong leadership, decision-making, and project management, being open to learn from others and allocating resources to possible necessary changes to work practices.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because the data consists of qualitative interview transcripts, and we do not consider this appropriate to make accessible outside the original study. Requests to access the datasets should be directed to maria.hagglund@kbh.uu.se.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

CC, RC, and MH participated in the design of the study and analysis of the interviews. CC was responsible for data collection and transcribing of interviews. All the authors participated in the writing of the paper, with CC and MH taking the main responsibility.

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Non-use of Digital Health Consultations Among Swedish Elderly Living in the Countryside

Sara Landgren[1]* *and Åsa Cajander*[1,2]

[1] *Department of Informatics and Media, Uppsala University, Uppsala, Sweden,* [2] *Department of Information Technology, Uppsala University, Uppsala, Sweden*

Digital health consultations in primary care have the advantage of offering equal healthcare for people residing in the countryside. While it is gaining acceptance among young- and middle-aged people, the elderly are reluctant to use it. The aim of this study was hence to identify reasons for non-use among elderly in the countryside and describe perceived possible challenges and opportunities with digital health consultations. Semi-structured interviews were conducted with 13 persons over 65 years old residing in the Swedish countryside. There was a mistrust for services offered by private companies and their public funding, a lack of knowledge of available services, and a lack of perceived usefulness. Personal interaction and continuity was more important than time or travel conveniences, although these advantages were recognized. To prevent digital exclusion, caregivers need to offer information, encouragement, or tools for the elderly. Digital primary care also needs to offer familiarity, with continuity and personal connections.

Keywords: e-health, digital health meeting services, digital healthcare, primary care, elderly, rural, countryside

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Nasim Bergman Farrokhnia,
Karolinska Institutet (KI), Sweden
Priyamvada Paudyal,
University of Sussex, United Kingdom

Correspondence:
Sara Landgren
landgrenmsara@gmail.com

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INTRODUCTION

An unprecedented development and innovation in e-health has resulted in the creation of new ways of delivering different kinds of healthcare digitally (1). Among the driving factors for this rapid development lie promises of increased healthcare equality, efficiency, and cost-effectiveness (2). Another potential advantage, which due to the ongoing COVID-19 pandemic, has been made notably relevant, is the possibility to deliver healthcare to those in need while protecting patients and staff from infection. Indeed, healthcare providers worldwide have been quickly changing their healthcare delivery, with digital video consultations that have been of particular interest (3, 4). This advantage is essential in protecting the most fragile population, namely those with underlying conditions and the elderly (5). Moreover, those residing in more rural areas, with limited healthcare availability nearby and long distances to specialized care, stand to benefit the most from this development (6).

With technological advances, many new digital healthcare services have emerged in Sweden in the last few years (7). Examples of these services are video and chat services used for consultation in primary care (8), (from now on referred to as *digital health consultations*). These services were initially introduced by private care providers (9, 10). In response, an increasing number of public health care providers have introduced digital services to complement their traditional offerings (11, 12). In addition, many regional councils in Sweden have already implemented, or are developing proprietary digital primary care applications or collaborating with private providers (13). The Swedish government recognizes this as a possible way to shorten waiting times, and is in the process of supporting and aiding the regions with developing these solutions together with 1,177 Vårdguiden (14).

However, the emergence of these ventures in Sweden has not been without controversy. Criticism has been raised regarding private care providers receiving financing and profiting from public funding (15). Another, perhaps more essential criticism, is that these services cater primarily to the younger, technologically competent, and healthier individuals (16). Recent numbers support this, showing that few elderly (65+ years old) use these services (8). Perhaps unsurprisingly, the elderly are often amongst the late adaptors in new technology implementations, which is frequently attributed to reasons such as "computer anxiety" and poor understanding of usefulness (17–19). This can result in "digital exclusion" amongst some elderly (6, 20). Thus, despite the elderly in Sweden having higher digital skills and using internet comparatively more than in most other countries (21, 22), they still risk digital exclusion (20). This is unfortunate, as these services offer the potential to alleviate a significant problem, excluding rural residents from access to equal healthcare. Furthermore, rural areas often lack healthcare infrastructure and access to specific specialist competence (23). The problem is exacerbated by the fact that the rural population is growing older and is generally poorer than urban populations (18, 24). The challenges above make it imperative to understand why the elderly are not using these services, particularly in rural areas. Studying this is of utmost relevance for potentially more significant societal benefit. It can offer insights into how to deliver equal healthcare, and the field of e-health and Human-Computer Interaction (HCI).

A recent Swedish study on elderly patients with chronic diseases attitudes toward different digital service tools in primary care gives us some insights on this topic; most seemed satisfied with the present primary care model and did not see a need for digital devices (25). There was also a mistrust in poorly designed IT systems and doubts about their abilities to cope with technology. However, they were somewhat curious about learning more. However, to our knowledge, no study has examined the opinions and attitudes toward digital health meeting services of elderly residing in rural areas who lack prior experience.

HCI is a broad field encompassing various topics relating to human behavior and technology, often focusing on technology users (26). Granted, this is fine for gauging and evaluating various phenomena relating to how people perceive and use technology. However, an important and often underappreciated part of HCI is the non-use; partly, as non-users can be considered as potential users, but perhaps more importantly, they harbor information on what makes them non-users. This, as non-use often, is not a passive process but instead motivated, considered, and meaningful (26). The elderly often belong to late adaptors, and digital care has particular difficulties reaching this population.

The primary focus of the research is hence to examine the thoughts and opinions of elderly persons (over 65 years old) living in Swedish urban countryside, who lack prior experience with digital health meeting services; in order to define reasons for their non-use, explore their attitude toward digital technology and opinions on traditional contacts, and identify and describe what possible challenges and opportunities for digital health meeting services that they see. The research questions addressed are:

- What factors contribute to the non-use of digital health consultations among the elderly in rural Sweden?
    - What are the general attitudes toward digital technology?
    - What are the opinions on traditional ways of primary care consultation?
    - What challenges and opportunities do the elderly in rural areas see with digital health consultations?

BACKGROUND

Elderly and Technology

Several studies have been conducted throughout the years concerning technology and the elderly. They have given us insights into the difficulties in reaching user acceptance amongst them (19, 27, 28). Consistent in many of these studies, perceived usefulness and perceived ease of use are of great importance for use intention. Perceived usefulness is lower in the elderly as they often weigh in what it takes to learn the new technology (19). However, skills in digital technology are becoming more of a need rather than a choice as technology continues to develop (29). Accordingly, one study suggests that there should be strategies for developing skills and self-efficiency among older adults (29). Another study reveals the importance of providing training tools or support services when developing new technology (30).

Other factors have been suggested as barriers causing difficulties. One recurring theme is the fear of failure or lack of confidence in using new technology, sometimes dubbed "computer anxiety" (17, 19, 31, 32). In a study about technology acceptance among elderly and young adults, older people, in general, had a higher need for assistance and encouragement than younger generations (28). This is consistent with results from another study, where elderly persons were found to perceive computers as the domain of younger generations (31). It is essential to understand what factors underlie this anxiety and even more to understand what factors are significant in affecting their attitude and usage to tackle them and effectively design services that are likely to be used by the elderly. There is likely more at play than computer anxiety. Although, while women are less frequent than men in their use of digital technology, they show more interest in health information online (33).

Elderly and Digital Services

It is of particular interest to note studies examining the elderly's perception of other online public services such as e-banking and e-government services. These services are also intended to be aimed toward the population as a whole. While not directly comparable, they could offer valuable lessons from hurdles and potential design considerations to make the services appeal to elderly populations. In recent years, sectors such as banking have moved toward more or less total digitalization of their services in Sweden (34, 35). Many elderly are now adapting to these developments, with 60 % of the population older than 65 years having an electronic identification (called BankID) in 2019 compared to only 11% in 2015 (34–36).

Significant factors shown to influence the elderly's attitudes and intention to use services such as online banking negatively include lack of personal contact, self-efficacy, technology discomfort, and personal attributes such as age, gender, health, and poor digital skills (27, 37). Perhaps unsurprisingly, perception of safety and trust is also an essential important factor affecting acceptance in both self-service banking technologies and e-government services (37, 38). Supposedly, all of these factors could affect their perception of e-health. It is similar in many ways to other public services.

Elderly and E-Health Services

Previous national and international studies have provided insights into some barriers preventing the elderly from adapting to e-health services, but further research is warranted (31, 32, 39). Consistent with these studies on user acceptance, the elderly use e-health services less frequently than young people (8, 40). In addition, low confidence is more common amongst the elderly than young people when using e-health services (17). Confidence and digital technology skills are recurring themes in the literature on e-health, with the elderly often doubting their skills when facing new technologies (41). Nonetheless, low confidence and computer anxiety aside, the elderly still use the Internet more to research health information than young people (17). Like the previous mentioned studies on electronic government services and online banking, trust in technology is essential for the elderly when using e-health services (41, 42).

In a recent literature review on older people and e-health, several barriers were identified to explain the non-use of e-health services; amongst these were impaired sensory, motor, and cognitive performance (41). These are essential aspects to consider, as many elderly persons might perceive digital healthcare solutions as positive but may also be too weak or sick to understand and correctly use them (43). This is suggested in a study about video consultations in primary care, where hearing impairment was a problem for some elderly (43). Thus, the users cognitive and health status should be considered in the design process, more so in e-health applications than most other services. Failing to address this may result in creating an even bigger digital and social exclusion (6). Indeed, it may be necessary to use specific strategies to undertake the distinct needs of people in various age groups, as suggested in a recent study (17).

Digital Health Consultations

There are currently numerous digital services in Sweden that can be referred to as e-health services; for instance, access to medical records and information online, online booking systems for healthcare, and digital consultations (7). However, in this paper, digital health consultations will only refer to the video and chat consultations used in primary care offered by private and public care providers.

The development of digital health consultations in Sweden has been increasing rapidly in the last few years (10). Being the first to implement digital health consultations, private care providers are unsurprisingly behind the majority of this increase, with the regions now attempting to catch up (10, 14). When private care providers started to offer these services, they became part of Sweden's public health offerings, which made them accessible to the whole population and granted access to public financing (10). However, as the number of these services increased rapidly, costs spiraled for some regions, and the "exploitative" business models of private care providers were publicly criticized through various media outlets (44, 45). As a result, the Swedish government formulated guidelines stating requirements that digital health consultations need to fulfill to receive compensation and limitations on charging (10).

Both chat and video consultations are offered through both mobile applications and web platforms. These services are commonly used when patients have questions about their condition, follow-ups after medical ordinations, and general consultations and diagnosis (46, 47). Although different providers utilize different ways to access their services, commonly, the patient signs in to the application or web platform with a mobile electronic ID (BankID), then answers questions and describes their issue before receiving a video call back in the application (48).

One study found that young and old patients familiar with text messaging were equally willing to adapt to the technology for communicating in text with their doctor (49). This is interesting since a recent Swedish study published in collaboration with SKL (Sweden's Municipalities and Counties) shows that the usage of digital health consultations differs significantly depending on age (8). The authors examined how inhabitants used digital health meeting services in the Swedish county of Jönköping between September 2017 and January 2019. They found that usage was highest among children, that usage continues to be high amongst young adults but already declines to half of the numbers for the population 31–50 years old. When looking at 65+ years olds, their usage was by far the lowest with four meetings per 1,000 inhabitants (compared to 29 on average for the total population) despite representing almost a quarter of the population. While these numbers are from one county in Sweden and some local variations are likely to exist, the results should be transferable to represent the current situation in Sweden as a whole. These statistics bring up an exciting inconsistency; if attitudes might be similar between young and elderly, but usage differs significantly, what other aspects impact their usage more than their attitudes?

E-Health and Rural Areas

There is no general definition for rural areas, and they vary in literature and different countries. However, commonly an area is defined as rural depending on population and geography (33). In this context, it is shortly defined as any sparsely populated settlement outside of more urban cities.

A recent study about today's e-health solutions in Sweden has brought up the potential creation of "digital health landscapes", where geographical distances will not be of concern when delivering healthcare to patients (6). Possible positive outcomes discussed in the study were that people living in sparsely populated areas in Sweden could access equal healthcare as people living in urban areas (6). This should not be underestimated, as Swedens vast and sparsely populated geography complicates and increases the cost of delivering equal healthcare to all citizens (6). In addition, attracting competent medical staff to rural areas is often difficult and expensive (33).

While these solutions seem positive for elderly and rural residents, insights from a government study in Sweden tell us that younger people consume more e-health services than the elderly and that residents in socio-economically vital areas consume more than people living in rural areas and countryside's (18). Moreover, countryside residents' health tends to be lower in general than people residing in cities (18). However, it is conceivable that some of these services need some time on solid markets to get a higher spread in usage, with young people often being among the "early adopters" (18), meaning they are the first to use new services.

Literature also shows that video consultations might not always be the preferred method of choice for people in rural areas, with issues in image quality being of great concern (43). In addition, the same literature brought up concerns about the ability of the physician to properly understand the patients' problems when not meeting face-to-face. In another study, the authors found similar results; people in rural areas saw the distance to care as an essential factor for accessibility, but were unsure if video consultation was a suitable solution (50). The main reasons were uncertainty about what problems these consultations were ideal for and what consequences digitalization could have on existing rural primary care.

Current findings on rural aspects of e-health are indeed interesting. However, few of these focus exclusively on the elderly and digital health consultations. Moreover, no study focuses solely on these aspects in the elderly with no prior experience to the best of our knowledge. As it currently stands, the elderly who have used these consultation services belong to a minority population. Focusing on the higher number of elderly who have not used digital health consultations would arguably provide even more valuable insights, especially what factors prevent them from trying. Further, with Sweden's vast and sparsely populated geography, it is of particular interest to study non-users in the countryside. They are often restricted in their access to healthcare and potentially stand to gain the most with properly implemented digital healthcare.

Summary of Previous Literature

The elderly have been shown to have lower confidence and doubting their skills in technology than young people. Moreover, they were shown to have a higher need for encouragement than younger individuals. Despite these hurdles, skills in digital technologies were shown to be high among the elderly in Sweden, with many frequently using e-services such as e-banking today. Factors of great importance affecting elderly person attitudes toward technology and e-services were personal contact, perceived usefulness, and perceived safety and trust. When it comes to the distances (regarding rural areas), it has been recognized as an essential factor for accessibility. However, in the literature on the elderly with experience of video consultations, it was unclear whether it always is a suitable solution. There is also a lack of research on non-users.

METHODOLOGY

Data Collection

The research question was explored qualitatively through semi-structured interviews with 13 subjects belonging to the population of concern (65+-year-old individuals). It was part of a master's thesis in Human-Computer Interaction during spring 2020. The present study carries both a deductive and an inductive approach. Deductive in that the interview questions were formulated based on previous literature of relevance and inductive in that there were no strict predefined themes for the analysis, with new themes identified during result analysis (51).

Based on the research question and previous studies, an interview guide was created to formulate the interview questions. Before the primary interviews, a pilot study was conducted on three individuals (including a physician) to evaluate the questions, estimate time requirements, and prevent too complicated and/or unclear questions. Following this feedback some questions were reformulated to refrain from gathering personal medical information, redundant questions were removed and some sections were reordered for clarity. To avoid influencing the participants, no specific background information on digital health consultations was provided prior to, or during the interviews.

Sampling

A purposive strategy was used for sampling. The target population was people over 65 years old who had not used digital health consultations before and lived in the countryside of Jämtland in northern Sweden. The countryside is defined as settlements with less than 2,000 inhabitants and with 5-45 minutes of travel time by car to the nearest city. Qualitative studies with semi-structured interviews are recommended to include a sample size of 5–25 (52). This study aimed to interview at least 12 people, preferably with an equal distribution of male and female participants to reach saturation.

The participants were recruited at meetings arranged for senior citizens in Swedish villages; they were presented with a written description of the study. They could express their interest in a form, where they also confirmed that they were over 65 years old and had not tried digital health consultations before. Further information was later provided to the interested, including policies on the handling of personal information. Written consent was collected from participants before all face-to-face interviews. During the phone interviews, a verbal statement was recorded and saved.

Semi-structured Interviews

A total of 13 participants were interviewed, seven of whom were female and six male. The mean age of all participants was 73, 6 years, with the female participants being slightly older than the male (mean age 74, 6 compared to 72, 5). The oldest woman was 82 years old, and the oldest male was 76. Education levels varied from secondary school and lower (9–12 completed grades) to university, with most participants having vocational education or higher. Furthermore, the entire sample population lived in countryside settlements, some of which did not offer any healthcare services, while others did. All interviews were conducted in the participants' native language (Swedish) to make it convenient for them and not miss any valuable information.

Ethical Considerations for Data Collection

The national recommendations for ethical approval have been met, and all international ethical guidelines have been followed. The interview questions were formulated to be as objective and unbiased as possible, avoiding leading questions and positive or negative connotations. To achieve this, an interview guide was constructed based on themes identified in previous literature. To further avoid irrelevant and or inappropriate questions, a pilot interview was conducted.

This study intended to gather opinions on why elderly persons residing in the countryside have not tried digital health consultations. No medical information or background was collected. The study's intention was carefully explained to the participants, including information on their right to withdraw from participation at any time, and that personal information would not be accessible to anyone besides the author of this study. Data processing and storage conforms to GDPR (ensuring adequate protection of collected personal information) (53).

Data Analysis

Thematic Analysis

A thematic analysis was conducted following Braun and Clarke (54): familiarizing with the data by transcribing and reading it through, generating initial codes, searching for themes among the codes, reviewing the themes, defining the themes, and finally selecting extract examples. All coding was performed using a qualitative analysis tool. The predefined overlaying categories based on previous studies were: *skills*, *attitude,* and *distance*. The themes that emerged from the thematic analysis were: *concerns and skepticism*, *personal interaction and continuity, knowledge,* and *perceived opportunities*. For an overview of the themes see **Table 1**.

After the analysis, the themes were grouped in a meaningful way to answer the research questions. All quotes presented in the results were initially Swedish but have been translated to English and made more readable.

TABLE 1 | Three predefined themes (skills, attitude and distance) based on previous literature.

Theme	Description of theme
Skills	Prior and current knowledge and usage of technology and e-services.
Attitude	Attitudes toward technology, digitalization in sociaty and digital healthcare.
Distance	Distance to the nearest helathcare center and availability of healthcare on the countryside.
Concerncs and skepticism	Concerns on different aspects of digital technology, the digitalization of healthcare and digital health consultations.
Personcal interaction and continuity	Views on patient-doctor interaction and the importance of continuity in healthcare.
Knowledge	Knowledge about digital health consultations; availability, how it works and when it can be used.
Perceived opportunities	Opportunities that the elderly see with digital health consultations.

Following the interviews, a thematic analysis identified (concerns and skepticism, personal interaction and continuity, knowledge and perceived opportunities). All seven themes were used in the final data analysis.

RESULT

Attitudes Toward Digital Technology

Almost all participants were using digital services daily. The two that did not were both amongst the oldest participants (both over 80 years old). These two were the only participants who did not consider themselves confident in using digital technologies such as computers, smartphones, or applications. All remaining participants considered themselves as either "pretty confident" (six participants) or "confident" (five participants).

All participants were using smartphones or computers daily. Moreover, all were familiar with sending text messages using their phone. Overall, the participants were proficient in digital technologies (such as smartphones, computers, applications), with all but two using multiple services daily. The two remaining participants were again the oldest in the study (both over 80 years old); however, they have access to technology, with one of them owning and using a smartphone and the other a computer. The 11 participants who used digital services daily commonly used social networking applications to contact friends and family. All but one used online banking services. The remaining participant relied on help from a younger relative for such errands.

Overall, most participants had positive attitudes toward digital services, describing them as valuable and time-saving. One participant describes the convenience: *"It is really efficient, I can even pay an invoice immediately when I get it. And it gets paid correctly. And I can do transfers on my bank between the accounts by myself, and that is really convenient."*

Opinions on Traditional Primary Care and Consultations

All participants traveled by car (driving themselves) to their health center when heading for an appointment. Furthermore, eight participants had over 10 km to their health center, and considered themselves dependent on their car for attending appointments. When discussing the possibilities of using public transportation, most mentioned poor public transport services that make it challenging to find a bus that would match the appointment time.

All the participants, except for one, primarily contacted their health centers via phone calls for booking appointments, with the remaining participant using the online service 1,177 Vårdguiden. The majority of the participants positively mentioned how easy it was to get an appointment at their health center. Further, some of them talked fondly of a voicemail feature that their health centers offered; when the phone line was experiencing prolonged waiting times, you could provide your personal phone number and have someone from the health center call you back at a later time. One participant explains: *"I call the health center on their phone number. Then you have to wait, but if you say your personal number, they will call you. And that works really well."*

Most participants had experience in using the online health service on 1,177 Vårdguiden for looking up their test results, book appointments, or renew their prescriptions. One of the participants expressed that he prefers to book his appointments online: *"Nowadays I don't call anymore, instead I am using Vårdguiden.. Or 1,177… Or what it is called..."*

Besides contacting the health center via phone or Vårdguiden 1,177, two participants had also booked appointments or requested contact with their physician through written notes, for example, when conducting blood pressure self-tests at the healthcare facility. One of them describes it: *"... and then you write on a note which pressure you have, and then I usually write there that I want to come in contact with my doctor."*

Some participants stated that they were connected to a personal family physician at their health center and recognized that this was of great importance. They considered it convenient and suitable for continuity without repeating their medical history with each doctor's visit. It was also perceived as more safe and trustful that the doctor personally knew them as patients. Two participants revealed that they previously had changed to health centers located further away from their residence to keep their family physicians who had changed their workplace.

Overall most participants were satisfied with the primary care, although some raised a few points and complaints. One common complaint was poor follow-up routines. Most participants mentioned that following appointments, responsibility regarding follow-ups were often placed on themselves. This included medication follow-up and prescription renewals. In instances where the health centers did reach out to them, the communication was conducted through written letters or phone calls. One participant expressed himself positively about the transition to increased digital communication: *"They send letters, which I think is a little unnecessary today. But, I think they are changing a little and sending calls or follow-ups digitally, and that is way better."*

Reasons for Non-use and Current Challenges

No participants included in this study had any prior experience with digital health consultations. To delineate possible reasons for this, their knowledge of and attitudes toward these types of consultations were explored.

Regarding knowledge of available digital health consultations services, most participants mentioned that they had seen ads for private companies offering this. Some responded that they knew nothing about how it works. Two said they imagined it being similar to other text messaging or video conferencing applications. No participant was aware of publicly financed digital healthcare. No one had any knowledge if their health center offered such a service. The participants, in general, did not know much about these services, how they work, and who is providing them. Thus, they were described to them in more detail.

Most participants were content with the current status of the primary healthcare system, and a few noted that they had not felt the need for using a digital alternative. Some participants stated that they had not engaged in the development of digital health consultations. One of them felt he lacked the energy and motivation to do so. Some participants also believed digital health consultations were a generational matter, not designed for the elderly population. One participant expressed: *"For the people who are working in this digital world, this is a meeting for them [...] So I believe it is really a generation thing."*

The participants shared some concerns and fears for the concept of digital health consultations, either about themselves or based on thoughts about other elderly. A commonly raised concern was that older people have difficulties using various digital technologies. Some participants believe that many elderly are afraid of these types of developments. A few participants raised concerns that users need to be technologically knowledgeable to use these kinds of healthcare services. Some were afraid that they would not be able to keep up and use it when getting older. Two mentioned that relatives might be able to help with potential technical difficulties; one of them said that she was concerned that the elderly might get left behind and excluded in the digitization of healthcare. She also believed that the elderly should receive financial support to purchase a computer and be offered education on digital technologies. The participant stated she would be interested in such an education. Lastly, a few participants were concerned that the increase in digitization of healthcare might lead to reduced employment in traditional healthcare.

One relatively common concern was the physician's feasibility to properly examine and derive a diagnosis without meeting the patient in real life. Most participants raised this concern, where one of them said: *"It feels like it can be a little difficult to get a correct diagnosis… Just with a camera or an app… Even though you sit there and talk. It would feel safer to sit and talk with a doctor eye to eye"*.

Some participants displayed various degrees of skepticism toward digital health consultations since they felt that these types of meetings were too impersonal. One participant considered himself too conservative.

By far, the most common reason for skepticism toward digital health consultations was financing. Many participants were very concerned about private care providers profiting from these consultations by charging the region. They had either heard from others or read themselves from news sources that private care providers were exploiting the reimbursement system for these consultations and wished to take a firm stance away from this; *"You get a notification [from a news service] on your phone that… 'Don't use that; it costs this and that'… So I have thought that 'no, this is something I probably will never use', because I don't want it to cost as much as it says [for the region]."*

Most participants that were skeptical about private care providers said that they could imagine themselves using this type of service if it was publicly controlled and preferably connected to their current health center. The remaining participant, while recognizing this type of solution as something positive, was still reluctant to consider trying it themselves as personal contact was too essential to overlook: *"It should be governed by public health care institutions, that there are no private companies. Then I think* *it is positive, but I will never use it [...] because I want to have a personal meeting, I think it is really important."*

Perceived Opportunities and Desires

Despite the concerns and skepticism outlined in the previous sections, the general attitude toward digital health consultations was positive. Given that their primary concern of private care providers profiting from digital health consultations was addressed, or public alternatives were made more broadly available (mainly, if the participants' own health centers would implement digital consultation features), most participants could see benefits and consider utilizing digital consultations. The majority of the participants responded that they believe digital health consultations are, or can be positive. All of them saw convenience and the potential to save time as the main advantages. In addition, one participant identified the potential benefit of a lessened risk of infection from other patients when conducting digital consultations.

As previously mentioned, all participants were reliant on their vehicle for transportation to health consultations; most participants thus recognized digital health consultations having the potential of being particularly beneficial for people residing in more isolated rural areas. For some, the ordeal of traveling to their health center or hospital for a short visit could take the whole day. Some pointed out that sufficient internet connectivity is crucial to benefit from digital health consultations but is not always available. A few also pointed out and recognized that while they may be independent now, their situation might change in the future, preventing them from driving, which made digital health consultations seem more alluring to them in the future.

Continuity was essential to the participants, most of whom preferred having repeated contacts with the same physician. They said they feel safer when the doctor knows them. However, opinions differed significantly between the participants. At the same time, two claimed that they would go as far as to change their health center to stay with the same physician. Others felt that continuity was not always necessary (particularly in more urgent situations). Many participants could see themselves using digital health consultations, but having their own family doctor and health center was a decisive factor for many and preferred amongst most others.

The importance of personal contact was a common theme throughout the interviews. Most participants reported that personal contact (in various forms and degrees) is essential to them. For example, one participant reported favoring waiting in a physical waiting room over waiting on the phone, mainly because of the human contact and interaction. Another participant did not mind phone meetings, but did not care for digital booking solutions through 1,177 Vårdguiden due to the lack of personal interaction. Some participants said eye contact was of particular importance for meetings in a healthcare setting. Reasons for this, amongst others, were that it allows for non-verbal communication of empathy and compassion and can signal mental or health status. Related to this, one of the participants brought up the importance of a pleasant treatment when in contact with the healthcare provider, implying that this is of greater importance than the mode of contact: *"If you only get a friendly response, then it doesn't matter if I see the person or not. If I get properly cared for over the phone, and they understand what I mean, then it is totally fine I think"*.

If they were to use digital health consultations in the future, most participants stated that they would prefer video calls over chat. The main reason for this being that it feels more personal and allowing for eye contact with the healthcare worker. Moreover, several participants saw that this would also aid in the physical examination. A few participants reported that they would prefer using a computer over a smartphone in such a meeting. The primary reason for this was a perceived lack of proficiency in using smartphones, mainly in slow typing speeds. In addition, the participants attributed to the small size on smartphone keyboards. The participants who were open to chat meetings with their health care provider could only consider this on the computer. A few participants preferred using a smartphone application, mainly as this was perceived as more flexible than using the computer.

Some participants brought up requests and desires for the functionality of a digital healthcare application. All were in some form related to the contact with the physician; a few wished to choose whether to book a digital meeting with their family physician or reach any doctor immediately for an urgent consultation. Another participant wished for an easy way to contact the consulting physician afterward if any questions arose. The last participant wished that digital services would offer follow-ups by the same healthcare personnel, similar to how it works currently in physical health centers.

DISCUSSION

This study aimed to identify reasons for the non-use of digital health consultations among the elderly in the countryside, and describe their perceived possible challenges and opportunities. As a result, several interesting insights were gathered by interviewing 13 persons belonging to this population in a semi-structured and qualitative manner. While some previous findings were confirmed, others were of lesser importance in this population, and some new aspects were discovered.

Indeed, the most commonly stated reason for the non-use of digital health consultations was the matter of its funding. This view coincides with the primary general critique that private digital healthcare has received in Sweden (44, 45). This suggests that the same factors affect both the opinions of younger and older populations in some ways. Granted, this opinion may have less of a deterring effect on younger individuals. Nevertheless, most interviewed participants were uneasy supporting private healthcare providers because their financing was sourced from public healthcare funds. An inherent limitation of the current study is its somewhat limited sampling heterogeneity, as all participants originated from the same county and shared many interests and views. This topic needs to be further investigated since opinions could vary in different regions and these findings. Moreover, healthcare in Sweden has recently been more or less exclusively public. The recent upswing of private care providers in Sweden has been perceived as daunting by many (15). Thus, this reason for non-use likely would not translate well compared to countries where private and public healthcare coexists, or is dominated by private providers. Besides this, the other main reason for skepticism and non-use was concerns regarding personal contact and interaction.

Overall, personal contact with the healthcare provider and treatment was deemed as more critical than conveniences. For example, multiple participants were prepared to travel a further distance for a physical meeting with someone they were more comfortable with. With that said, most participants were also open to putting aside their reservations and trying digital health consultations, mainly if they were possible to conduct with their current physician. Literature has shown that a lack of personal contact negatively influences the acceptance of e-services by the elderly (37). Similarly, the participants in this study thought that personal contact was more valuable than the potential saved time and efficiency it could offer.

Somewhat related, the aspect of continuity was decisive for many participants. Here again, they expressed a desire to consult their physician whom they trust, who is familiar with their medical history, and who knows them on a more personal level. The participants perceived private care providers to have limited possibilities to offer such services. If their health centers would offer digital consultations, this barrier of perceived impersonality and mistrust could be more easily overcome. Here, education and knowledge of current offerings also come into perspective. Many public health centers are already offering some digital services. However, private care providers where the first to reach the market and are overrepresented in marketing, overshadowing and obscuring the perception of what is available.

Another substantial reason for non-use among the participants was the lack of perceived usefulness. They were satisfied with how their contact with primary care today and failed to see any potential improvements digital healthcare could bring. Of course, the time required for learning a new technology is a factor for the perception of usefulness (19). However, in the current study population, this was generally not the case. Instead, it was the perceived lack of personal contact and lack of safety and trust (especially for private care providers) that affected their opinions on digital healthcare. For instance, most participants could see numerous benefits that digital healthcare could bring, such as increased practicality, saved time, improved healthcare coverage (especially for more isolated rural/countryside residents), increased flexibility, and decreased risk of infections. Nonetheless, the perceived lack of sufficient personal contact and mistrust for private care providers outweighed most practical benefits. These are exciting findings, as one might expect that aging rural residents with poor public transportation availability and a dependence on personal transportation by car would value these aspects higher and consider digital services more valuable.

Literature showed that trust in technology's integrity and safety is essential (42), which was not considered a concern among this study population. Most participants believed it was essential to feeling that the healthcare workers in digital healthcare were competent, caring, had access to their medical records, and genuinely interested in helping. Indeed, emotional investment and good contact with the treating physician appear to be decisive factors for elderly persons' commitment to use digital health consultations. One hurdle might be the overrepresentation of private ventures, as many participants expressed mistrust for these. So, if the patients could contact their health center and physician that they trust and recognize, many participants were open to trying digital health consultations. As more public caregivers are implementing digital services, it will be interesting to see if this has an impact on their usage. The importance of personal contact and emotional investment from the care provider reflects the participants' preferences for digital contacts. A vast majority prefer video calls over chat.

Multiple participants expressed concerns about the healthcare workers' abilities to properly examine and diagnose the patient by digital means, which concurs with what previous literature found when they studied video consultations in primary care (43). Again this partially stems from preconceptions and poor understanding of what types of consultations can be conducted through video calls and chat.

Previous literature suggests computer anxiety to be one of the main reasons for elderly's reluctance to adapt to new technologies (17, 19, 31, 32). Somewhat surprisingly, this was barely an issue at all with the study population. Almost all participants were very comfortable with modern technologies. The two oldest participants (who were both in their eighties) did express some anxiety but were still optimistic about the idea and open to learning more and trying digital health consultations if only some assistance were offered at first.

As the participants have sufficient skills in using digital technology, and in a broader sense, are favorable to increased digitization of public healthcare, a reasonable first step could be to increase their knowledge on and comfort with digital health consultations and services. This process needs to be gradual to prevent causing exclusion and paralleled with ample information and education. Essential to consider here is also which type of communication channels are offered to elderly patients. The participants perceived smartphones as small and expressed difficulties with writing quickly, such as in a chat. Video calls could thus be a more preferred mode to contact healthcare digitally. Although the elderly in Sweden have high digital skills (22), as was the case for the participants in this study, it is conceivable that attitudes and literacy could differ in a broader study.

At the time of writing, the global COVID-19 pandemic is ongoing, bringing numerous consequences and altered recommendations, particularly for the elderly (5). The interviews in this study were conducted before the mass outbreak in Sweden. Since then, persons above the age of 70 were recommended to self-isolate as they were considered risk groups (5). However, even before the pandemic outbreak, some participants recognized the benefits of a lessened risk of infection with digital health consultations. Even without ongoing pandemics, the yearly influenza outbreaks are coupled with an increased death rate among the elderly (55).

Earlier findings on technology acceptance have suggested that the elderly are in greater need of encouragement and assistance (28). While this might seem obvious, there is still much that can be done. For instance, there was a general lack of knowledge and information on digital care amongst the study population. General news media was their primary source of information. With digital healthcare expected to increase in prevalence (14, 56), explicit measures must be taken to include the elderly in this expansion, seeing that it is unlikely that they will spontaneously find the motivation to adapt to this new and foreign concept of care.

The study population pointed out a lack of follow-ups in the current primary care. This could be one opportunity to integrate the elderly more into the digitization of healthcare. For example, follow-ups that do not require extensive physical examination could be offered through a video call. These types of meetings could allow the patients to familiarize themselves with the concept of digital health consultations and intuitively learn its possibilities and limitations without the personal and emotional stress of a regular, more severe, and urgent visit. While there is no guarantee that this would affect their behavior, based on the insights gathered from the current study population it seems to be an appropriate first step that could be interesting to evaluate on a smaller population.

Efforts must be made to adapt digital care not only to the potential needs and limitations of the elderly but also to prevent exclusion. No matter how digitally literate and confident, the elderly cannot be expected to integrate and come to digital care themselves - digital care must come to them by being inclusively structured with their preferences and opinions in mind. In addition, special considerations must be made for the aging populations in rural areas, with the potential limitations such as internet connectivity - as was brought up by some participants, despite themselves not suffering from that problem. This is perhaps the issue; today's elderly are technologically competent and open to digitalization. Their reasons for non-use of digital health consultations appear to match the general issues and critiques of the population. Howver, there is an evident lack of information on availability and options and encouragement from public care providers.

While it is of particular importance in today's global situation to protect our elderly, we should feel motivated to do so at all times. Thus, care providers could take more responsibility and encourage digital care if they wish to transition into more digitilized healthcare. With the elderly in the present study expressing trust in their current health centers and physicians, public care providers should acknowledge this trust when implementing digital services, not doing it carelessly, and providing ample support and knowledge. With good information and methodological introduction, the elderly can become familiar with digital health consultations and can accept it, at least based on the opinions and insights gathered from the current study population.

LIMITATIONS

As both the field of e-health and the technological competence amongst the elderly rapidly advances, early studies lose their relevance and ability to be generalized in current times. Moreover, different populations, access to the internet, personal computers, and smart devices should be kept in mind when studying international literature. In international comparisons, Sweden is frequently at the forefront regarding internet usage and digital skills amongst the elderly (21, 22).

This study does not fully capture all aspects of digital health consultations as the participants lack prior experience with such services. Furthermore, the elderly (65+ years old) is a vastly heterogeneous population. While the needs of some individuals might correlate with those of younger populations, but as age increases, so does the relative proportion of people with different healthcare requirements. For example, this study population was dependent on driving but could do so independently. Moreover, the definition of countryside can vary greatly. It would thus be interesting to look more into the opinions of the elderly who are more dependent on public transport or help from others and those residing in more isolated rural areas. Finally, as mentioned, the opinions on private care providers might also be specific to this study population and primarily limited to Sweden.

CONCLUSION

This study aimed to identify reasons for non-use of digital health consultations among the elderly in the countryside and describe their perceived possible challenges and opportunities. Based on the analysis of 13 qualitative interviews, some conclusions can be drawn.

The main reasons for non-use were: (1) concerns regarding the funding of digital health consultation services and mistrust for private care providers, (2) a lack of knowledge of available services, both from their health center, public providers, and on what types of consultations were possible, and (3) a lack of perceived usefulness as they felt satisfied with their current form of primary care and were unphased by current limitations such as distance.

Regarding challenges, personal interaction and continuity were deemed more important than potential conveniences. There was also a general skepticism in the platform's capabilities of allowing the physician to conduct a proper examination or recognize their problems. Furthermore, there was a fear of increased complexity that could result in future exclusion provided that they do not cope with the technical development.

The participants did recognize numerous opportunities; most were avid users of digital technologies and services and were open to trying digital health consultations given that their current healthcare provider offered it. They were open to the concepts of both computer and phone application based meetings, with a general preference toward video consultations as they offer to preserve the feeling of personal interaction that they value. Computers were most often preferred over smartphone given the larger keyboard and screen size. The participants could also recognize the potential benefits of digital health consultations, such as increased convenience, time-saving and lessened risk of infection.

Future Work

Future research on a broader population of non-users, with a higher inclusion of very isolated rural residents and persons being more dependent on public transportation or the help of others, would be warranted to expand on the findings. Moreover, research on rural areas following the impact of the ongoing COVID-19 pandemic that has brought on new recommendations for the elderly and rapidly increased public healthcare digitization will be highly relevant.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SL and ÅC designed the study. SL conducted the interviews, collected and analyzed the data. SL wrote the manuscript with support from ÅC. Both authors reviewed and approved of the final submission.

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Elena+ Care for COVID-19, a Pandemic Lifestyle Care Intervention: Intervention Design and Study Protocol

Joseph Ollier[1]*, Simon Neff[2], Christine Dworschak[3], Arber Sejdiji[2], Prabhakaran Santhanam[1], Roman Keller[4], Grace Xiao[5], Alina Asisof[1], Dominik Rüegger[1], Caterina Bérubé[1], Lena Hilfiker Tomas[6], Joël Neff[6], Jiali Yao[4], Aishah Alattas[4], Veronica Varela-Mato[7], Amanda Pitkethly[8], Mª Dolores Vara[9,10], Rocío Herrero[9,10], Rosa Mª Baños[9,10,11], Carolina Parada[12], Rajashree Sundaram Agatheswaran[13], Victor Villalobos[14], Olivia Clare Keller[1,15], Wai Sze Chan[16], Varun Mishra[17], Nicholas Jacobson[18], Catherine Stanger[18], Xinming He[19], Viktor von Wyl[20,21], Steffi Weidt[22], Severin Haug[23], Michael Schaub[23], Birgit Kleim[3], Jürgen Barth[24], Claudia Witt[24], Urte Scholz[25,26], Elgar Fleisch[1,4,15], Florian von Wangenheim[1,4], Lorainne Tudor Car[4,27], Falk Müller-Riemenschneider[28,29], Sandra Hauser-Ulrich[30], Alejandra Núñez Asomoza[31], Alicia Salamanca-Sanabria[4], Jacqueline Louise Mair[4] and Tobias Kowatsch[1,4,15]

[1] Centre for Digital Health Interventions, Department of Management, Technology and Economics, Eidgenössische Technische Hochschule (ETH) Zurich, Zurich, Switzerland, [2] Department of Management, Technology, and Economics, Eidgenössische Technische Hochschule (ETH) Zurich, Zurich, Switzerland, [3] Department of Psychology, University of Zurich, Zurich, Switzerland, [4] Future Health Technologies, Singapore-ETH Centre, Campus for Research Excellence and Technological Enterprise (CREATE), Singapore, Singapore, [5] School of Medicine, Johns Hopkins University, Baltimore, MD, United States, [6] Executive School of Management, Technology and Law, University of St. Gallen, St. Gallen, Switzerland, [7] School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, United Kingdom, [8] Sport, Exercise and Health Sciences, Edinburgh Napier University, Edinburgh, United Kingdom, [9] Polibienestar Research Institute, University of Valencia, Valencia, Spain, [10] Centro de Investigación Biomédica en Red de Fisiopatología de la Obesidad y Nutrición (CIBERObn) Physiopathology of Obesity and Nutrition, Instituto de Salud Carlos III, Madrid, Spain, [11] Department of Personality, Evaluation and Psychological Treatment, Faculty of Psychology, University of Valencia, Valencia, Spain, [12] Department of Psychology, Universidad San Buenaventura, Bogotá, Colombia, [13] National Institute of Education, Nanyang Technological University, Singapore, Singapore, [14] Interdisciplinary Center for Health Workplaces, University of California, Berkeley, Berkeley, CA, United States, [15] Centre for Digital Health Interventions, Institute of Technology Management, University of St. Gallen, St. Gallen, Switzerland, [16] Department of Psychology, University of Hong Kong, Pokfulam, Hong Kong, SAR China, [17] Department of Computer Science, Dartmouth College, Hanover, NH, United States, [18] Center for Technology and Behavioral Health, Geisel School of Medicine, Hanover, NH, United States, [19] Business School, Durham University, Durham, United Kingdom, [20] Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland, [21] Institute for Implementation Science in Health Care, University of Zurich, Zurich, Switzerland, [22] Department of Psychiatry, Psychotherapy and Psychosomatics, University of Zurich, Zurich, Switzerland, [23] Swiss Research Institute for Public Health and Addiction, University of Zurich, Zurich, Switzerland, [24] Institute for Complementary and Integrative Medicine, University Hospital Zurich, University of Zurich, Zurich, Switzerland, [25] Applied Social and Health Psychology, Department of Psychology, University of Zurich, Zurich, Switzerland, [26] Dynamics of Healthy Aging, University of Zurich, Zurich, Switzerland, [27] Family Medicine and Primary Care, Lee Kong Chian School of Medicine, Nanyang Technological University, Singapore, Singapore, [28] Department of Medicine, Saw Swee Hock School of Public Health, Yong Loo Lin School of Medicine, National University of Singapore, Singapore, Singapore, [29] Center for Digital Health, Berlin Institute of Health and Charité, Berlin, Germany, [30] Department of Applied Psychology, University of Applied Sciences Zurich, Zurich, Switzerland, [31] Unidad Académica de Cultura, Universidad Autónoma de Zacatecas, Zacatecas, Mexico

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Edited by:
Hanife Rexhepi,
University of Skövde, Sweden

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Angel Enrique Roig,
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Tahreem Chaudhry,
University College London,
United Kingdom

****Correspondence:***
Joseph Ollier
jollier@ethz.ch

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Background: The current COVID-19 coronavirus pandemic is an emergency on a global scale, with huge swathes of the population required to remain indoors for prolonged periods to tackle the virus. In this new context, individuals' health-promoting routines are under greater strain, contributing to poorer mental and physical health. Additionally, individuals are required to keep up to date with latest health guidelines about the virus, which may be confusing in an age of social-media disinformation and shifting guidelines. To tackle these factors, we developed Elena+, a smartphone-based and conversational agent (CA) delivered pandemic lifestyle care intervention.

Methods: Elena+ utilizes varied intervention components to deliver a psychoeducation-focused coaching program on the topics of: COVID-19 information, physical activity, mental health (anxiety, loneliness, mental resources), sleep and diet and nutrition. Over 43 subtopics, a CA guides individuals through content and tracks progress over time, such as changes in health outcome assessments per topic, alongside user-set behavioral intentions and user-reported actual behaviors. Ratings of the usage experience, social demographics and the user profile are also captured. Elena+ is available for public download on iOS and Android devices in English, European Spanish and Latin American Spanish with future languages and launch countries planned, and no limits on planned recruitment. Panel data methods will be used to track user progress over time in subsequent analyses. The Elena+ intervention is open-source under the Apache 2 license (MobileCoach software) and the Creative Commons 4.0 license CC BY-NC-SA (intervention logic and content), allowing future collaborations; such as cultural adaptions, integration of new sensor-related features or the development of new topics.

Discussion: Digital health applications offer a low-cost and scalable route to meet challenges to public health. As Elena+ was developed by an international and interdisciplinary team in a short time frame to meet the COVID-19 pandemic, empirical data are required to discern how effective such solutions can be in meeting real world, emergent health crises. Additionally, clustering Elena+ users based on characteristics and usage behaviors could help public health practitioners understand how population-level digital health interventions can reach at-risk and sub-populations.

Keywords: chatbot, conversational agent (CA), digital coaching, digital health, coronavirus–COVID-19, gamification, mental health, pandemic lifestyle care

INTRODUCTION

The emergence of the COVID-19 coronavirus pandemic has created a global health emergency on an unprecedented scale (1). From the call to arms of research to tackle the pandemic, comes the challenge of delivering what the authors term *pandemic lifestyle care*. Pandemic lifestyle care concerns boosting population-level health during a period when many typical health promoting routines are severely disrupted and simple health promoting behaviors such as going for a walk or having personal space for relaxing hobbies have become much more difficult (2). Problems related to social isolation requirements have been rising; including flaunting of social distancing rules, lack of health promoting behaviors (physical activity, nutrition, sleep routines) and mental health issues (anxiety, loneliness) (3–5). In such circumstances, without additional intervention, individuals' health and well-being may deteriorate, particularly among at-risk groups with whom a lower level of health literacy, self-efficacy and/or access to resources exists already (6, 7). Additionally, without trusted resources and guidance readily and freely available at the population level, individuals may be more likely to ignore governmental guidelines, undermining public health efforts to tackle the pandemic (8).

In a variety of other behavioral health fields, digital health interventions utilizing smartphone technology have found success (9). In particular, conversational agents (CAs) have been applied to a variety of chronic disease contexts to help coach individuals and offer behavioral lifestyle interventions (10–12). Such applications have been shown to build working alliances with users (13), leverage benefits of gamification (14), utilize techniques from psychotherapy (e.g., cognitive behavioral therapy, motivational interviewing) (15) and enhance behavioral coaching in a manner similar to human-delivered coaching (11, 12, 16–19). Importantly, these interventions can be designed in a low-cost and accessible manner (20), so they have high potential to scale widely and offer a healthcare service to those whom may be lacking in treatment coverage (21, 22).

In this paper, we overview a digital health intervention that leverages findings from digital health research, combining varied theoretical and treatment approaches from different health domains into a single lifestyle intervention. The smartphone app, Elena+, named in honor of the Italian Nurse Elena Pagliarini, who was photographed exhausted from treating COVID-19 patients, has been developed within a short-time frame by a team of researchers from around the world. It aims to capitalize upon the key findings from behavioral and digital health fields to implement current best practices for the public good during the current emergency in public health. The Elena+ app, freely available on both iOS and Android devices in a variety of nations (United Kingdom, United States, Switzerland, Ireland, Spain, Colombia, Mexico), utilizes a CA to interact with users and offers personalized coaching in lifestyle health topics which may be under strain during this COVID-19 period. Topics included are: (i) COVID-19 health information, (ii) physical activity, (iii) mental health (loneliness, anxiety, utilizing mental resources), (iv) sleep and (v) diet and nutrition. The project also lays the groundwork for future interventions by providing open-source intervention logic, content, and software, which may serve as a useful start-point for tackling other chronic and mental illness and/or provide the basis of a digital control condition for other digital health interventions.

In addition to its function as a publicly available coaching tool Elena+ also doubles as a single-arm interventional study where we track individual progress through a series of psychoeducation and activity-based coaching sessions. The research aims of Elena+ are as follows; first, we measure changes from baseline to follow-up health assessments for each topic; second, we track self-reported behavioral intentions and actual behaviors during the coaching progress, to see if these measures mediate the change process, as demonstrated by differences over time in a topic's main assessment health outcome as outlined above; third, we capture data related to the patient profile and usage experience, to understand how the success of Elena+ may vary based on clusters of user/usage characteristics, that will enable better segmenting of the population and tailoring of approaches in future health interventions (23–25).

INTERVENTION DESIGN

Elena+ is a smartphone app that uses a CA to lead individuals through a series of psychoeducation coaching sessions, comprising primarily of psychoeducational materials, behavior change activities, planning activities and intention/goal formation. Created rapidly to meet the emergent COVID-19 coronavirus pandemic, Elena+ delivers coaching sessions created by experts in their respective fields to attempt to reach in-need/at-risk sub-populations. A variety of intervention components have been utilized to: (i) foster engagement with the Elena+ app, and (ii) boost care potential in delivering pandemic lifestyle health outcomes. This harmonizes the intervention with current best-practice from digital service and health intervention fields as far as possible, whilst considering current time and resource constraints in developing the app. For the intervention design of Elena+, we combined various theory-driven and practice-led approaches from different fields and tailored coaching materials accordingly. In total 43 coaching sessions have been created on the topics of: COVID-19 health information, physical activity, loneliness, anxiety, utilizing mental resources, sleep, and diet/nutrition. A full overview of coaching topics and subtopics within them is given in section Coaching Topics.

The conceptual model in **Figure 1** overviews the driving engine of the Elena+ intervention, outlining how intervention components target: (i) theoretical constructs, (ii) antecedent causes of behavioral intentions, and (iii) behavioral activation. The Elena+ Engagement Intervention Components outline design choices for the app usage experience, the CA, and the promotional strategy aimed to promote positive perceptions of the Elena+ app usage experience. As stated in both Theory of Planned Behavior (TPB) (26) and Technology Acceptance Model (TAM) (27), once sufficiently positive evaluations of the app usage experience are created, users will intend to use the app, and thus exhibit a state of engagement. Once engaged, individuals are then able to benefit from the Lifestyle Intervention Components of: (i) psychoeducation, (ii) behavior change activities, and (ii) planning activities in the respective seven coaching topics. This in turn influences the perceived usefulness of the coaching sessions, and by completing further psychoeducational coaching content and activities, individuals will exhibit greater self-efficacy and feelings of social support (28). This empowers coachees to set behavioral intentions and follow them through as "actual behaviors" in their daily lives, during a period of reflection, implementation, and experiential learning as part of the coaching process (29). As individuals apply psychoeducation and behavior change/planning activities into their own lives, health outcome assessment scores are expected to improve leading to positive reinforcement loop via greater engagement with the Elena+ app. The intervention is therefore unique in its broad approach to target multiple facets of an individual's lifestyle, and varies from other CA interventions which typically focus on a single health domain but in greater depth (10) representing both a novel treatment and research opportunity in digital public health efforts (30).

Intervention Components

Engagement Intervention Components

Interpersonal Style of the Elena+ CA

The working alliance represents the relationship quality between patients and healthcare professionals, and is robustly linked to treatment success in both offline and digital settings (13, 31–33). Comprising of task, bonds and goals (34) shared between coach and coachee, it is a key predictor of health behavior and attitude change (35). In digital contexts it can be boosted by creating interactions that adhere to principles outlined in positive psychology coaching and motivational interviewing (18, 35–37) such as leveraging interpersonal cues (38), expressing empathy (39), and eliciting change talk (29, 37, 40, 41). For Elena+ we utilize past findings such as blending both social and task-oriented dialogue (42), depiction of a pictorial avatar representation for the agent (38, 43, 44), and utilization of some backstory for the CA (45, 46) (i.e., it is a digital representation of a real nurse like Elena that helps fight COVID-19). In this vein, to help nurture a coaching atmosphere, terms such as "menu" or "next time you use the app" are avoided, and terms relevant to face-to-face communication such as "coaching choices" or "in your next coaching session" are utilized by the CA.

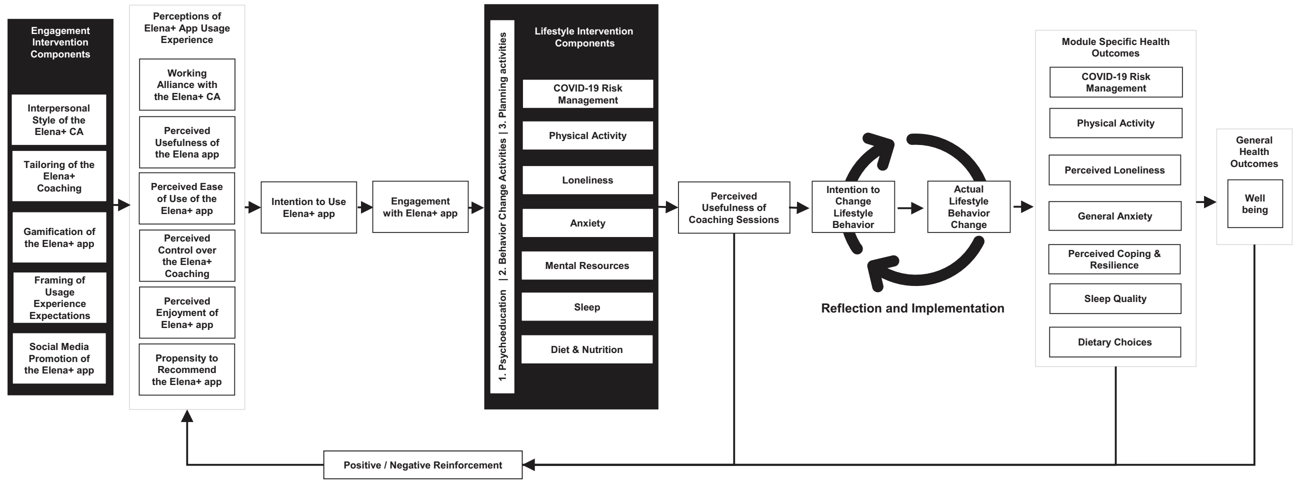

FIGURE 1 | Elena+ conceptual model.

Personalization of Elena+ Coaching

Personalization is a key factor eliciting trust, feelings of familiarity and adoption of technologies (47) and in turn positively influences the user experience (48). Efforts were therefore put into giving user choice and autonomy as far as possible throughout the experience, and using non-forceful language in line with self-determination theory and motivational interviewing (49–51). Examples include the selection of your digital coach (Elena or Elliot), use of an assessment quiz to make topic recommendations, and the opportunity to set personalized goals related to behavior change. Additionally, Elena+ also offers "on demand coaching" i.e., individuals may continue coaching at any time they wish, and there are no limits on content availability which differs from other digital health interventions which limit content available per day.

Gamification

Gamification i.e., "gaming elements used outside of games" is a key factor in motivating users (52) and creating an engaged state (14, 53). It has been successfully used in mental health and psychiatry care (52) by applying gaming mechanics to non-game contexts (45), for example, winning points to add instrumental and experiential value to activities (54).

For the current Elena+ intervention, we utilize gamification concepts by rewarding individuals with badges to symbolize progress through the app, and awarding hearts for coaching session/assessment question completion, helping to evoke behavioral economic aspects related to avoiding losses and maximizing gains (55). Surprise bonus hearts are also awarded during the intervention, which has been found to instill additional motivation via random variable scheduling of rewards (56). These bonuses may be awarded for timely completion of all intervention content (whereby timely consists of completing 1–2 coaching sessions per day, requiring ∼70 days to complete). This serves as a control mechanism to nudge coachees to complete Elena+ in an optimal time frame so that users' can adequately process and apply coaching content to their daily lives (see section Intervention Timeframe). Additionally, hearts are framed to coachees with a social message during the intervention onboarding; "hearts help our healthcare heroes," with further details explaining to coachees that by earning hearts, individuals are following a path of action that helps frontline carers safe by ensuring healthcare systems are not overloaded. This is to strengthen altruistic and social motivation for using the app, which has been linked to internalized values and intrinsic forms of motivation (57, 58).

Framing of Usage Experience Expectations

Positively framing user expectations on usage experience enables feelings of transparency and value co-creation (59), and has been linked to increased behavioral intentions (60), relationship formation (61), and satisfaction (62). In Elena+ "onboarding" disclosures (i.e., disclosures from the CA related to service experience) are utilized during the first interactions and prior to selection of coaching topics for the first time a topic category is chosen, orienting coachees to the coaching process. Additionally, research has shown that failure to disclose privacy information in a transparent way may cause individuals to drop-out from digital services and cause poor trust in platforms (41). A recent review of CA use in digital health interventions has recommended disclosing privacy information transparently to avoid such complications (13). In this spirit, the Elena+ CA briefly outlines how information is kept safe and stored in an anonymous fashion within the chat, in addition to the minimum legal requirements of displaying the terms and conditions.

Social Media Promotion of the Elena+ App

Social media has been harnessed both as a tool to recruit participants (63) as well as for health promotion and behavior change (64). For the current intervention we created social media accounts on Facebook, Twitter, Instagram, and LinkedIn, as well as a separate website. At present the Facebook Ad Manager platform is used actively for both promotional and recruitment purposes through use of advertisements. As the project evolves, we may experiment with use of other platforms.

Lifestyle Intervention Components

Psychoeducation

Health literacy has been defined as "the cognitive and social skills which determine motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" (65). On the population level, promoting patient health literacy is linked to reduced chronic illness prevalence, reduced early mortality and effective use of health services (66), while on a patient level, it represents the "personal and relational factors that affect a person's ability to acquire, understand and use information about health and health services" (67).

In Elena+ psychoeducation is employed "to enhance the likelihood of provision and receipt of effective and collaborative health care" (66) and boost patients' health literacy. As the app is aimed broadly at the general public, several steps have been taken to better ensure the understandability of psychoeducational material (68). These include; writing health information using layman's terms where possible, using specific terms with definitions, and allowing individuals the option to enquire for further explanations and definitions, whilst also ensuring the coaching experience is not unnecessarily slowed for high literacy coachees (69). An additional consideration was the division of materials across the intervention into beginner and intermediate levels (where appropriate) to better match individual knowledge, experiential background and/or motivational state (as detailed in section Coaching Topics).

Behavior Change Activities

To support the psychoeducation efforts that influence behavioral intention formation (70, 71), behavior change activities are utilized as part of the coaching and change process (29, 72). These activities are taken from a variety of specific fields (motivational interviewing, cognitive behavioral therapy) and adapted to the digital CA coaching context (18). Examples of activities used include the "5 good things technique," cognitive restructuring, mindfulness/breathing exercises, anxiety diaries and more (40, 73, 74) depending on the coaching topic covered (see section Coaching Topics). This helps bring psychoeducational material to light by outlining practical techniques individuals can utilize to manage their health in the short term, as well as teaching longer term coping skills to manage symptoms in new contexts.

Planning Activities

Behavioral supports such as planning activities can be effective in simplifying decision making across the patient health literacy spectrum, helping to set clear and specific goals (75). They are particularly important for low health literacy groups whom may struggle in comprehending and applying information to their own lifestyles without support (76). In Elena+ planning activities are utilized to aid goal formation, for example, in the physical activity module; goal setting outcomes, goal setting behaviors, discrepancy between current behavior and idealized outcomes are discussed. Individuals can also set and review physical activity goals in line with the Capability, Opportunity, Motivation, Behavior (COM-B) approach (77). Additionally, at the end of each session, individuals are encouraged to set behavioral intention(s) based on content covered, offering concrete next steps to facilitate their behavioral activation (78). As the danger of the "intention-behavior" gap exists (79–81), individuals' actual behaviors are followed up upon *via* messaging 4–10 days following completion of a coaching session. This helps sync with extant research on using situational cues (82), and short text-message reminders of action-plans (83), to increase the effectiveness of goal/behavior planning activities.

Coaching Topics

In the Elena+, individuals may complete coaching content in several different health topics. These represent the pandemic lifestyle areas where aforementioned techniques detailed in the intervention components (such as psychoeducation or planning activities) are applied to each health domain. For any given overarching coaching topic (e.g., Anxiety), a variety of sub-topics (e.g., "Breathing Away Anxiety") are available for completion with the CA, each lasting ∼5–10 min (see **Table 1**). Coaching for each subtopic content was created by an international and interdisciplinary team of domain health experts during April and May 2020, based on scientific findings and their expertise, and is continually reviewed regarding any new COVID-19 guidance from the World Health Organization (WHO).

For the design of coaching content, we followed relevant theoretical approaches. For the topics of COVID-19 health information, sleep, diet and nutrition, and physical activity a Health Action Process Approach (HAPA) inspired design was used and we divided materials between beginner and intermediate+ difficulty levels so that Elena+ users with a greater degree of knowledge, experiential background and/or motivation (as discerned during a gamified health assessment, detailed in section Intervention Logic) are directed ahead to intermediate+ coaching materials to better promote their learning and engagement (84, 85). Presently, diet and nutrition contains three beginner coaching sessions with further intermediate+ materials planned. For the mental health topics (anxiety, loneliness, utilizing mental resources) intervention materials were conceptualized along a series of continua (rather than divided into discrete categories of beginner and intermediate+) following evidence-based transdiagnostic treatment in mental health (86–88). Lastly, in planning all topics, we also took inspiration from the Behavioral Change Wheel and COM-B model of behavior change (77), for example using the APEASE criteria to identify intervention functions and behavior change techniques suitable to deliver the COM-B components of psychological capability, reflective motivation, automatic motivation, and social opportunity (77). An overview of the rationale for including each coaching topic and specific content is given in the current section.

COVID-19 Health Information

Having individuals within society enact COVID-19 guidelines widely is vital for tackling the virus (8), however this requires

TABLE 1 | Coaching topic overview.

Module topic	Beginner coaching subtopics	Intermediate+ coaching subtopics
COVID-19	What is COVID-19 and what are coronaviruses?	What are pandemics and why do they occur?
	What are the symptoms and how do they differ from the flu?	How and when should I self-isolate?
	How is COVID-19 coronavirus spread?	How can I get tested/diagnosed for COVID-19?
	What groups are most at risk?	Are hospitals/medical facilities safe to visit?
	How can we prevent the spread?	More advanced information on preventing transmission/catching COVID-19
Physical activity	What is physical activity and how much should I do?	How does physical activity affect my immune system?
	What are the benefits of being active?	Safety, inspiration and fitness goals during COVID-19
	Getting more active during COVID-19	How can I improve my fitness?
	Safe exercising during COVID-19	How can I maximize the benefits of physical activity?
Sleep	Why is sleep important?	What is sleep hygiene?
	How does healthy sleep help to protect me from COVID-19?	What hinders and helps good sleep?
	Is good sleep important for my mental health?	How does poor sleep put me at risk for COVID-19?
	What happens if I do not sleep well?	How can I manage to sleep well during confinement?
	Can anxiety, stress and poor sleep cause COVID-19?	
Diet and nutrition	Unhealthy food hazards	
	The positive effects of a nutrition-rich diet	
	Preparing meals with the daily dozen	
Anxiety	What is anxiety and why is it hard to control?	
	COVID-19, risk perception and anxiety	
	How can I control my anxiety?	
	Breathing away anxiety	
	Confinement and anxiety	
Loneliness	What is loneliness?	
	Can loneliness make you sick?	
	How can we deal with loneliness?	
Mental resources	The fundamentals of mental resources	
	The functions of mental resources	
	The neuroscience behind mental resources	
	Identifying our mental resources	
	Activating our mental resources	

a large information processing burden on the part of the individual, whom must vigilantly pay attention to developments. Additionally, one-way media channels must compete with a more interactive social media platforms, which presently contains the danger of misinformation and "fake news" (8), for example, stories claiming 5 g mobile-phone networks caused the COVID-19 outbreak (89). Certain individuals in traditionally at-risk groups lower in self-efficacy and/or health-literacy may be particularly vulnerable for a failure to follow guidelines (6, 90) and more susceptible to "fake news" stories (91). To tackle these factors, Elena+ offers the COVID-19 health information module based on trustworthy and legitimate sources including the core guidelines and information provided by the World Health Organization and other governmental bodies and/or charities/agencies.

Physical Activity

Current restrictions on individuals' lifestyles (gym closures, requirements to stay indoors, social distancing guidelines) are making physical activity levels more challenging to maintain (92). This may pose a particular issue for individuals that prefer socially oriented exercise contents (93, 94) (i.e., exercise classes, running with friends) and now experience a lack of motivation or structured guidance for solo exercise. The physical activity (PA) module delivers a variety of sub-topics and enables the development (or continuation) of physical activity routines to contribute to strengthened immune systems and improved population health. By providing information on suitable activity types (aerobic, strength, mixed) that individuals can perform whilst maintaining social distancing guidelines, we influence individual outcome expectancies, self-efficacy and goal setting to facilitate behavioral activation, and stay active while adhering to public health guidelines.

Sleep

Sleep is known to contribute to overall immune system health (95) and bolster mental health resilience (96), however, the pandemic creates additional stressors (such as increased use of electronic devices, less time spent physical active, additional stress) which has deleterious effects on sleep quality (97, 98).

The sleep module therefore employs multicomponent cognitive behavioral therapy as recommended by the Standards of Practice Committee (SPC) of the American Academy of Sleep Medicine (AASM) (99) as an effective, non-pharmacological intervention to improve sleep hygiene (100, 101). Sleep education in Elena+ includes: (i) information about the neurophysiological components of sleep from the vigilance model (102), (ii) the different stages of sleep and associated oscillatory patters, (iii) the role of certain neurotransmitters (e.g., serotonin, dopamine) which help with the transition of said stages (102), as well as, (iv) explaining how sleep is regulated by the circadian rhythm (Process C) and the sleep-wake homeostasis (Process S) from the two-process model (103). Other sleep-relevant recommendations such as improving physical activity, nutrition, creating a sleep routine or reducing device use prior to bed are also discussed (97, 100, 104).

Diet and Nutrition

Diet and nutrition is known to contribute to the immune system and physical health generally (105). In the current period of COVID-19, ensuring individuals eat well and maintain a nutritional diet is key in boosting overall population health (106). Eating habits often become routine (107), and for many individuals their current eating routines will be in a period of flux; additional time at home may provide the chance to re-assess previous eating habits, and with sufficient guidance, allow individuals to develop new routines and exerting greater control over dietary choices. The module therefore functions to provide nutrition and diet information and support individuals in making healthy choices; influencing outcomes expectancies and self-efficacy regarding food and diet choices based upon guidelines from the World Health Organization (108) and publications recommending plant-centered diets in managing and preventing chronic diseases (109–111).

Mental Health

During the pandemic strains on mental health have been exhibited; with individuals experiencing periods of increased isolation, uncertainty regarding their employment and safety, and less freedom to enjoy stress-reducing activities (112, 113). Without guidance therefore, there exists the ever present danger that such stressors may lead to unhealthy coping strategies, creating a negative feedback loop and increased strains upon mental health (112). While mental health has previously been considered a delicate topic for automated agents to address, there exists a growing literature body on utilizing CAs to deliver high quality care (15, 19, 114). Contributing to this emergent stream of research, the mental health module offers the topics of: (i) anxiety, (ii) loneliness and (iii) discovering mental resources.

Anxiety

A CBT-inspired approach was used for anxiety materials, focusing on dysfunctional thoughts that affect behavior and functioning and emotion-regulation (115–117), whereby emotion regulation refers to decreasing the experiential and behavioral aspects of negative emotions (73). Some emotional regulation strategies utilized in Elena+ involve: (i) situation election (e.g., choosing not to watch or read news about COVID-19 throughout the day, only once or twice daily), (ii) attentional deployment (e.g., scheduling and directing attention to enjoyable activities activities), (iii) cognitive change (e.g., modifying how one appraises a situation so as to alter its emotional significance), and (iv) response modulation (e.g., using deep-breathing relaxation techniques) (73). In this way, the anxiety module has been developed considering the strategies recommended by Sanderson et al. (118), offering an evidence-based treatment for anxiety tailored toward pandemic circumstances.

Loneliness

Loneliness has been defined as the discrepancy between an individual's preferred and actual social relations (119). Prior to COVID-19 outbreak, loneliness was a major public health concern and had been linked to increased morbidity and mortality risks (120–122). As typical treatment for alleviating loneliness such as increasing opportunities for social interaction (123) is not presently possible, these issues are addressed by our intervention in several steps: (i) by discussing opportunities for social interaction compatible with COVID-19 recommendations, (ii) by implementing psychoeducation to make users aware of the increased risk of feeling lonely and its negative impact on well-being (124), and (iii) directly addressing these consequences in behavior change activities such pleasant activity scheduling (125).

Mental Resources

Coping resources have been found to reduce psychological distress and buffer the consequences of stressful life events (126, 127) however if individuals underestimate their potential to cope with stress, no adaptive coping strategies will be developed. Emotion-focused coping in Elena+ therefore adjusts an individual's emotional response to the varied and subjective stressors affecting them, and focuses on regulating negative emotional reactions to these stressors, following the Transactional Model of Stress and Coping by Lazarus and Folkman (128). This is done by using various cognitive and behavioral skills, such as positive-thinking, reframing, or distraction (e.g., defining a resource to enjoy such as writing down positive memories, utilizing relaxing space in the home or garden) with downstream consequences of boosting an individual's perceived competence and self-efficacy to manage stressors (129).

TECHNICAL IMPLEMENTATION

Intervention Logic

The intervention logic for Elena+ is displayed in **Figures 2**, **3**. **Figure 2** shows the coachee process from download of the Elena+ app to completing their first coaching session.

Referring to **Figure 2** (and to the diagram numbers), the intervention starts off by *"exploring the coaching agenda"* whereby: (1) coachees are onboarded to the Elena+ experience (i.e., explanations of the coaching service are given and expectations framed, privacy protection steps are mentioned) and simple demographics are taken, and (2) the coaching agenda is explored in greater depth where coachees input their coaching

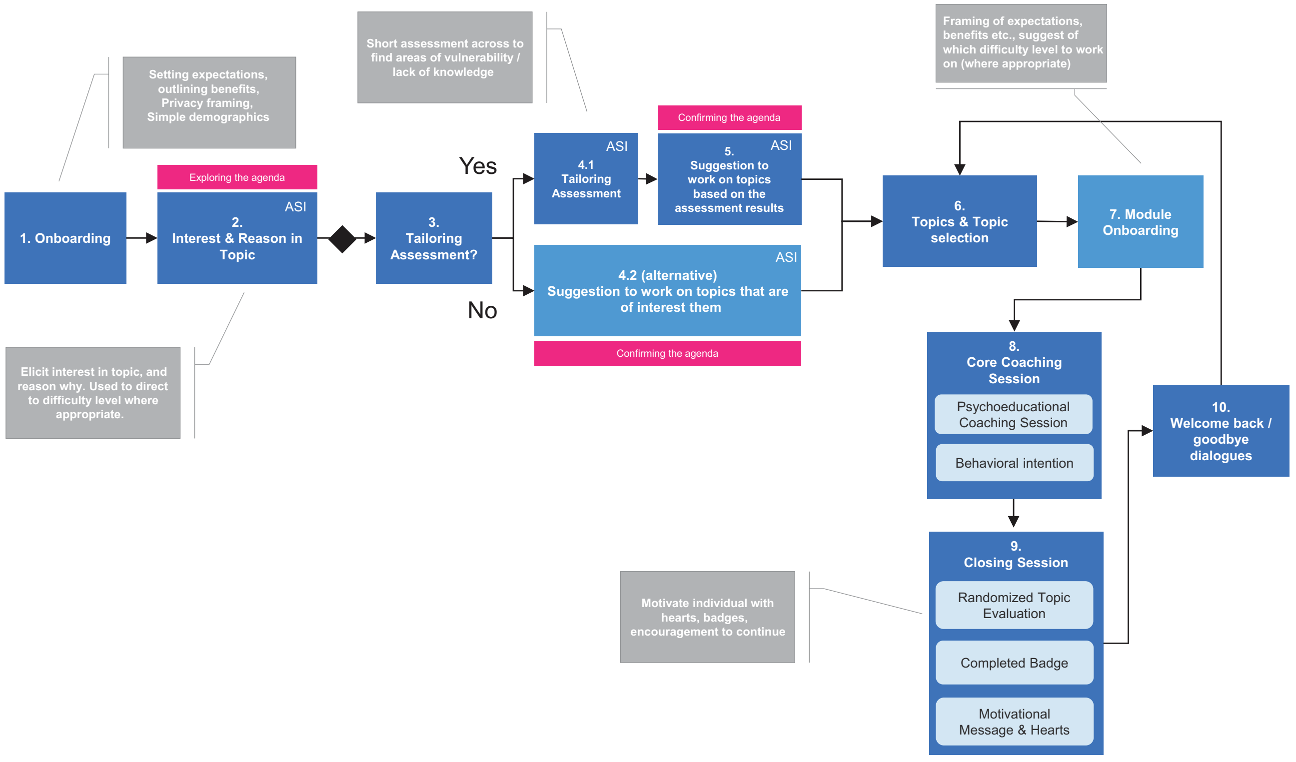

FIGURE 2 | First use of Elena+. ASI, Agenda Setting Input.

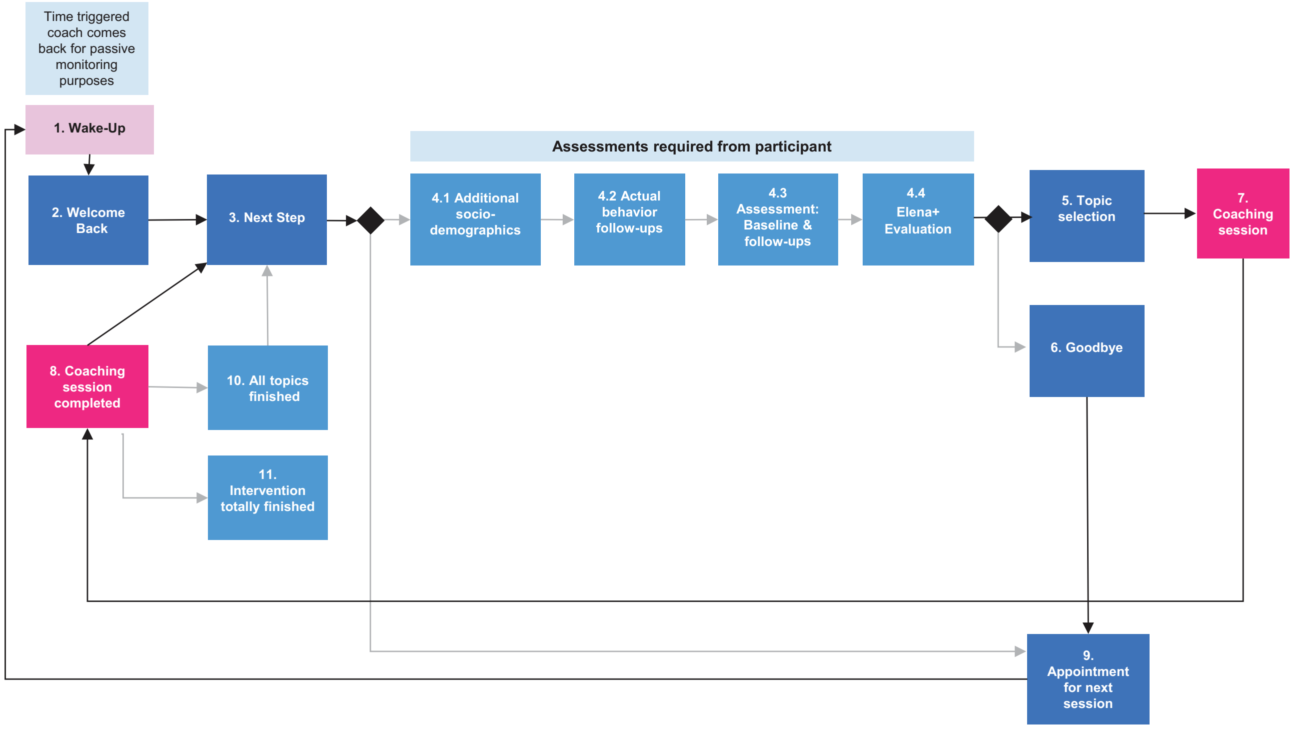

FIGURE 3 | Ongoing use of Elena+.

interest in the various coaching topics and optionally select from reasons why (e.g., the user states they are curious, or they have been struggling with a given topic), which is used as an input to tailor coaching content later between both topics and difficulty where appropriate. During the *"confirming the agenda"* stage (3–5) individuals are strongly encouraged to take the tailoring assessment which functions as a type of gamified quiz (4.1) by outlining benefits (i.e., the app will be better tailored to them and their circumstances). Based on the assessment results from this quiz, individuals are given a suggestion of which coaching topics are likely to be of most use to them and then they go to topic selection. Individuals may also opt to skip the assessment (4.2) to preserve user autonomy and go straight to topic selection (6). Following topic selection (6), individuals are directed to the module onboarding (7) which gives an overview of the benefits of taking this series of coaching topics and baseline assessment measures are taken, so that individuals pre and post health outcome scores from using coaching materials can be assessed at a later time. The module onboarding also occurs only once, on the first-time starting a given module.

A topic is then completed by an individual (8) which contains psychoeducation and behavior change/planning activities as appropriate, and a behavioral intention may be set based on the materials covered in that session. Typically, a single coaching session lasts from between 5 and 10 min. After this, individuals move to (9) closing session, where a badge is awarded for specific topic completion, hearts are also awarded for progress in the Elena+ coaching experience and a randomized session evaluation may occur (asking individuals how they perceived the coaching session). Lastly, individuals move to the (10) welcome back/goodbye dialogue where individuals can choose to: (i) continue coaching with another topic selection, (ii) set a date for the next coaching session, (iii) choose to "wake up" the coach to continue coaching at a non-scheduled time (e.g., before their next appointment).

Figure 3 shows ongoing use, whereby, individuals begin at the (2) "welcome back" dialogue (which can be coach or coachee triggered) and following this typically proceed to the next step (3) which may state that some questions (assessments) are required from the participant. If needed, the participant completes the (4) assessments, and typically proceeds to (5) topic selection and then (7) completes a coaching session, and when finished continues to (8) the closing session dialogue, subsequently choosing (3) next steps they would like to take. However, following the assessments, individuals may choose to also (6) finish, which may typically be the case when an individual has just completed a coaching session and does not wish to start another. This may also occur when an individual has completed all coaching sessions but continues to use Elena+ for behavioral reminders or to earn hearts to combat the pandemic (i.e., "hearts help our healthcare heroes" – as highlighted in **Table 2**). In either case, users would then go to (9) the "appointment for next session" dialogue (ANS) to set a date when Elena should come back to them for more coaching, and after this is confirmed a (1) wake up button is displayed where the user can trigger more coaching at any time. If the coachee does not select the wake-up button (1) then the coach will restart dialogue at (2) with the welcome back dialogue at the appointed time.

Lastly, the (10) "all topics finished" dialogue is triggered when an individual has completed all coaching topics, a congratulations message and additional hearts and summary of achievements are given. Individuals are given motivation for continuing to use the app (i.e., that it can keep you on track with intentions you have set) and a social motivation (answering assessment helps combat COVID-19). When all topics, assessments and actual behavior follow-ups are completed by individuals, the (11) "intervention totally finished" dialogue occurs, and the intervention ends for this participant.

Development

Elena+ was developed during Summer 2020 using MobileCoach (www.mobile-coach.eu), an open source software platform, available under the industry and academic-friendly Apache 2 license (137) for smartphone-based and CA-delivered digital health interventions and ecological momentary assessments (138, 139). MobileCoach allows intervention authors to design fully automated data collection protocols and interventions consistent with the *talk-and-tools* paradigm (140). It offers a chat-based interface with free text/number input and predefined answer options that are used to simulate conversational turns commonly applied in counseling sessions with health professionals and their clients (the "talk"). The Elena app also delivers a wide range of "tools," i.e., various micro-interventions such as reminders or psychoeducational video clips. Against this background, Elena+ can complement existing video mediated or personal counseling sessions with general practitioners, lifestyle coaches or mental health coaches, and can also reach individuals in a scalable way when a personal coaching approach is neither appropriate, nor geographically accessible, or beyond financial limits and personal resources (e.g., in epidemic times of isolation and social distancing). The intervention content for Elena+ is also available under the Creative Commons license CC BY-NC-SA, a non-commercial license that allows free access to content and requires the sharing of new developed features with the original intervention authors, to encourage scientific sharing and collaboration internationally. A screencast is available on the project website www.elena.plus as well as in the **Supplementary Material**.

EVALUATION OF ELENA+

Sample and Data Collection

The Elena+ app is listed on both Apple/Google app stores as "Elena+ Care for COVID-19" (Spanish: "Elena+ cuidados ante la COVID-19") and may be used on both iOS and Android devices in the United Kingdom, Ireland, Switzerland, and on Android devices only at present in the United States, Spain, Mexico, and Colombia with further launch countries planned. The app is listed in the search index with the following keywords (and Spanish equivalents): COVID-19, coronavirus, mental health, sleep, exercise, diet, nutrition, coaching, and thus a natural amount of organic recruitment occurs by individuals searching for these terms. In addition, we utilize the Facebook

TABLE 2 | Intervention components.

Intervention components	Brief description	Theoretical background
Engagement intervention components		
Interpersonal style of the Elena+ CA	Interpersonal and empathetic communication in line with coaching literature to increase relational between coach and coachee	Working Alliance, Horvath and Greenberg (130); Establishing and Maintaining Long-Term Human- Computer Relationships, Bickmore et al. (32).
Tailoring of the Elena+ coaching	Where possible, personalization is offered to tailor the intervention. Examples include the assessment quiz making tailored recommendations, self-selection of coaching topics, being available 24/7 for users between coaching session appointments. In line with coaching literature, individual choice and autonomy are preserved throughout, which also includes only making suggestions in a non-forceful manner.	Self-determination Theory, Ryan and Deci (49); Positive psychology coaching, Passmore and Oades (29)
Gamification of the Elena+ app	Gamification in the form of winning hearts and badges for demonstration of progress and motivational reinforcement	Serious Games and Gamification for Mental Health, Fleming et al. (52); Gamification for Health Promotion: Edwards et al. (131).
Framing of usage experience expectations	In line with services marketing, information systems research, and human-computer interaction research, we take inspiration in shaping first encounters through use of onboarding individuals regarding usage expectations and privacy matters.	Role Theory in the Service Encounter (132); The Onboarding Effect (133) Cardoso 2017; Communication Privacy Management Theory, Metzger (134)
Social media promotion of the Elena+ app	Advertisements and posts are used to promote, recruit and shape perceptions of the Elena+ app to adults 18+. At the time of writing, Facebook is actively used, we also have reserved Twitter, LinkedIn and Instagram accounts.	Using Social Media For Health Research, Arigo et al. (63); Harnessing Social Media for Health Promotion and Behavior Change, Korda and Itani (64)
Lifestyle intervention components		
Psychoeducation	Coaching sessions centered around health literacy information delivered by domain experts and put into an easy to understand format for those of varied health literacy levels.	Health Promotion, Nutbeam and Kickbusch (65), Health Literacy, World Health Organization (135).
Behavior change activities	Activities from certain coaching traditions as relevant to the domain (e.g. Cognitive Behavioral Therapy, Motivational Interviewing etc.) are used to put health information in context in the coachees life.	The Psychology of Coaching and Mentoring, Passmore et al. (37)
Planning activities	At the end of a coaching session, individuals are encouraged to set a behavioral intention. This synthesizes information participants may have learnt and by setting an intention, crystalizes it to a concrete next step, helping in the behavioral change process. Additionally, planning activities may be used during sessions with regard to straightforward plans to help implement behavioral intentions.	Health Action Process Approach, Schwarzer (85), Gollwitzer (136).

TABLE 3 | Baseline and follow-up assessments.

For topic	Instrument	References
COVID-19	COVID-19: risk perception and Coping strategies	Gerhold (142).
Diet and nutrition	Short survey instruments for children's diet and physical activity: the evidence	SAX Institute (143).
Sleep	Insomnia severity index: ISI-7	Bastien et al. (144).
Anxiety	General anxiety disorder: GAD-7	Spitzer et al. (145).
Loneliness	UCLA loneliness scale: ULS-6	Neto (146).
Physical activity	Single-item physical activity measure	Milton et al. (147)
	International physical activity questionnaire short form	YOUTHREX (148) and Booth (149)
Mental resources	Brief resilience coping scale	Sinclaire and Wallston (150).
Wellbeing	Patient health questionnaire: PHQ-2	Kronke et al. (151).

Ad Manager platform to target adults aged 18 or above, with no upper limits on age. At present we have capacity for up to two thousand users on our server and are currently exploring how to expand server capacity, so that more active users can be accommodated. Data collection began in June 2020.

Full ethical clearance was given by the ethical board of the university, ETH Zurich, for the project (application number: EK 2020-N-49) and the app content was reviewed by both Apple and Google who requested a list of scientific references to be included within the app before accepting. To use the app, users

TABLE 4 | Timing schedule of assessment and actual behavior questions in days.

Topic	Actual behavior follow-ups:				Assessments:					±Days
	1st	2nd	3rd	4th	1st	2nd	3rd	4th	5th	
Anxiety	7	21	35	77	14	28	42	84	126	0
Mental resources	8	22	36	78	15	29	43	85	127	+1
Loneliness	9	23	37	79	16	30	44	86	128	+2
Sleep	10	24	38	80	17	31	45	87	129	+3
Physical activity	6	20	34	76	13	27	41	83	125	−1
Diet and nutrition	5	19	33	75	12	26	40	82	124	−2
COVID-19 info	4	18	32	75	11	25	39	81	123	−3

must: (i) be aged 18 years or over, (ii) accept the app terms and conditions and (iii) give informed consent for study purposes. If any of these are not true, individuals are screened out early in the Elena+ dialogue. All procedures were in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments.

Care was put into reducing unintended negative consequences. For example, during the tailoring assessment, individuals that score highly in the General Anxiety Disorder scale or Patient Health Questionnaire or (≥5) are recommended by the CA to seek human assistance (e.g., from their family doctor or a mental health charity) (141). As we gather no personally identifying information (as part of privacy protection measures) we cannot report these individuals who may benefit from human intervention to medical authorities nor compel individuals to seek out care. However, it was decided not to exclude these individuals from further use of the app, as while receiving human support would be optimal, receiving assistance through the Elena+ app is still better than receiving no support whatsoever. Regarding unintended consequences related to data safety, in the highly unlikely case of an attack on the Elena+ servers, user data will remain anonymous as we collect no personally identifying data, only simple non-identifiable information such as user gender, age, "nickname" and the language version in use. It could be possible that users specify their full name as their "nickname," however, without further personally identifiable information collected (such as telephone number or e-mail address), it is extremely improbable individuals could be personally identified. Lastly, while efforts were put into making informed consent and app terms and conditions as understandable as possible (*via* dialogue from the CA in addition to the standard legal text displayed in all apps) it is possible that users could accept without fully understanding data will be used for analysis. Nonetheless, users always have the right to request the deletion of their data at any point in time.

Study Design

Elena+ functions as a single-arm interventional study, whereby individuals' self-reported health assessment outcomes (see **Table 3**), the user-selected behavioral intentions at the end of each coaching session, and self-reported actual behaviors (see **Table 4**) are recorded as the core health and behavioral outcomes of interest. Additionally, we also collect ratings of the app usage experience, social demographic information and "marker variables" (i.e., user choices within the dialogues detailing the patient profile/usage experience objectively) shown in **Table 5**. Socio-demographic data is collected during first usage and before fifth subtopic completion, usage evaluations on a randomized basis after topic completion, and "marker" variables across all dialogues. Marker variables can be used to detail the user profile and usage experience, for example when a participant replies to coach that they do not understand terms used and need further explanation, this is saved as *health literacy marker variable*. Alternatively, if a user chooses to ask the CA for a joke, this choice is saved as a *humor marker variable*. As Elena+ has no control group, the authors plan to examine how individual attainment changes based on variations of app usage patterns and user profile over time.

TABLE 5 | Summary selection of marker variables.

Marker variable	Explanation
Literacy marker	Whether an individual is confused or not
Sedentary marker	Whether an individual is sedentary or not
Anxiety marker	Whether an individual is currently experiencing anxiety or not
Depression marker	Whether an individual is currently feels depressed or not
Weight marker	Whether an individual is reports struggling with their weight or not
Sleep Marker	Whether an individual is reports struggling with their sleep patterns or not
Humor marker	Whether an individual is engages in humor with the CA or not
More coaching marker	Whether an individual indicates desire for more coaching on a specific topic or not
Devices marker	Whether an individual uses many electronic devices or not
Loneliness marker	Whether an individual is currently feels lonely or not
Smoker marker	Whether an individual smokes tobacco or not

Methods

To meet the project research aims, we will utilize panel data methods to track changes in health outcome scores gathered at baseline (i.e., after a topic has been selected but no coaching content has been completed yet) compared with follow-up intervals as individuals continue to use the app (timing specified in **Table 4**). To do this we will specify Auto-Regressive Moving Average (ARMA) models (152), whereby: (i) health outcome assessment scores are regressed on time, (ii) health outcome assessment scores are regressed on time, with no. of coaching subtopics completed specified as a moderating variable, (iii) health outcome assessment scores are regressed on time, with user selected behavioral intentions and user reported actual behaviors specified as serial mediators. A practical example of this would be examining whether setting intentions and reporting actual behaviors of abstaining from electronic devices before bed serially mediates the relationship between time spent using the app and lower scores for the Insomnia Severity Index.

Should sufficient observations be gathered, it may also be possible to adapt the aforementioned models and make forecasts based upon functions of past independent variable value(s) and/or past errors, as well as the present time error (153). In this case we would divide the dataset into training and test datasets, specify the ARMA model on training data, and compare its efficacy on test data. If suitable fit is found, the model may be used to make predictions (as to the impact of time spent using the app/no. of coaching subtopics completed/no. of intentions/actual behaviors reported) and their impact on health assessment scores. Additional analyses may include using socio-demographic and marker variables as inputs in Cluster Analyses such as Supervised k-Means Clustering (154) whereby individuals are grouped into sub-populations based upon health assessment scores and marker variables selected while using the app. In such a manner, it would be possible to identify aspects of the usage experience (for example, selection of humor marker variables, indicative of greater user engagement) that are linked to superior health outcome assessments.

Intervention Timeframe

The Elena+ intervention timeframe is estimated to last for approximately half a year if individuals complete all intervention content, as well as all subsequent assessments and actual behavior monitoring questions. However, the time to complete all content fully depends upon how quickly individuals complete all coaching sessions, and the subsequent assessments and actual behavior questions that are triggered by completing coaching sessions. The schedule of follow up health assessments and actual behaviors questions is given in **Table 4**. We utilize some "intervention jitter" (i.e., variation in timing of follow-up questions after coaching sessions) so that assessments are less likely to co-occur on the same day and that the potential burden for users is lessened. For example, for the anxiety topic health outcome assessments occur from 14 days after the first anxiety coaching session, and actual behavior questions 7 days.

OUTLOOK

At the time of writing, Elena+ is available in three language versions: (i) English (in Switzerland, Ireland, the United Kingdom, and the United States), European Spanish (in Spain) and Latin American Spanish (in Mexico and Colombia) with data collection on going. Finished translations have been created for Tamil which will be launched in India, Sri Lanka, and Singapore. Work is also pending to improve server infrastructure which currently has capacity for 2,000 users.

Moving forward, increasing the effectiveness of Elena+ around the world may comprise of adapting and improving coaching content, features and visual aesthetics, for example, making cultural adaptations to match the profile of users in new launch countries. With the help of a sponsor, it could be possible to strengthen the social motivation for using Elena+ by having gamified hearts redeemable for certain medical equipment (for example, winning hearts providing a donation of money to supply personal protective equipment or ventilators to at-risk areas). In a similar vein, understanding the "state of receptivity" (155, 156) of participants and sending reminders and notifications at the correct moment may represent a fruitful research direction. Post-pandemic, Elena+ intervention materials may also be adapted to function as a type of digital control condition for other digital health interventions, which would help measure the degree of change attributed to the design choices of a specific digital treatment tailored to a certain disease content against a general lifestyle digital intervention. Researchers may then be able to assess the efficacy of their treatment, over and above the effect of simply using any type of digital tool.

Elena+ intervention content is available under the Creative Commons license 4.0 CC BY-NC-SA, and MobileCoach (the underlying software for Elena+) is available under the Apache 2 license. Materials have been made available to help foster a dynamic research community around Elena+, so that researchers can utilize, adapt, and build on our content, working autonomously in new contexts to add new features/contents whilst sharing findings with other intervention authors. To this end, a collaboration has begun with colleagues from Dartmouth College in the United States to adapt elements of Elena+ into a "just-in-time-adaptive intervention" (157) whereby sensor data (such as GPS location, date and time, Wi-Fi connection status) is utilized to match phone notifications to user state of receptivity (156). Additionally, discussions are underway with colleagues from Singapore-ETH Centre to build upon Elena+ dialogues for use in studies preventing type-2 diabetes and depression at the population-level. Further interested collaborators are warmly invited to contact the authors for further collaboration opportunities.

CONCLUDING THOUGHTS

Taken in total then, Elena+ represents a highly innovative digital health intervention developed at speed during the COVID-19 coronavirus pandemic to deliver *pandemic lifestyle care*. In the long term, Elena is not envisioned to be a static intervention, but rather an intervention which will evolve and adapt, leveraging the revolutionary potential of digital health to learn, innovate and apply solutions (30). Results will demonstrate areas of successes of the tool, as well as how improvements can be added to improve effectiveness of this and other future digital health interventions. These findings may be particularly applicable to other population-level threats to public health moving forward, such as obesity epidemic (158), and contribute to a greater understanding of digital health interventions for public health promotion.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by ETH Zurich, Zurich, Switzerland. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct and intellectual contribution to the to the Elena+ project, and have approved the paper for publication.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.625640/full#supplementary-material

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Data Checkers: A Grid-Based UI for Managing Patient-Generated Data Sharing to Support Collaborative Self-Care

Pei-Yao Hung[1]*, Drew Canada[2], Michelle A. Meade[3] and Mark S. Ackerman[1,2,4]

[1] School of Information, University of Michigan, Ann Arbor, MI, United States, [2] College of Engineering, University of Michigan, Ann Arbor, MI, United States, [3] Department of Physical Medicine and Rehabilitation, Medical School, University of Michigan, Ann Arbor, MI, United States, [4] Department of Learning Health Sciences, Medical School, University of Michigan, Ann Arbor, MI, United States

Chronic health conditions are becoming increasingly prevalent. As part of chronic care, sharing patient-generated health data (PGHD) is likely to play a prominent role. Sharing PGHD is increasingly recognized as potentially useful for not only monitoring health conditions but for informing and supporting collaboration with caregivers and healthcare providers. In this paper, we describe a new design for the fine-grained control over sharing one's PGHD to support collaborative self-care, one that centers on giving people with health conditions control over their own data. The system, Data Checkers (DC), uses a grid-based interface and a preview feature to provide users with the ability to control data access and dissemination. DC is of particular use in the case of severe chronic conditions, such as spinal cord injuries and disorders (SCI/D), that require not just intermittent involvement of healthcare providers but daily support and assistance from caregivers. In this paper, after providing relevant background information, we articulate our steps for developing this innovative system for sharing PGHD including (a) use of a co-design process; (b) identification of design requirements; and (c) creation of the DC System. We then present a qualitative evaluation of DC to show how DC satisfied these design requirements in a way that provided advantages for care. Our work extends existing research in the areas of Human-Computer Interaction (HCI), Computer-Supported Cooperative Work (CSCW), Ubiquitous Computing (Ubicomp), and Health Informatics about sharing data and PGHD.

Keywords: patient-generated health data (PGHD), data sharing, disability, self-care, self-management, care network, independence, privacy

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Bridget T. Kane,
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Laszlo Balkanyi,
University of Pannonia, Hungary
Adamantios Koumpis,
RWTH Aachen University, Germany

Correspondence:
Pei-Yao Hung
peiyaoh@umich.edu

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1. INTRODUCTION

Chronic health conditions are prevalent in the U.S.[1] and across the globe[2]. Supporting people with chronic conditions in conducting self-care is critical to their quality of life (Anderson, 1995). Consumer devices such as mobile phones, fitness trackers, and Internet of Things (IoT) devices, as well as in-home medical sensor networks allow people to generate a vast amount of data that

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[1] https://www.cdc.gov/chronicdisease/about/index.htm

[2] https://www.who.int/chp/about/integrated_cd/en/

characterize their health and daily activities. These patient-generated health data (PGHD) could be useful for monitoring one's health, behaviors, and daily activities. Sharing such data is increasingly recognized as potentially useful not only for monitoring one's own health but also for informing and supporting collaboration with caregivers and healthcare providers.

Sharing PGHD, however, should be under the control of people with health conditions[3] or their caregivers. We want to investigate ways to allow people to control their own data sharing, instead of putting it under the purview of large corporations or healthcare systems. If data sharing is to be under the purview of people with health conditions, we need to keep the task from being overwhelming. With severe chronic conditions, a person with a health condition is likely to need to change sharing settings as their health deteriorates, a time in which they may not be able to focus or find the energy to do so. Moreover, this will become an increasingly difficult problem for users as healthcare sensors become cheaper and proliferate. We need to find ways to make it simpler and easier for people with health conditions to control their data sharing.

In this paper, we present a prototype solution to an important aspect of this problem, creating settings that will control sharing PGHD. While our overall agenda is large, we have begun to investigate this issue in the context of working with people with high-level spinal cord injuries and disorders (SCI/D) [4] and other neurological disorders, such as cerebral palsy [5]. As people with SCI/D experience increasing levels of impairments, they begin to require assistance from others to perform activities of daily living (ADLs), including activities such as getting dressed, having a meal, taking a bath, or using the bathroom (Meade, 2009; Ackerman et al., 2018).

Recently, the research community has started to examine how to support individuals with severe chronic conditions, such as SCI/D, within the context of a care team at home (Consolvo et al., 2004; Tixier et al., 2009; Tixier and Lewkowicz, 2016), since care for people with chronic conditions with more severe levels of impairment is usually a team-based effort (Nunes and Fitzpatrick, 2015). While some researchers use "care networks" (e.g., Consolvo et al., 2004) to denote a broader collectivity of involved others, Gronvall and Verdezoto (2013) use "intimate care network" to include only family and the closest friends who participate in health management. In this paper, we use "care team" to denote an at-home care team that includes only the person with a health condition, caregivers (primary, secondary, hired/paid, and volunteers), and clinicians—those most immediately bound up in day-to-day care or in the necessary clinical care (Meade, 2009; Büyüktür et al., 2017, 2018), and PCT to refer to a person with a health condition requiring a care team.

Using PGHD generated from sensing devices can facilitate collaboration within a care team outside of the hospital environment, but it also raises a number of issues. The combination of technical complexity, changing health conditions, and social dynamics make it challenging to share data, as PCTs need to consider with whom to share data, what data to share, the contexts in which to share, how much detail to share, and the degree of control desired as a care-receiver.

On the social side, the co-existence of different relationships (e.g., parent-child and caregiver-receiver) (Toscos et al., 2012; Büyüktür et al., 2018) and health conditions that are constantly evolving may require nuanced considerations by PCTs (Ackerman et al., 2018), including the sharing of data. Sharing data could support collaborative monitoring, but could also create challenging tensions, as people need to be allowed to make developmentally appropriate decisions about their lives and health management even as they rely on others' assistance with ADLs (Hong et al., 2016). For instance, while a primary caregiver (e.g., a mother) may take on the responsibility to oversee care, her parent-child relationship with the PCT (the child) might affect the types of information the person is willing to share with her. The person might feel the need to maintain independence by controlling the data being shared with the parent, since having control over data is potentially a way for PCTs to obtain a sense of control over their lives (Unruh and Pratt, 2007; Nafus and Sherman, 2014; Büyüktür et al., 2018). At the same time, deterioration in the person's health might require sharing more data for the sake of safety.

The Human-Computer Interaction (HCI) and Ubiquitous Computing (Ubicomp) communities have recognized the complexity and challenges of allowing users to manage the sharing of sensor data to support chronic care. While usable privacy and security research in these fields has proposed a number of designs for authoring privacy settings and sharing settings (or policies), these designs are not suitable for care: they do not support fine-grained control over data details or do not take into consideration the chronic care context (Reeder et al., 2008; Lipford et al., 2010). We will return to the context of care below, detailing requirements, but as an example, existing systems do not include support for dynamically changing care teams, the fine-grained control necessary to support personalized sub-groups within care teams, or the support necessary for the long term. As such, this paper reports our investigation into a user interface design that addressed these concerns to better support data sharing within care teams.

In this work, we have sought to find a middle ground technical solution that is comprehensive enough to allow fine-grained control of data sharing without overwhelming users with complex representations. We did so by co-designing with a person with a health condition to create an application with a grid-based visual interface. After developing our prototype Data Checkers (DC), we performed a qualitative evaluation to understand its potential.

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[3] We use the term "person with a health condition" interchangeably with "patient" in this paper, to emphasize her identity as a human being. We recognize the unfortunate connotations of "patient" in that it privileges the medicalization of care and the clinical participants in care. However, we use "patient" in some parts of the paper, such as in the related work, to avoid confusion and to maintain consistency with some existing literature.

[4] https://www.hopkinsmedicine.org/health/conditions-and-diseases/acute-spinal-cord-injury

[5] http://www.cdc.gov/ncbddd/cp/index.html

1.1. Related Work

1.1.1. Collaborative Self-Care for Chronic Conditions

Chronic medical conditions vary widely. Some may cause only small concern on the part of a person with a health condition (e.g, mild allergies); some may require only self-management of the condition, at least in some forms (e.g., mild depression). Other medical conditions, and some disabilities, may require a team of clinicians (e.g., congestive heart failure or oncology), and yet others may require an at-home care team to help with self-care and self-management along with a team of clinicians. We use as our example in this paper Spinal Cord Injuries/Disorders (SCI/D) and related conditions, which require an at-home care team.

Self-care has been identified as critical for managing all kinds of chronic conditions (Anderson, 1995). Self-care includes the everyday activities that people do to take care of themselves, manage their health, and allow for involvement and participation in life. For people with a severe chronic condition, such as people with SCI/D [6], self-care becomes incrementally complex as it expands to consciously integrate the additional activities needed to maintain health. These activities could include maintaining specific types of diet, taking medication, cleaning one's environment and the medical equipment being used, bathing, or even monitoring pain (Ackerman et al., 2018). In the HCI literature, self-care and self-management as terms are usually used interchangeably. Here, we will use self-care to include self-management tasks performed by people with chronic conditions and disabilities (Nunes and Fitzpatrick, 2015).

One of the early, yet on going, streams of research has been to design technology to help medical professionals to monitor people' health, facilitating medication adherence (Botella et al., 2013) or, more broadly, assisting individuals in following and executing the steps recommended by trusted professionals (Lee and Dey, 2015). Another major direction examines how to empower people with health conditions by designing technological support for them to monitor their self-care practices, with the ultimate goal of achieving better health. Research has found it beneficial to do so, as it could trigger reflection, while also increasing a sense of control when managing a health condition (Mamykina et al., 2008).

Specific to different individuals, care teams might have different compositions and communication structures (Consolvo et al., 2004). These teams of family members, hired caregivers, and medical professionals collaborate in a loosely-coupled manner (Birnholtz and Jones-Rounds, 2010) to address health changes and develop care routines (Büyüktür et al., 2017; Ackerman et al., 2018). It is through collaboration among care team members that an individual can slowly develop her own independence (Birnholtz and Jones-Rounds, 2010; Caldeira et al., 2017; Büyüktür et al., 2018). Our work explores designs that can support individuals with chronic conditions to work with care teams while maintaining control over their care through data.

1.1.2. Patient-Generated Health Data

Information needs vary widely among chronic medical conditions. Significant research has examined the information needs and information sharing among people with chronic medical conditions and disabilities. For example, people want to share their status with their relatives, friends, and larger social network. People readily seek both information (Civan et al., 2009; Klasnja et al., 2011b; Valdez et al., 2015) and emotional support (e.g., Feng et al., 2004) from these sources, including non-healthcare professionals. For instance, Skeels et al. (2010) reported that people with breast cancer seek and receive help from family members, other people with health conditions, community members, and professional connections. Valdez and Brennan (2015) and Valdez et al. (2017) highlighted getting support and information within the person's social network. In short, people with chronic medical conditions as well as people with disabilities engage in considerable information work (Hogan and Palmer, 2005; Kaziunas et al., 2013; Strauss et al., 2017), a kind of work done by patients and people with health conditions (Valdez et al., 2015).

Part of that information work, increasingly, is data work (Kaziunas et al., 2018), a term that extends the concept of information work to involve raw data, including data from sensors, medical devices, and consumer electronics. People with health conditions and their caregivers must understand the uses of data, understand how to understand data, and know when to share data (and with whom) (Kaziunas et al., 2017).

In this paper, we focus on an important source of data for healthcare PGHD. The term PGHD is defined to include health-relevant data captured by the person with a health condition or other care team members outside of a medical environment (Figueiredo and Chen, 2020). PGHD include data that are captured by devices (e.g., sensors or medical equipment), those captured manually by people (e.g., journal entries), or a combination of both [e.g., semi-automated tracking (Choe et al., 2017)]. With the proliferation of consumer sensing devices, a massive amount of data can be gathered that describe the physiological, behavioral, emotional, social, and other factors that could be relevant to health. These data hold great potential for supporting the collaboration of care teams to improve self-care at home, as they can be used to support individual care team members as well as between-member interactions. At the individual level, research has shown that tracking and use of PGHD allow people to understand their conditions (Mamykina et al., 2008), maintain a sense of control (Mamykina et al., 2008; Gronvall and Verdezoto, 2013; Ayobi et al., 2017), and make plans for self-management (Mamykina et al., 2008; Felipe et al., 2015). At the social level, PGHD can empower people with health conditions to have a voice in conversations with clinicians (Bagalkot and Sokoler, 2011; Murnane et al., 2018), as well as allow clinicians to gain a more holistic view of their self-care practices during clinic visits (Chung et al., 2019).

Using and sharing PGHD show great promise, but there are issues that need to be considered in designs that aim to support chronic care. PGHD, as the definition suggests, could contain a variety of data that reveal details about one's life. Collecting

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[6] https://www.hopkinsmedicine.org/health/conditions-and-diseases/acute-spinal-cord-injury

detailed data could be valuable in diagnostic tracking, as people with health conditions could then investigate the association of potential triggers with symptoms (Rooksby et al., 2014; Karkar et al., 2017). Sharing these data within a care team could certainly be helpful so people (PCTs) can work with caregivers and clinicians to collaboratively problem-solve (Raj et al., 2017). However, people with health conditions might not know how to understand and interpret each data type (Choe et al., 2014). Furthermore, revelations from the data could create undesirable impressions of them and affect their relationships with their care team members (Murnane et al., 2018). Privacy issues could be a major concern if these data are not handled properly (Pina et al., 2017; Murnane et al., 2018; Chung et al., 2019). In addition to impression management and privacy concerns, prior research also suggests that maintaining fine-grained control over data is important for PCTs to negotiate the desired level of independence, namely the ability to fine-tune the details for sharing and how data are shared. This is particularly important, since they often want to acquire decisional independence and a sense of control over their lives (Büyüktür et al., 2018). Without such support, PCTs might be in a vulnerable position and lose control of their data to others or large institutions, such as healthcare systems. In this paper, we propose a design to facilitate the sharing of PGHD while allowing PCTs to maintain their sense of control and independence.

1.1.3. Data Sharing Control and Support

Researchers investigating controlling data sharing have focused on two different research streams to mediate between users and the underlying access control mechanisms. The two research streams align with the major two factors that people consider in controlling data sharing (Bahirat et al., 2018): person (recipient) and data.

The first stream of effort focuses on the person dimension, with specific support for using meaningful groupings to help users categorize data-receivers. One prominent application area is to select who should receive data on social network platforms (e.g., Facebook) where users need to decide who or which social circles should receive a status update. For instance, PViz (Mazzia et al., 2012) provided views with different granularity (e.g., group, sub-group, sub-group of sub-group) for users to understand how their profile information would be shared with their friends based on group memberships. Privacy Wedges (Raber et al., 2016) proposed a user interface to allow users to interactively select audiences with certain attributes (e.g., tie strength or friend group) so as to control social media sharing.

The other stream of effort focuses on the data dimension. Since data need to be presented for human consumption, it is important that a user can exert control over how the data are presented. Existing work has explored the use of user interface (UI) designs and interactive data manipulations to prepare data for sharing. For example, Epstein et al. (2013) and Wang et al. (2015) proposed interactive techniques and applications for users to manipulate visualizations to prepare personal data for sharing. Vescovi et al. (2014) and Schaub et al. (2014) proposed allowing users to vary the level of details they wished to reveal using anonymity and summarization semi-automatically.

There have also been designs that accommodate the need to control both factors. For instance, Reno (Iachello et al., 2005) supported computer-assisted semi-automatic location data sharing through location-based and recipient-based rules. Reeder et al. (2008) used a matrix representation to enable access control through describing relationships between files and people's data access. Könings (2015) employed a similar matrix representation with reduced complexity on a mobile platform through rule-based mechanisms. Bahirat et al. (2018) designed a data-driven layered mobile UI for users to control IoT data sharing, from coarse-grained (e.g., whose device and what data) to fine-grained (e.g., purpose and frequency of sharing) control.

The designs introduced above have different focuses on people and data in terms of the audience size and the types of control. The audience size ranges from a family, an office unit, contacts, an organization, social media, to the Internet. Most designs provide only coarse-grained control, and only a few support fine-grained control (Epstein et al., 2013; Könings, 2015; Bahirat et al., 2018). The scenarios considered include personal data control for sharing with digital devices/services, social media sharing within social circles, and office sharing with colleagues. Less is known about how to design UIs for people to exert fine-grained control over sharing, especially within healthcare. There is a need for a design that allows PCTs and their caregivers to control PGHD sharing while taking into consideration the needs of a care team and of the conduct of their chronic care. Our design offers one such prototype.

We next turn to our design process, a representative scenario of care, and a set of design requirements.

2. MATERIALS AND METHODS

2.1. Co-designing the Prototype Application

In order to create a person-centered solution for managing PGHD sharing, we adopted a co-design approach to work with a person (PCT) with similar care needs as SCI/D patients to explore the design space and develop an application concept.

We first describe the process of collaborating with this person on designing DC.

Co-design is an effective way for participants to organize and illustrate their experiences (Hieftje et al., 2014; McCarthy et al., 2017; Hong et al., 2018) and bring them into the design process. Co-design also allows participants to join in the research in a way that can be dynamically adjusted to a participant's level of energy and comfort in taking the lead, both of which are particularly important for participants who are dealing with illness (Lindberg, 2013).

Our research team formed a partnership, based on prior research interactions, with a person with congenital muscular dystrophy, a condition that in this case has resulted in severe physical disability and requires complex care management. Muscular dystrophy is a progressive and degenerative condition, and he has diminished use of his limbs. In addition to muscle weakness, his respiratory system is also affected and requires additional care and monitoring. As a result, he uses a power wheelchair and requires assistance from caregivers to navigate different aspects of everyday life such as commuting, monitoring heart rate and fluid intake, assistance during the night, and using a ventilator when required. He has a team of people who assist him with self-care, including parents as his primary caregivers, a sibling as a secondary caregiver, 10-15 hired caregivers, and clinicians.

The partnership was beneficial as our co-design partner has the perspective of a person with a severe chronic condition working with a care team and is passionate about the potential of technology to improve the life of PCTs like himself. As a co-design partner, he was instrumental in shaping the design of DC and provided valuable insights on the life of a PCT.

During an eight-month engagement with weekly working sessions, the first author and the co-design partner worked to collaboratively explore the design space of PGHD sharing applications, based on prior research and personal experience.

Our co-design process followed the Cooperative Inquiry method proposed by Druin (1999) and subsequently extended by Garzotto (2008). Druin argued that researchers should systematically involve users as design partners to participate in the entire research, design, and development process.

The first step of Druin's process is contextual inquiry, a form of user-centered design (UCD) (Cooper et al., 2012). We conducted observations and reflections on the chronic care process as well as stakeholders' involvement (e.g., caregivers and medical professionals). We iteratively discussed our findings and created representations such as personas and scenarios to document stakeholders' experiences of collaborating on care. These personas and scenarios also made explicit potential concerns and issues in sharing PGHD. This step mapped out an understanding of the lived experience of a person with a severe chronic condition that could be used to ground the design and to examine what features were needed, in our case, for a system to facilitate data sharing with care team members in a way that respects a person's need for control.

Druin's second step is technology immersion, to allow design partners to get suitable exposure to technology, in our case, sensor data and sensing devices. We surveyed commercially available sensing devices and techniques so that our co-design partner understood what data could potentially be captured to characterize different aspects of people's health.

Druin's third step, participatory design, consists of collaboratively exploring potential designs through an iterative process. Based on the personas, scenarios, and understandings of sensor data (the previous two steps), the first author and co-design partner investigated potential design requirements. They also created design artifacts such as sketches, lo-fidelity paper prototypes (Snyder, 2003), and hi-fidelity interactive mock-ups to iteratively design a software system that could be used to manage PGHD sharing with care team members while being mindful of PCTs' concerns about independence and privacy.

Exploring different designs including the basic user interface. The co-design partner is passionate about games in general, and often brought up his observations about games as examples of visual interfaces that would allow him to exert control. Examples of games we examined ranged from poker cards, board games, to 3D games. The design exploration, therefore, moved away from a typical smartphone app with a hierarchy of lists and toggles to a more visually-oriented user interface featuring elements that could be viewed at a glance. The design exploration also started examining designs where users could easily change states by rearranging different visual elements (as in games). The first author, and the co-design partner brainstormed ideas, and the first author drew sketches that served as a medium for both authors to collaboratively iterate on designs.

Overall, the co-design process between the first author and the co-design partner led to three outcomes. The first was scenarios of use. The second was a set of design requirements, based on standard usability concerns and in care requirements. The third outcome was an application concept, DC. In the end, the first author implemented the agreed-upon design as a web application, DC, that featured a grid-based interface, as shown in **Figure 1**.

At the end of the co-design process, we invited our co-design partner to be a co-author (the second author) to acknowledge his contributions to the research.

2.2. Care Scenario

Here, we present one of the scenarios envisioned for our design. The scenario uses a person with SCI/D to ground the design requirements and the evaluation of our design.

The care scenario: Peter is a 19-year-old college student with spinal cord injuries due to a car accident that happened 3 years ago. With quadriplegia, Peter's upper limbs, trunk, and lower limbs are paralyzed, with only limited control over some parts of his upper body. As a result, Peter has a limited range of motion and physical activity without assistive devices. Peter, like others with quadriplegia (tetraplegia), also lost the ability to sense his body. For instance, he does not feel thirsty even if needing water, and so he cannot maintain proper hydration. Peter, therefore, needs assistance to perform various self-care activities to keep himself healthy. These activities include both doing and monitoring fluid intake, stretching, executing a bowel/bladder program, checking his heart rate, checking his body temperature, and moving his body during sleep to prevent pressure sores.

Such assistance comes from a dynamic team of family members, hired caregivers, and clinicians. Peter's mother is his primary caregiver who oversees his care. Peter and his mother hire 10–15 caregivers who are college students to take shifts and assist him day and night. Sometimes, a caregiver cannot make their shift or has to leave the position permanently for school or work. Peter's father and brother then have to jump in to assist until more caregivers can be found or hired. Similarly, adjustments need to be made when Peter's health changes. The primary and hired caregivers will then monitor more factors, including heart rate, fluid intake, sleep quality, and physical activity, in order to investigate potential causes and to develop care routines to manage any health contingencies. Clinicians from different clinics and health systems, including his primary care provider (family physician) and his Physical Medicine and Rehabilitation (PM&R) doctor, are involved when their medical expertise is needed, especially when Peter's health worsens. All

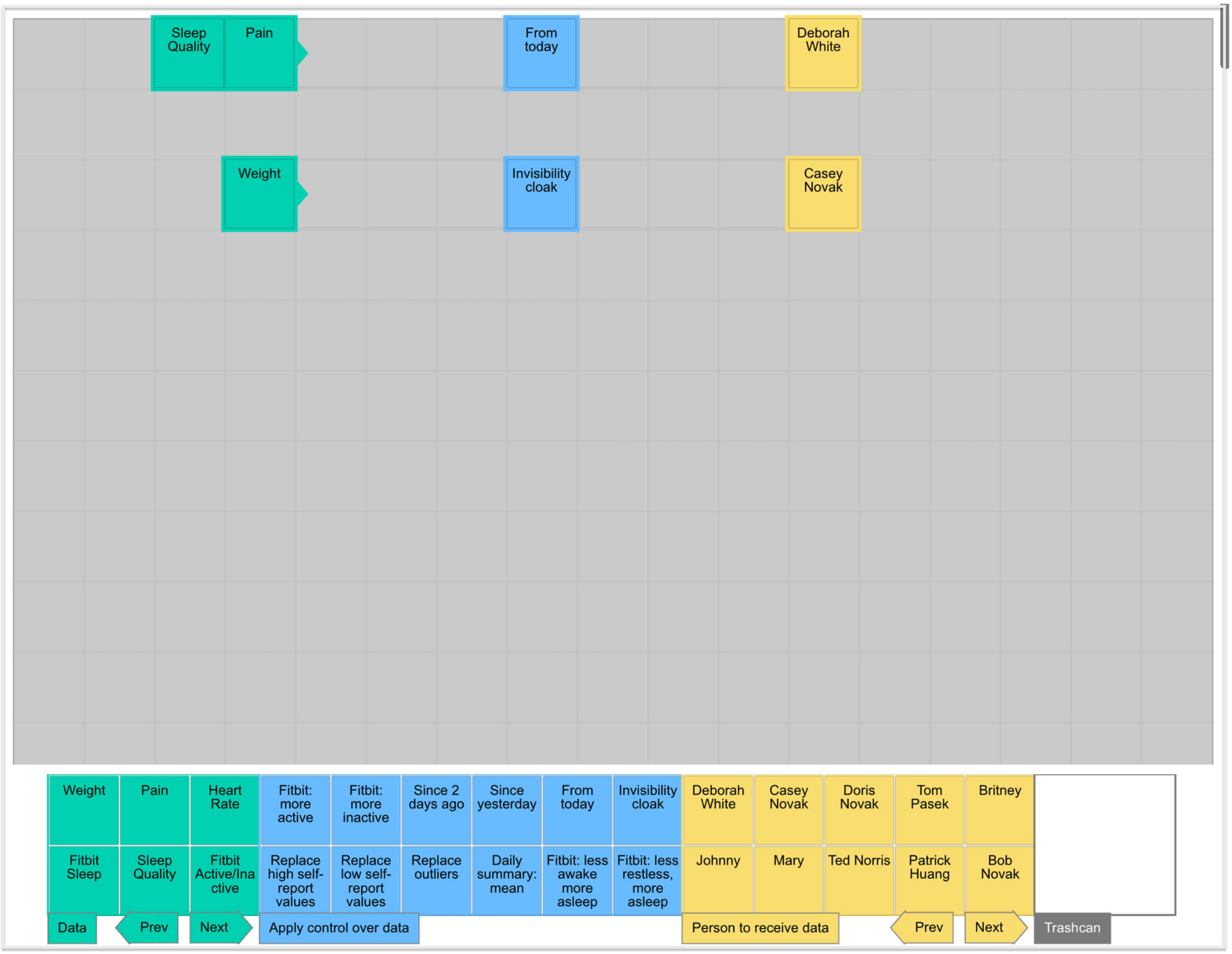

FIGURE 1 | Data Checkers (DC) has a grid-based interface for specifying sharing settings.

these care team members would benefit from seeing data about Peter's health and care.

2.3. Design Requirements

Based on the prior literature, observations and interviews from our and others' prior work (Büyüktür et al., 2017, 2018; Ackerman et al., 2018) and our co-design process, we formulated five requirements necessary to adequately support the control of PGHD data sharing for people (PCTs, such as Peter) to share with their care teams. While these requirements were developed within the context of SCI/D care, we believe they are true for other conditions that require similar care. This list of requirements is not exhaustive. Other requirements may be uncovered in the future, but we believe if these are not satisfied at a minimum, an application will not adequately address the data sharing needs of people in severe chronic care settings such as SCI/D.

These five requirements build on each of the previous ones. The requirements are:

Require1: Provide a user-friendly interface for specifying sharing settings. As a basic requirement, a system should provide a user-friendly interface that people without technical expertise can use (Demiris et al., 2008). Users should be able to navigate what Norman (2013) called the "gulf of execution," the alignment of system capabilities and what users perceive to be achievable through the system. Users (i.e., PCTs) should be able to quickly learn how to use the system to efficiently accomplish what they intend to do (Rubin and Chisnell, 2008). With the goal of controlling their data sharing, users should be able to create and modify sharing settings easily, without having difficulty in using the interface to achieve their goal (Kuniavsky, 2003; Cooper et al., 2012; Bevan et al., 2015).

Require2: Support sending data to multiple members of a sufficiently-sized care team. Self-care is often a collaborative effort (Nunes and Fitzpatrick, 2015; Ackerman et al., 2018; Büyüktür et al., 2018). Care team members may need to have access to the same set of data to support day-to-day collaboration, including monitoring. Research has shown that such collaborative monitoring is beneficial or even critical (Birnholtz and Jones-Rounds, 2010; Caldeira et al., 2017). A system to support data-sharing within a care team must be able to support sharing specific types of data with multiple care team members. Our co-design process revealed that a size ranging from 10 to 20 is necessary for SCI/D, which includes family caregivers (1–5), hired caregivers (5–10), and clinicians who closely work with the person with a health condition (around 5). Users (PCTs or their proxies) should be able to express how they want to share different data with each care team member, as opposed to a one-size-fits-all setting for everyone.

Require3: Support understanding of sharing settings. A system should present sharing settings for the care team in a way that is easy to comprehend. Users should be able to answer basic questions (Büyüktür et al., 2018), such as "Who has access to the heart rate data?," simply by looking at what is shown. PCTs and caregivers should be able to navigate Norman's (2013) "gulf of evaluation," letting users assess the state of the sharing. In the context of care, a system should also support users in answering questions such as "How do my data look like for my father?" so PCTs or their helpers can understand how sharing settings have affected the resultant data flows.

Require4: Support PCTs (or their primary caregivers) having fine-grained control over their data. In collaborative self-care, one should be able to control how much PGHD could reveal about one's life by having fine-grained control over the sharing of PGHD within the care team. In addition to users being able to choose recipients (Require2) and understand what the sharing settings are (Require3), they should be able to closely control how much detail is shared with each recipient (Prasad et al., 2012; Büyüktür et al., 2018; Murnane et al., 2018). This could include, but is not limited to, hiding or manipulating certain data (Epstein et al., 2013) and presenting summary instead of raw data (Büyüktür et al., 2018). For example, through the co-design process, we identified four kinds of tools, which we termed "controls," that can help PCTs control the level of detail (e.g., daily summary), length of history (e.g., up to 7 days or 3 h), the shape of data (e.g., remove outliers), and visibility of data (e.g., temporarily suspend sharing).

Require5: Support long-term sharing management by addressing health and care team changes. Chronic care is a long-term process (perhaps a lifetime), where the care team continuously creates and re-creates care routines to manage health contingencies (Büyüktür et al., 2017; Ackerman et al., 2018). This process requires monitoring different health indicators and care activities (Rooksby et al., 2014; Karkar et al., 2017). Members of a care team come and go for various reasons, such as having multiple responsibilities and priorities (e.g., other jobs), relocating for job or school, and accommodating changes in a person's health (e.g., new symptoms or co-morbities) (Consolvo et al., 2004; Büyüktür et al., 2018). A system designed to support care should make it easy to manage data sharing to accommodate different occasions (i.e., health or team changes). This includes capabilities to tailor sharing settings for a particular set of data or people through understanding and re-purposing existing sharing settings.

Data Checkers was designed to fit these requirements. We stress that while this list of requirements is by no means exhaustive, it includes a range of considerations that are critical for PCTs (i.e., people with SCI/D). We believe these requirements will also be true for many people with severe care needs who are involved with making care management decisions.

2.4. Data Checkers System Overview

Data Checkers was designed, based on the design requirements outlined above, to manage PGHD sharing. As shown in **Figure 2**, DC contains two features, the grid-based interface and a preview, which are particularly important to allow users to implement fine-grained control and support ongoing management of self-care.

The grid-based interface, similar to what is usually seen in checkers and chess, allowing users to strategically express data sharing preferences for different stakeholders. Users can (a) place different blocks on the grid to specify how they prefer to share data with different care team members. Users can (b) dynamically adjust the location of blocks to change sharing settings in reaction to changing health conditions and changing relationships among care team members. After specifying sharing preferences, users can (c) preview data according to stakeholders' perspectives so as to understand how data sharing is regulated by any given sharing setting.

2.5. Create Sharing Settings

In DC, one configures sharing settings by laying out visual blocks on a board. As shown in **Figure 3**, there are three types of blocks: person (yellow), data (green), and control (blue) blocks. The lists of data, person, and control blocks can be extended if necessary.

- Person: DC currently supports sharing within a moderate sized care team, including family caregivers, hired caregivers, and clinicians (e.g., occupational therapist, doctor, nurse).
- Data: Data sources can include biomedical (e.g., heart rate), behavioral (e.g., activity status), and self-report data (e.g., pain).
- Control: There are four categories of controls (12 in total), tools that tailor the details of data being shared (e.g., share data only as an aggregated daily summary). These were the outcome of the co-design process described in section 2.1.

There are two simple rules in DC that define how different blocks work together.

- Rule 1: a type of data (as a block) can be received by any person (as a block) on the right in the same horizontal row.
- Rule 2: any control block being placed along that segment between a data block and a person block regulates how the person receives the data.

With these two simple rules, DC supports three basic operations that make it easy to create, modify, and extend sharing settings through visual composition. **Figure 4** shows one example for each of these actions. First, to create a sharing setting to give a person access to certain data, a user can simply put a person block (e.g., Dr. White) on the right of a data

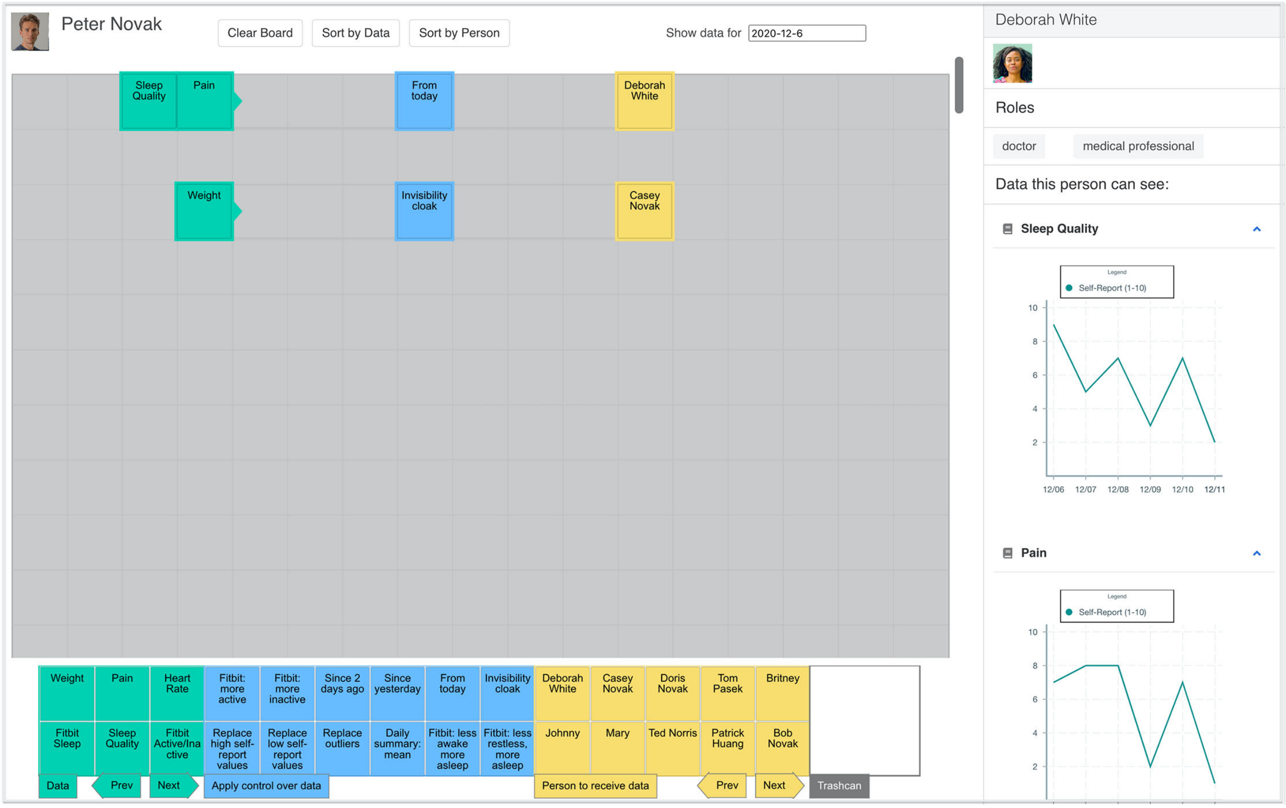

FIGURE 2 | DC: On the left is (a) a grid-based interface for specifying sharing settings, and on the right (c) is a panel that shows the preview of data being shared in a recipient's view (Profile photos by Julian Wan and Leon Ell' on Unsplash).

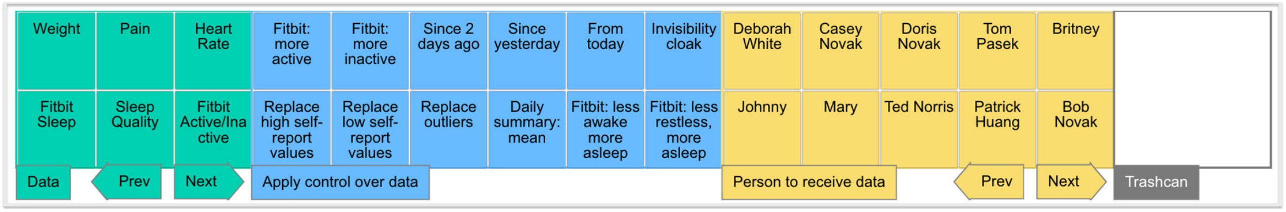

FIGURE 3 | Essential elements in DC: On the left are blocks that represent different data sources (e.g., Heart Rate and Sleep Quality). On the right are yellow blocks that represent different people (e.g., Johnny and Doris Novak) with whom to share data. In the middle are blue blocks that represent different controls (e.g., Daily Summary) that can tailor the details being shared.

block (e.g., Heart Rate). Second, to modify a sharing setting such as adding a restriction (i.e., limiting access to data to the past week), a user can simply put a control block (e.g., Past Week) between the data and person blocks. Lastly, to allow an additional person (e.g., the nurse Johnny) to have the same sharing setting for an existing person (e.g., Dr. White), a user can simply add the desired person (Johnny in this case) to the right of people already included in the sharing setting.

Following these two rules, users can strategically use the three basic operations to add and remove blocks on the board to allow or disallow people to receive different data sources. DC also allows users to enable and disable sharing settings within a selected row.

Note that laying out a set of blocks (e.g., Heart Rate, past week, Dr. White) in the first row has the same effect as laying out the same blocks in any other row. By doing this, DC offers users the flexibility to arrange sharing settings in a personalized manner.

To support managing data sharing with different care team members, DC also supports creating sharing settings using roles such as "primary care professional," "nurse," or even "medical professional," (similar to the use of roles in role-based access control, Ferraiolo and Kuhn, 1992; Sandhu et al., 1996). With both the individual and role blocks, it is possible that users could

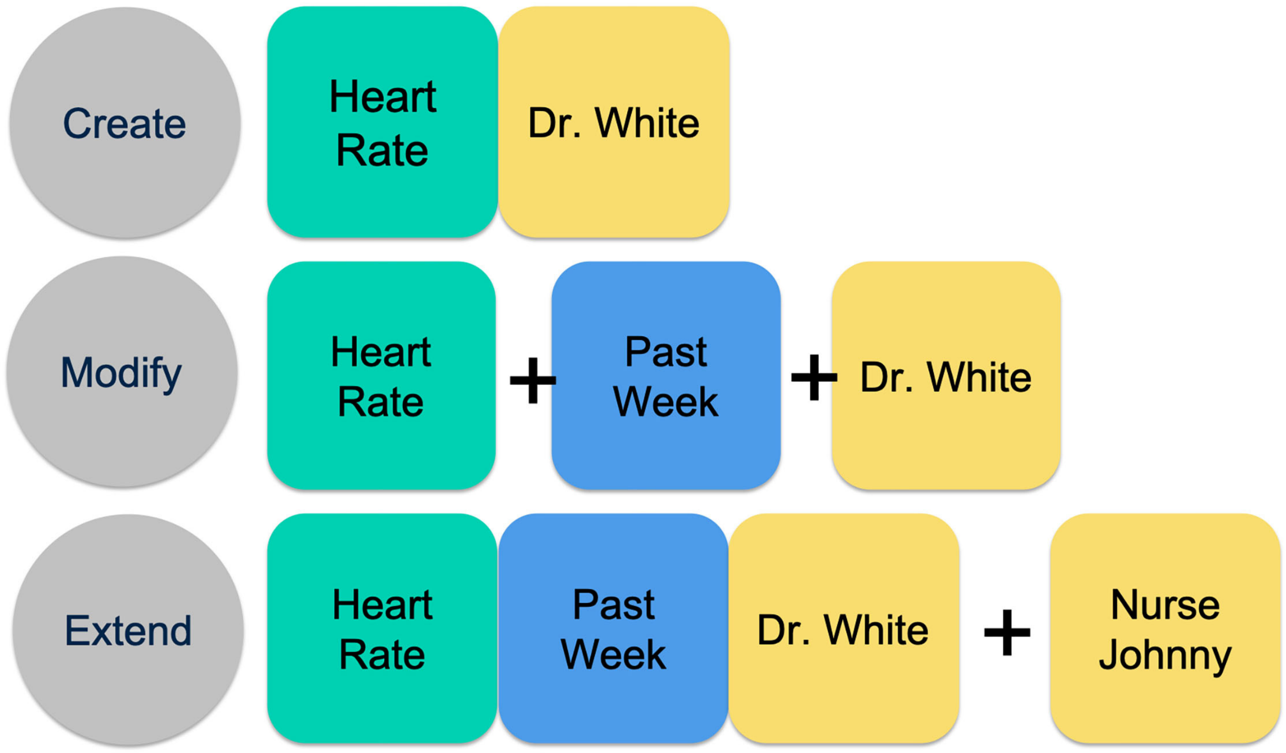

FIGURE 4 | DC supports three basic operations that make it easy to specify and reuse sharing settings: create (top), modify (middle), and extend (bottom).

create sharing settings that are conflicting. Currently, DC honors the most specific (e.g., for the individual) sharing decision when a conflict exists. This resolution mechanism also enables users to create exceptions for a specific individual (e.g., Patrick).

As the number of sharing settings increases, it is expected that users will need support to find sharing settings involving a specific person or data type. DC allows users to re-layout sharing settings through "sort by data" and "sort by person" features, so that it is easier to locate sharing settings about a specific data type or care team member.

Note that in the remaining part of this paper, we will use "sharing setting" to refer to a data-controls-recipients tuple that specifies "I want to share what data (data) to whom (recipients) after some data processing (controls)."

2.6. Previewing Data From the Stakeholders' Perspectives

The other major feature of DC is the ability to see a preview of data flows from the perspective of the data's recipients. As prior work (Büyüktür et al., 2018) suggests, allowing PCTs to see how data will be presented is important; users want to understand the effect of sharing settings. In DC, users can see the effects of sharing settings when viewing different care team members (**Figure 6**). This feature is designed to allow users to 1) experiment with different combinations of person, control, and data blocks while learning about the effects, and 2) verify whether data sharing settings have been configured as intended.

For instance, if a user indicates that she wants to share both sleep quality and pain with her physician, Deborah White, she can use the data preview capability to examine whether this physician will receive data as planned. As shown in **Figure 5**, this user can select Deborah White on the board, and the panel on the right (shown in **Figure 6**) will display information about Deborah White, including profile photo, name, and roles, as well as the different data, presented in visualizations, for which Deborah has access, given the current set of sharing settings.

3. RESULTS

To examine whether DC allows users to better control data sharing within care teams, we invited people with chronic conditions or disabilities as well as caregivers to help evaluate DC. The goal of our evaluation study was to examine the design features of DC, including its grid-based interface and the capability to preview data, to determine whether they offered advantages over a conventional design in supporting data sharing for care.

To do this, we evaluated DC against a state-of-the-art design, which we will call Reference Design (RD). As our comparison, we chose a design that used a hierarchical design that is standard for organizing settings and options on all major desktop, web, and mobile platforms. This hierarchical design uses a list as the main layout for organizing different options. Such a conventional design allows users to progressively navigate through layers of

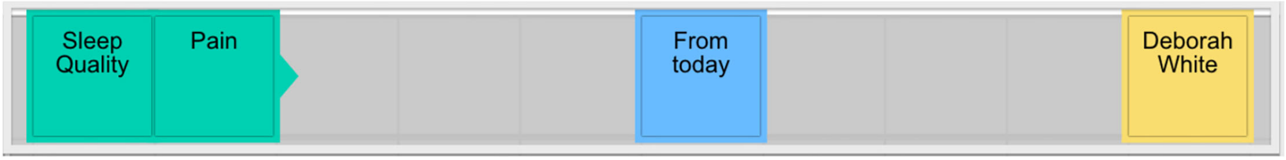

FIGURE 5 | On this board, there are sharing settings that enable Sleep Quality access for Deborah White, in addition to Pain data.

options to execute a specific action through, for example, buttons or toggles - as seen in settings within iOS or Android applications.

We chose to adopt the state-of-the-art application described in Bahirat et al. (2018) for the following reasons. First, their use case was for fine-grained control over the the Internet of Things data collection, including the use of sensing devices to generate data characterizing an individual's life at home, which is similar to what is needed for PGHD. Second, the design uses a conventional design that features standard GUI widgets, such as lists and toggles, which provide familiarity to users and allowed us to examine the feasibility and advantages of using the grid-based interface offered by DC. Third, Bahirat et al.'s design can accommodate people, data, and controls, while giving different elements equal presence. To the best of our knowledge, there were not any individual-facing applications (i.e., for people with health conditions) designed to support fine-grained control over PGHD sharing with care teams for the long-term. Existing consumer health apps lack the capability of fine-grained control (e.g., Apple Health[7], Fit[8] by Google, and HealthMate[9] by Withings) and thus were not suitable for comparison. As a result, we chose the design used in Bahirat et al. as our Reference Design.

However, we found it necessary to modify Bahirat et al.'s design slightly. It was originally designed for mobile platforms with limited screen space, and we felt that comparing our web application on a browser with a mobile app on a handheld device would create confounds from different device screen sizes and potentially different interaction techniques such as swiping. For a fair comparison, we implemented a web version of RD that provided more screen space and allowed users to see layers of options simultaneously, as commonly seen in Windows or Macintosh desktop software. We structured sharing settings in the following order, person-data-control, as shown in **Figure 7**. This followed research findings where person and data had been found to be the dominant parameters people considered regarding privacy risks in sharing (Lederer et al., 2003; Bahirat et al., 2018). The order of different persons, data, and controls were randomized to reduce the effect of ordering on study results. The same order was used by both DC and RD. We followed the design by Bahirat et al. as faithfully as possible, including the use of toggle position and color scheme as indicators of further options.

3.1. Evaluation Participants

The target users of DC are people with severe chronic conditions, such as people with SCI/D, and their caregivers. In addition to supporting people with health conditions requiring care teams (PCTs) to gain independence through sharing control, we recognize that caregivers might need to assist with data sharing when people's health fluctuates and thereby might have limited capacity for self-managing their data. As a result, we recruited people with chronic conditions as well as people with caregiving experience who were 18 years and older. Participants were recruited through university mailing lists. Our study included fifteen participants, with 13 women and 2 men. Participants' backgrounds were varied (shown in **Table 1** for more details). At least 8 participants had direct experience with conditions that were likely to require care teams at some point in care, including caregivers or nursing professionals who had provided care for individuals with autism, stroke, neurological impairments, and SCI/D.

3.2. Study Procedure

The study was conducted remotely through video-conferencing software (Zoom[10]) with screen-sharing enabled. Each study session took 60–90 min and was recorded. Consent was obtained through email prior to each study session. During each study session, participants first filled out a biographical questionnaire and watched two videos that explained the design and features of DC and RD, respectively, to learn about how to use both applications. The videos were created to provide consistent training across participants. We then provided participants with a tutorial task so that participants could ask questions to clarify their understanding of how to use the two applications.

After the tutorial tasks, each participant was then asked to complete four tasks (shown in the following section) that involved creating and modifying sharing settings using both DC and RD. The instructions for each task was displayed above the interface.

After participants finished tasks and acquired experience using DC and RD, the first author conducted a semi-structured interview with each participant to probe how DC supports or hinders users' capabilities to control PGHD sharing with care teams.

Participants who successfully completed the study were compensated for their time with a $20 gift card. The Institutional Review Board at our university reviewed this study. All data

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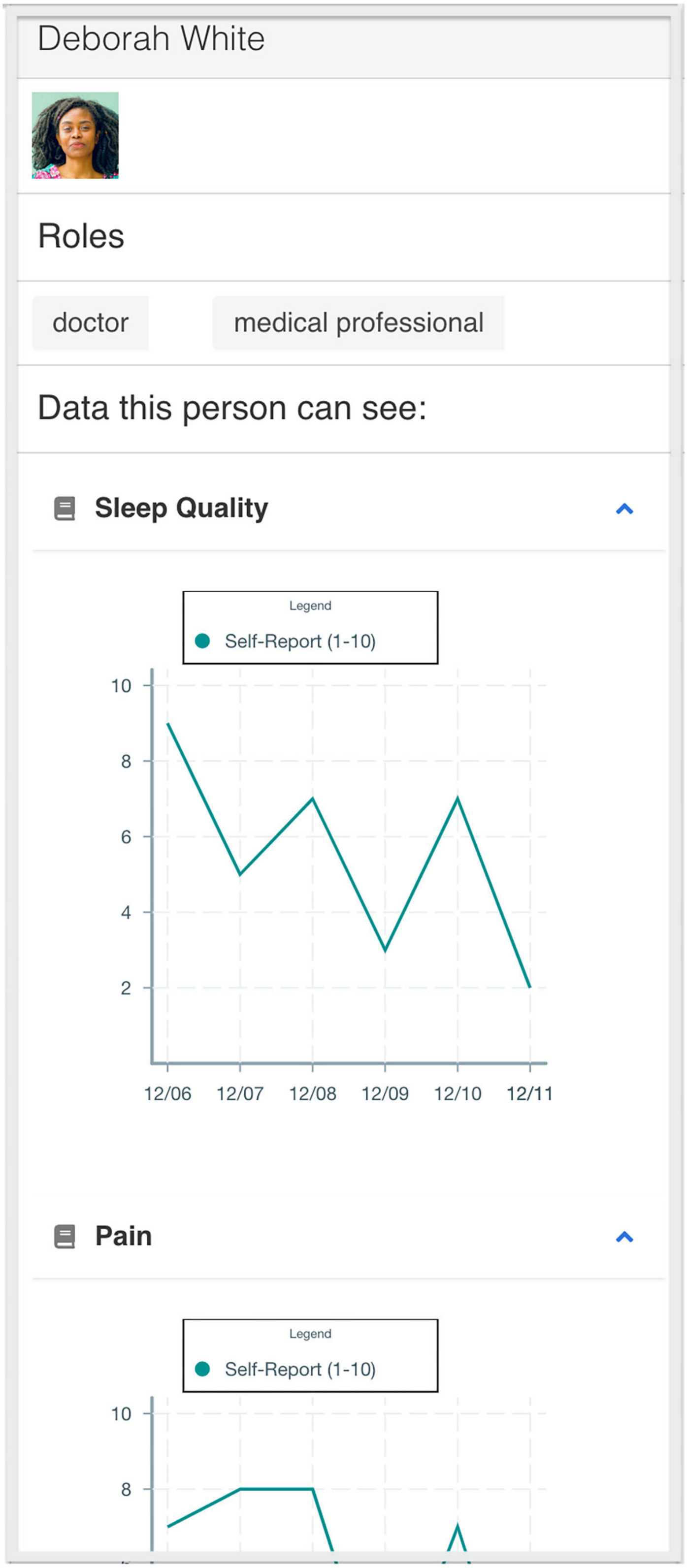
[7] https://www.apple.com/ios/health/

[8] https://www.google.com/intl/en_us/fit/

[9] https://www.withings.com/us/en/health-mate

[10] https://zoom.us/



Deborah White

Roles

doctor

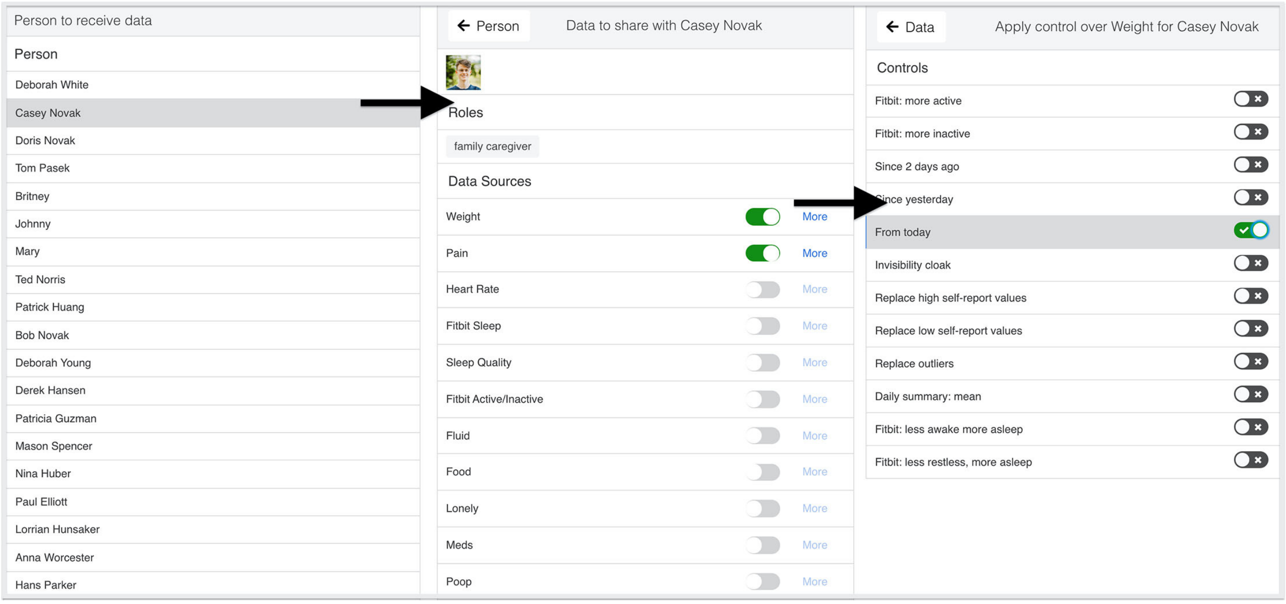
medical professional

Data this person can see:

Sleep Quality

Pain

FIGURE 6 | Data Preview: showing data access (Sleep Quality and Pain) for Deborah White. Users can use the data preview to see the effect of the sharing settings (The profile photo used in this screenshot is by Leon Ell' on Unsplash).



Person to receive data

Person

- Deborah White
- Casey Novak
- Doris Novak
- Tom Pasek
- Britney
- Johnny
- Mary
- Ted Norris
- Patrick Huang
- Bob Novak
- Deborah Young
- Derek Hansen
- Patricia Guzman
- Mason Spencer
- Nina Huber
- Paul Elliott
- Lorrian Hunsaker
- Anna Worcester
- Hans Parker

Data to share with Casey Novak

Roles

family caregiver

Data Sources

Data source	Shared	
Weight	●	More
Pain	●	More
Heart Rate	○	More
Fitbit Sleep	○	More
Sleep Quality	○	More
Fitbit Active/Inactive	○	More
Fluid	○	More
Food	○	More
Lonely	○	More
Meds	○	More
Poop	○	More

Apply control over Weight for Casey Novak

Controls

Control	
Fitbit: more active	☒
Fitbit: more inactive	☒
Since 2 days ago	☒
Since yesterday	☒
From today	☑
Invisibility cloak	☒
Replace high self-report values	☒
Replace low self-report values	☒
Replace outliers	☒
Daily summary: mean	☒
Fitbit: less awake more asleep	☒
Fitbit: less restless, more asleep	☒

FIGURE 7 | An adapted version of the layered design by Bahirat et al. (2018): each layer provides options to fine-tune data sharing, starting with the person, data, and then control. Users who want to fine-tune the details being shared can find different options in subsequent layers (Profile photo by Carlos Lindner on Unsplash).

reported here have been anonymized; we have done some light editing of quotes for readability.

3.3. Evaluation Tasks and Semi-structured Interviews

We designed four tasks that involved viewing, changing, and finding special cases among data sharing settings. These are three of the fundamental policy-authoring operations proposed by Reeder et al. (2008). We left Reeder et al.'s operation of viewing group membership (e.g., a person is a member of a hospital system) to future work.

During these tasks, a participant assumed the role of an individual with a severe chronic condition, who received assistance from a care team (e.g., as a PCT like Peter in the scenario described in section 2.2), and is actively considering how to share a set of data (shown in **Table 2**) with members of her care team (shown in **Table 3**).

These tasks were designed to verify whether a design could satisfy the 5 design requirements from section 2.3. The tasks we asked participants to solve were as follows:

- T1 – create a set of sharing settings to share data with care team members.
- T2 – modify a set of sharing settings to accommodate changes in a care team.
- T3 – reuse a set of sharing settings recommended by health professionals in reaction to changes in health, and tailor the settings to one's care team.
- T4 – make maintenance changes to sharing settings after sharing data with a care team for a period of time to accommodate the varying time commitments of care team members.

TABLE 1 | Participant description: The educational status of our participants was high school degree or equivalent (3), bachelor or some college education (7) and masters (5).

	Age	Occupation	Background	Care related experience
P01	26–30	Student	Nursing	C
P02	18–25	Student	Information	P
P03	18–25	Student	Medicine	P
P04	60–65	Higher Education	Information	C
P05	26–30	Student	Information	C
P06	26–30	Student	Health Informatics	C
P07	26–30	Behavioral Scientist	Health Informatics	C
P08	56–60	Unemployed	Latin American Studies	P
P09	18–25	Nurse Aide	Nursing	C
P10	18–25	Nurse Aide	Nursing	C
P11	18–25	Student	Neuroscience	P
P12	18–25	Student	Nursing	C
P13	18–25	Student	Nursing	C
P14	18–25	Student	Nursing	P and C
P15	18–25	Student	Nursing	P and C

"Caregiver"(C) refers to a participant who has caregiving experience (including as a nursing professional), and "person"(P) refers to "a person with a chronic condition."

Each participant was asked to complete T1–T3 using both DC and RD, where the order of designs was counter-balanced to reduce any learning effects. Using RD allowed participants to have a basis for comparison to ground the discussion about why DC might or might not be a promising design. Participants were asked to complete T4 two times, first without and second with

TABLE 2 | Selection of patient-generated health data (PGHD) types.

Exercise	Farting	Activeness	Sleep monitoring	Fluid input
Food	Hanging out	Heart Rate	Location	Loneliness
Medication	Mood	Pain	Skin condition	Sleep quality
Smoking	Bowel movements	Stress	Urine	Weight

TABLE 3 | Selection of care team roles.

Family caregiver	Paid caregiver	Primary care physician	Nurse
Psychologist	Respiratory therapist	Pulmonologist	Nutritionist
Social worker	PM&R doctor	Cardiologist	Occupational therapist

the preview feature, to facilitate the discussion on whether the preview feature is helpful for controlling PGHD sharing.

These scenario-task combinations which exemplify the characteristics of data sharing in care and in care team collaboration, allowed us to examine whether DC's design sufficiently supports data sharing. Note that in the evaluation, we used "the grid" to refer to DC and "the list" to refer to Reference Design so that participants had easy-to-understand and consistent vocabulary when discussing and comparing the two designs. This will be reflected in some of the quotations below.

After a participant completed *each* task, a follow-up question examined how useful a given design was for completing the task:

- Which of these designs (grid or list) is more useful for you to control data sharing for this task? Why?

If necessary, this was followed with the probe:

- How did the features or characteristics of each design helps support the task? Hinder the task?

After all tasks were completed, a semi-structured interview was conducted to examine the overall experience of using both designs (DC and RD), as well as to investigate the potential of supporting data sharing over the long term to manage change. The questions were posed as comparing the two designs so as to tease out the dimensions participants might use for evaluation and comparison. The semi-structured interview schedule consisted of the following:

- Which of these designs, grid or list, was more useful for you to control data sharing for care? Why?
- Which of these designs do you think would be more useful for controlling data sharing among multiple caregivers and clinicians? Why?
- Chronic care is a long-term process. Which of these user interfaces do you think would help people with health conditions or caregivers to control data sharing with care teams over a long period of time? Why?

Below, we present only qualitative data from the evaluation study. While the study was non-probability based, we believe the qualitative data are sufficient, however, to show the feasibility of DC's design for supporting care.

3.4. Data Analysis

We recorded both what the participants did and said through video and audio capture and answers to interview questions were transcribed.

We used Situational Analysis (Clarke, 2005), an updated version of grounded theory, in our analysis. Situational Analysis recognizes the importance of Symbolic Interactionism (Strauss, 2008) in the interpretivist analysis of qualitative data; it also incorporates practice theory, among other additions. Situational Analysis can be seen, in Clarke's terms, as a theory/method package. This perspective was critical as background for our analysis. We see the problem and the application presented here as part of patients' and caregivers' data work (Kaziunas et al., 2017), which in turn is an increasingly important aspect of patient work (Valdez et al., 2015) and more broadly of interaction work (Strauss, 2008; Strauss et al., 2017). In our evaluation, we examined how our participants weighed potential changes in care practices in light of the data work.

In Situational Analysis, iterative cycles of data collection and analysis inform one another. Initial interviews were transcribed and analyzed using open coding to identify significant themes, utilizing Atlas.ti[11]. The coded interviews were then discussed by the first and last authors in weekly data analysis sessions. New codes were generated collaboratively, as important concepts were identified, compared, and revised. These codes were later used as the basis for probes in future interviews. The process was repeated iteratively. Prior interviews were recoded to maintain consistency, and over time, new and recoded interviews led to important themes that emerged from the data. As part of the process, analytical memos were written and discussed as theoretical insights emerged from the ongoing data collection and analysis.

3.5. Findings

In general, our participants were able to perform the evaluation tasks. DC was praised for enabling users to easily grasp how data were currently shared within care teams through the grid-based interface. Moreover, our participants found that DC enabled them to make changes to existing settings intuitively through visual composition. The data preview feature was well-received for allowing users to confirm their understanding of sharing settings and to learn about the effect of applying controls. In comparison, RD, with a design that participants could instantly recognize and were familiar with, was considered not as useful for performing data sharing within care teams. The evaluation results showed that RD's hierarchical design, while technically allowing users to achieve the same goals, was useful only in simple cases. RD's design made it challenging for users to consider multiple care team members simultaneously in the process of creating and modifying sharing settings for care teams. We

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[11] https://atlasti.com/

were surprised, but delighted, by how much our participants generally found DC to be better for the requirements of complex care than RD.

In the rest of this section, we elaborate on how the design of DC satisfies each of the requirements from section 2.3 in turn. Note that an interactive system such as DC provides an integrated experience through the combination of different features. The same feature, in combination with others, could offer a utility that satisfies multiple requirements. We present how aspects of DC support each requirement by our participants. These results, we believe, show why DC is a promising design for sharing PGHD in a care context, while also identifying room for improvement.

3.5.1. (Require1) DC Is Usable and Useful for Specifying Sharing Settings

Our participants generally found DC to be usable with its grid-based interface and its features to support the expression and use of sharing settings. All participants (15 out of 15) reported that DC was easy to use.

However, DC's interface and capabilities were offered through a novel grid-based interface, and some participants needed time to learn it. All participants reported that DC was easy to use, but only five considered DC easy to use up-front. The other 10 stated they needed a period of learning how to use DC, and then creating or modifying sharing settings was easy. For example, P03 suggested that once she understood how to use DC, by "getting the hang of it," it was effective for controlling sharing:

> I think, yeah, once you get the hang of it, it's pretty intuitive to use. I don't think I've seen [the grid of DC] before. It's not something that people normally see. But I don't think it's something that's hard to learn. I think it's definitely a better alternative than the list [RD] - P03 (person with a chronic condition)

The novelty of DC's interface did not appear to be a huge hindrance. All our participants were able to use DC to control the required data sharing in the evaluation tasks.

Acceptance, however, was not uniform. All participants thought DC would be useful for chronic care that dealt with complex care situations. One participant added that DC's unconventional design was effective but intimidating and overwhelming; this appeared to be from the novelty of DC's interface. However, some participants (6 of 15) stated they would prefer RD for simple cases that consisted of only one or two care team members or a small number of PGHD data streams. We note that DC was not designed for these simple cases; it was an attempt to handle near-future scenarios with moderate sized care teams and a number of data streams. We will return to this issue in the Discussion, because it suggests a relatively simple modification that can handle all cases.

There were several other usability issues mentioned by participants. These are relatively minor issues; none kept our participants from finishing the evaluation tasks. DC uses a click-to-focus (because of accessibility); a few participants wanted drag-and-drop as an additional user interface focus mechanism. One participant wanted a more recognizable format for the trash/delete area as can be found in Windows or Macintosh OS. There were several complaints about the use of screen real estate in DC; those participants wanted a tighter use of the screen.

Our participants were also able to use the conventional design of RD to complete the tasks. However, since the tasks assumed moderate complexity in a care team, participants noted the difficulty of creating or modifying settings using RD's user interface. All participants mentioned the burden of too much clicking to navigate or how sharing settings are visually hidden, which made it difficult when creating sharing settings involving multiple care team members. We will discuss these issues further below.

In summary, our participants found DC even with its non-conventional design to be usable. Participants noted that a learning curve was required, but within the context of complex care tasks, as embodied by tasks T1 through T4, DC was sufficiently usable for specifying sharing settings. P13 stated:

> I would have thought the list [RD] would have been easier just from looking at it... [the list] looks a little more user friendly, but [it takes] many clicks to do things like changing the settings... With the grid [DC], you could just drag it [a data or a control block] and then it would be applied to like all three people. - P13 (caregiver)

3.5.2. (Require2) DC Is Effective for PGHD Sharing Involving Multiple Members of a Sufficiently-Sized Care Team

Data checkers was designed to support a care team with up to 20 members, currently a reasonable size suggested by prior work and our co-design process. All our tasks, from T1 to T4, were designed to involve different numbers of care team members ranging from 3 to 20, including family caregivers, hired caregivers, and different clinicians, so as to examine this requirement. We found that all participants who started T1 through T4 were able to complete the tasks (14 out of 15). (One participant was unable to start T4 because of Internet difficulties, but completed T1 through T3). More importantly, every participant stated that DC was capable of supporting sharing settings that could involve multiple care team members.

Participants expressed this capability in terms of either the utility resulting from being able to add or remove a care team member to/from a group (12 participants) or the utility resulting from being able to group relevant care team members together (13 participants) (Ten participants mentioned both benefits). Five participants used their own experience to highlight the value of grouping care team members together. P08, one of the five, stated that DC would allow her to express sharing settings involving multiple doctors at the same time:

> I have [had] many, many situations where the grid [DC] would have helped immensely....This happens a lot with my care. [With DC,] I could put all of my doctors in one row and have them share the same data... assuming that all of the systems work together. If I could just have a system [like DC] where I go, boom, boom, boom, and that information gets shared, it would be lovely. - P08 (person with a chronic condition)

While supporting a moderately-sized care team was also possible with the conventional interface of RD, all participants found it repetitious to create sharing settings involving multiple care team members. They had to individually specify settings for each care team member (and data type), as opposed to including multiple care team members simultaneously in the process of creating sharing settings. For them, DC's ability to have meaningful groupings of data and persons was valued when having sharing settings involving multiple care team members.

3.5.3. (Require3) DC's Presentation of Sharing Settings Facilitates the Understanding of Sharing Within a Care Team

All of our participants (15 out of 15) expressed the belief that DC's grid-based interface would allow them to understand sets of sharing settings easily. They stated the ability to read sharing settings in one screen, as opposed to navigating through a hierarchy (as in RD), allowed them to quickly understand how the data was currently shared within the care team. There were three types of participant comments about their sense of understanding, all of which pointed to the advantages of the visual style of DC. Many comments were about taking in the team visually: being able to see everything at once or being able to form an overall picture (12 comments), not forgetting an individual (2), or seeing the entire team especially with changes and dynamics (6). (Participants could make multiple comments about understanding). Other comments included not needing to rely on one's short-term memory but instead on visual perception, including not relying on short-term memory when creating or modifying settings (13), modifying one individual's settings by being able to see another's (3), and being able to visually double-check one's actions (4). A few made general statements about preferring visuals (2). All of these point to the efficacy in visually handling care situations where there are multiple recipients, each of which has multiple data types and perhaps multiple types of data flows (controls).

> I think if...God forbid, my mom has a mobility-related accident and she needs a care team for 24-hour support and assistance, I really, really love the grid [DC] because, yeah, it gives you that blueprint outline of who has access to what. It gives you that zoom out view... like the full picture. - P05 (caregiver)

In addition to the evaluation of the grid-based design, we asked participants to use and then discuss the data preview feature in DC. In T4, data preview was enabled to investigate whether it could assist participants in creating sharing settings and understanding their effects. Almost everyone (13 participants, with the other 2 participants missing data) stated the data preview was helpful for strengthening their understanding of the settings. However, two of the 13 positive participants commented that they could complete the task without using the preview but still thought it was useful. As to why the participants thought the preview was helpful, more than half (8) stated that the preview enabled them to view what a care team member would see, as P06 expressed.

> I like the fact that you're letting the user of the tool to see, like, oh, that's how granular that the information is like, that's what I'm really sharing. I think that's really important. - P06 (caregiver)

Additionally, nine participants said that the preview helped them confirm the effects of the sharing setting, with two specifically stating that the preview helped them verify the effect of controls, as P07 stated. (Four participants mentioned both benefits.)

> ...if I was a newer caregiver...I could imagine it [DC with preview] being useful to trust that... when I toggle a setting, I can see it [the data preview] change right away and know that it worked....It [data preview] lets me trust myself and the system that I did the right thing to adjust the settings. - P07 (caregiver)

The data preview feature solidified their understanding of sharing settings, and it also gave users enough feedback to make them confident that they were doing fine-grained control correctly (which supported Require4 as well). This was in contrast to the state-of-the-art interface in RD, which hid an overview of settings behind a cascade of menus and toggles and which provided no feedback about whether data would be accessible appropriately.

3.5.4. (Require4) DC Enables PCTs (or Their Primary Caregivers) to Perform Fine-Grained Control Effectively

In our evaluation, we examined whether DC would allow users to exert fine-grained control by applying types of controls: level of detail, length of history, the shape of data, and visibility of data (refer to section 2.3). We found that DC supports fine-grained control through the combination of directing data flows between groups of PGHD and recipients, and the ability to simultaneously apply controls to each of these data flows. While doing Tasks T1 to T3, which required participants to apply controls to fine-tune how data were shared with members of a care team, nearly all of the participants (14 out of 15) explicitly acknowledged the usefulness of DC to efficiently fine-tune these data flows between groups of PGHD and care team members. Specifically, of the 14 participants, three valued DC's ability to apply controls to groups of PGHD and recipients, two reiterated the same point by stating that applying controls using RD is individual-based, and nine mentioned both characteristics. The ability to apply controls to affect multiple PGHD and recipients was considered helpful, as P04 stated:

> I liked that you could group a set of categories and define relationships [using controls] in clusters, so that you could have this cluster of things [data and receivers], and you didn't have to handle them individually. You could treat them as a collective, so you could put weight and pain together and say, these [data] I am handling this way [control] and that you could group people, you can group symptoms [data], you could group actions [controls]. - P04 (caregiver)

Five participants elaborated how DC would enable the efficient control of data flows. Their examples included how to modify standard settings for special occasions (e.g., going out or on a vacation) or for changes in the person's health condition.

Their examples also demonstrated that DC's controls, developed in our co-design process, are useful and practical for complex chronic care processes. For instance, P07 commented on how she would apply controls to share only summaries with specialists but could share more with people with whom she was close.

> A lot of people who were close [to me] might get a good amount of data, but then specialist might just...need to get the summaries, and that might not need to get changed all the time. [For cases that need frequent changes,] being able to affect them quickly with just [a visual block representing a control] really was a nice idea. - P07 (caregiver)

3.5.5. (Require5) DC Supports Health and Team Changes in the Long-Term by Allowing Reuse, Reflection, and Customization

As we argued earlier in section 2.3, a suitable design should support PCTs and caregivers in adapting to changes in health conditions and care teams over the long term. While the long-term benefits and tradeoffs of a design can only be validated through field deployments or randomized control trials, we adopt the approach recommended by Klasnja et al. (2011a, 2017): to focus our investigation on how the design features of DC support simple tasks (proximal goals) that could be essential for the long term.

When asked about which design (DC or RD) was preferred to control data sharing over a longer period of time after finishing all of the tasks. Eleven participants (out of 15) thought DC would be suitable for long-term use, based on their experience of participating in chronic care (We are missing explicit answers for the other four participants as the question was not asked due to lack of time). However, six participants said stated that RD would be useful when dealing with the simple case of having one recipient.

Participants noted the ability to get a quick overview of settings (refer to section 2.3) would be of significant help. This, we believe, led participants to state that DC's grid-based interface provided three unique advantages over a conventional design (as in RD) for adapting to changes in the care.

First, nearly all of the participants (ten of the 11 participants answering the long-term question) felt that the ability to visually compose sharing settings would enable PCTs to reference or reuse existing sharing settings, which is essential for long-term use. All of these participants commented that DC allowed them to add (or edit) elements in existing settings to create a new sharing setting. As we noted above, participants valued the ability to visually reference existing settings during the creation of new settings or the modification of prior settings when making adjustments, such as allowing additional data to be seen by care team members or adding controls to regulate data access. On the topic of reusing settings, P06 commented that DC allowed him to create settings confidently, knowing that he was accurately reusing what had been done before (which had previously worked).

> This task was a good example.... There are new people that I want to share data with. I have already thought about my data sharing preferences. I don't need to think about them again. [In this task] you were bringing on three paid caregivers and a doctor. I want them to be able to see the same stuff as my mom....it's as simple as just putting those blocks at the end and assigning them the same preferences as my mom. - P06 (caregiver)

Second, some participants (4) noted that DC's way of displaying sharing settings in one screen created opportunities for reflection about their prior sharing decisions, which is important over the long term. As PCTs and caregivers will adjust sharing settings only when necessary, such stimulation for reflection is likely to be critical in making healthcare decisions (Mamykina et al., 2006, 2008; Owen et al., 2015). P06 stated this point by saying that DC allowed him to rethink the big picture and prior decisions, which was not offered by the hierarchical design of RD, where details of sharing settings were buried inside the hierarchy:

> The grid [DC] is really good because it shows you what decisions you made in the past....let's say a new relative, Tom, moves closer and has more care-giving responsibilities, you give him more data... When looking at the grid to remove or add privileges for Tom, you might say, oh, Crystal was my other caregiver that we forgot to take the permissions off for or, oh, why isn't Uncle Rob seeing that? - P06 (caregiver)

Third, a person's health situation will vary over the long term. Some participants (4) specifically noted that DC's organization would allow them to create sharing settings for special cases (e.g., an event or healthcare crisis), which would be useful for adapting to changes in life. As P07 commented, DC, which does not have a strong restriction on how sharing settings are arranged and provides the capability to turn on/off sharing settings, would allow her to manage sharing settings for different use cases in a personalized way:

> ... For a person in maintenance mode for spinal cord injury...[DC] empowers me to make the data on one side and all the recipients on the other. I can imagine...three or four examples [of use cases] and a row for each use case. I could kind of turn it off right away and then add it again when I was ready. - P07 (caregiver)

Data checkers, then, offers three important capabilities that participants found likely to be beneficial for PCTs and caregivers throughout PCTs' health journeys: supporting the reuse of sharing settings, providing stimulation for reflection, and allowing personalized arrangements of sharing settings for different use cases. These capabilities were substantially more difficult to achieve in RD.

In summary, participants in our evaluation found DC, because of its design, was able to fulfill the five requirements discussed in section 2.3. These requirements, we argued above, are necessary in supporting chronic care—especially in chronic care situations like SCI/D. It was gratifying but surprising to us how uniformly our participants noted the advantages of DC over RD in meeting these requirements. DC's ability to meet the requirements was in sharp contrast, for our participants, with RD, a current state-of-the-art conventional interface for managing data access.

4. DISCUSSION

This paper presented the design and evaluation of DC, a grid-based prototype application that allows people with health conditions requiring care teams (PCTs) and caregivers to share patient-generated health data effectively with an at-home care team while still maintaining control and enhancing privacy. Results from our qualitative evaluation, based on a scenario of care for SCI/D, indicate that DC meets the five design requirements outlined in section 2.3, and therefore DC is likely to be usable and useful for SCI/D care.

Results from this study highlight the importance of the identified design requirements and systems like DC which are built upon them. The results also argue for additional work in this area to meet the expanding need for managing PGHD and integrating it into the care management paradigm.

More work will be necessary to fully consider the promise of DC. There were a number of limitations of this study that have to be recognized. We developed the scenario and the initial designs around SCI/D. SCI/D often requires a medium sized care team (e.g., 5–20 care team members) and 20 data sources that include both sensor-generated and self-report data. While a focused setting allowed us to contextualize the design as well as ground the evaluation of DC with our participants, future work will be necessary to determine whether additional considerations are necessary for different sized care teams and different numbers of sensors.

Because of the prototype and evaluation site, we also constrained the care network. We did not consider important information sources and recipients, such as casual friends, church members, and social network acquaintances (Consolvo et al., 2004; Skeels et al., 2010; Gronvall and Verdezoto, 2013). Future work will be required to understand whether DC can be extended to include these groups and in what ways.

In addition, the evaluation study for our prototype was qualitative in nature. As with any interpretivist study, generalization is difficult. While the need for assistance can also be seen in care for conditions such as Alzheimer's disease, Parkinson's, dementia, bipolar disorders, and a broad range of other complex health conditions, further studies will be needed to confirm our findings for other health conditions.

To demonstrate DCs' effectiveness and cost-efficacy, with particular considerations of other health conditions, we will need to verify how our findings generalize. While the associated resources for conducting this type of analysis were beyond the scope of the current project, the data and findings will be important for pushing for the integration of programs such as DC into healthcare systems.

Furthermore, our participants consisted of mainly people with chronic conditions or caregiving experience who were young and educated, whose experience might affect the feedback on the user experience of an unconventional design such as DC. Future studies would benefit from larger sample sizes and appropriate analyses.

There are also a number of potential avenues for future work, in addition to those suggested above. First, with more specialization in the healthcare system and increasingly available Internet of Things (IoT) and smart home solutions, supporting an increasingly more complex care team structure and more diverse data sources will be required. One line of future work will be finding additional UI mechanisms to support increasing numbers of sharing settings, more complex teams, and a larger diversity of data sources.

Second, our participants wanted several usability additions. They wanted better use of screen real estate. More importantly, they felt that DC lacked an easy ability to find and change a single recipient's settings; this could be seen in the preference for RD in simple cases. DC currently has the ability to sort settings; adding the capability to filter for recipients would be an easy addition and would likely solve this issue for users.

Third, PCTs or caregivers will need to intermittently engage with sharing settings to accommodate changes throughout a person's health journey, a theme that emerged from our findings. While DC's grid-based presentation allows users to be more aware of other sharing settings and provides an opportunity for users to reflect on existing sharing settings, future work will be needed to facilitate such re-engagement over the long term.

Fourth, our study highlighted the visual benefits provided by the grid-based UI of DC, which relied on vision and mouse interaction (e.g., moving and clicking). Additional consideration will be needed to support individuals with different constraints, such as visual impairments or fine-motor issues. Conforming to Web Content Accessibility Guidelines (WCAG) [12] would ensure that DC is perceivable and operable.

Finally, we plan to integrate machine assistance with DC as small intelligent agents, or "critics" (Fischer et al., 1990) that can work independently to identify and solve problems. For example, critics could be developed for DC to assist with re-engagement. A critic could also help people with health conditions and caregivers examine settings that might need adjustments to accommodate changes in health and care conditions. Such assistance could be particularly beneficial when PCTs have a reduced capacity for sharing management as a result of illness.

4.1. Concluding Remarks

This paper presented DC, an application for enabling users with chronic and complex health management needs to have fine-grained control over their sharing of PGHD with a care team. DC offers a grid-based user interface that utilizes people's familiarity with other grid-based designs such as checkers. DC also visualizes the effects of sharing settings by presenting data from the perspective of the data's receivers, helping people understand the implications of their sharing settings. Using a scenario based in the care of SCI/D, our evaluation study showed that the combination of DC' fine-grained control over data sharing, as well as its ability to preview outcomes, was usable and useful. These findings suggest Data Checkers has considerable potential

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[12] https://www.w3.org/WAI/standards-guidelines/wcag/

to better support people with health conditions requiring care teams (PCTs) in sharing PGHD.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

P-YH and DC designed the presented idea with feedback from MM and MA. P-YH developed the proposed system, recruited participants with the help of MM, carried out the user study in discussion with MA, and wrote the manuscript with support from DC, MM, and MA. P-YH and MA analyzed the data. MM provided expertise related to self-management and disability health. MA supervised the project. All authors contributed to the article and approved the submitted version.

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