Development and evaluation of a digital patient-provider communication intervention to facilitate shared decision making in chronic health care settings: InvolveMe

Berit Seljelid, MSc

Faculty of Medicine, University of Oslo

Department of Digital Health Research, Division of Medicine, Oslo University Hospital

Oslo, 2023

UiO : Faculty of Medicine
University of Oslo

OSLO UNIVERSITY HOSPITAL

Series of dissertations submitted to the
Faculty of Medicine, University of Oslo

ISBN 978-82-348-0398-7

Cover: UiO.
Print production: Graphic center, University of Oslo.

Contents

Acknowledgements

This dissertation was carried out at the Department of Digital Health Research in collaboration with the Department of Nephrology and the Section of Specialized Endocrinology at Oslo University Hospital. It was funded by the Norwegian Nurses Association, grant #847382; "Implementing eHealth interventions into regular clinical practice to enhance care planning, communication and patient involvement", also called the InvolveMe project. Senior researcher and Head of Research and Education Elin Børøsund was the Principal Investigator.

This dissertation could not have been conducted without the support and contribution of numerous people, and I would like to express my gratitude to all of you. I will start by thanking those who collaborated and contributed during the dissertation. First of all, I would like to express my deepest gratitude to my main supervisor and Principal Investigator of the InvolveMe project, Elin Børøsund. Thank you for believing in me, guiding and encouraging me. I have learned so much from you, especially regarding the logistics of a research process and the scientific writing process throughout this dissertation. Your constant insightful encouragement and motivational feedback was utmost important, especially when several delays occurred. I would also like to give a special thanks to co-supervisors Cecilie Varsi and Lise Solberg Nes. Cecilie, thank you for sharing your knowledge and expertise from the qualitative research field, for insight, advice and feedback regarding analyses and paper writing. Lise, thank you for sharing your knowledge and expertise from the eHealth research field, and your supportive and insightful comments, encouragement and constructive feedback regarding the scientific writing process.

I would also like to thank the department editorial group, especially Elise Flakk Nordang, Eleanor Halvorsen Brendmo, Marianne Westeng, Anne Bergland, Marianne Olivier and Christine Rygg, who contributed to the development of InvolveMe and its evaluation process, we could not manage without your help to conduct tasks small and major! Thank you to the department software and development team, led by Per Tømmer, especially Stein Jacob Nordbø, and designer Yizhak Itzchaki for your collaborations, insightful ideas and creative solutions. I also thank Kaia Spillhaug Thorkildsen and Håkon Vestli, your help in integrating and testing InvolveMe in the hospital patient portal was invaluable.

This dissertation would not have been possible without the cooperation and assistance of Jens Bollerslev and Aud-E Stenehjem, respectively the Section of Specialized Endocrinology and Department of Nephrology. They provided valuable inputs as co-authors on Paper I, and were always positive and supportive. Thanks to patients and health care providers from the two participating outpatient clinics. A special thank you to Ida Sofie Grorud, Kari Abelsen, Line Cecilie Krabbe, Hilde Hestvåg and Helene Welander for their ongoing engagement, assistance and input in the project. You are the very best nurses in the world! Thank you to co-author Kristin Astrid Øystese for your patience and important inputs. A warm thanks to Heidi Larsen and Marianne Øiahals for their encouragement, support and inspiring input.

A big thank you also to my fellow PhD students at the Department of Digital Health Research, Ingrid, Stian, Katrine, Rikke og Solbjørg. Our discussions, laughter (and sometimes tears), creativity and positivism enriched my PhD life. You rock! I will miss you! A special thanks to my fellow PhD student, friend and colleague, Berit Hofset Larsen, with whom I have shared many miles and deep conversations. Especially important were our weekly running meetings during the pandemic. Your race to complete your dissertation nudged and motivated me to complete my own. I really enjoy running and working with you, and I do hope our running, friendship and collaboration will continue in the years to come!

In January 2021, I started a new full-time job. Not an ideal situation with regards to completing this dissertation. However, it was necessary and in my new job I have used many of my acquired knowledge and skills. I would like to thank head of Department of Cooperation, Patient Education and Equivalent Health Services, Kari Skredsvig for believing in and hiring me, and for her successor Sigrun Skåland Brun for facilitating the completion of this dissertation. Thanks also to all my colleagues at work who have been patient and supportive in the completion of this dissertation. I would also like to express my deepest gratitude to my close colleague Kjersti, who has become a dear friend who has been very supportive and patient with me.

I extend thanks to my family and friends for cheering me on, and for your love and support. Thanks to May, for listening to me, and for providing help and support in relocation and childcare (and much more). Thanks to Gunhild, for listening and supporting me in a difficult period of my life. Thanks to my brother Eivind and his family, for being positive and lending

me all the tools I needed to redecorate my new apartment. Very special thanks to my parents Anne and Ulf for believing in me, and for the love and support you always give me.

Finally, I thank the important anchor in my life, my unconditional love, my children, Anna, Jakob and Agnes. Thank you for being patient with me (most of the time) and supporting me, and for always making me focus on the things that matters the most in life. Anna, when you were handed a threatening diagnosis, you showed tremendous strength and resilience. How you cope and overcome the challenges you face are a constant inspiration to me. Jakob, you loud boy, your complete recovery from a traumatic accident with numerous fractures provided me with insights into meeting challenges with magical hugs and a fighting spirit. Agnes, your hugs, kisses and laughing fits mean the world to me. My love for you three is endless, you are the best thing that has happened in my life.

Dear Reidar, your passion and love for me and what I am doing is overwhelming. Your humorous and down-to-earth nature has helped me to stay focused. Thank you for being in my life!

List of papers

Paper I

Seljelid B, Varsi C, Solberg Nes L, Stenehjem AE, Bollerslev J, Børøsund E. Content and system development of a digital patient-provider communication tool to support shared decision making in chronic health care: InvolveMe. BMC Medical Informatics and Decision Making. 2020;20(1):46.

Paper II

Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E. A Digital Patient-Provider Communication Intervention (InvolveMe): Qualitative Study on the Implementation Preparation Based on Identified Facilitators and Barriers. Journal of Medical Internet Research. 2021;23(4):e22399.

Paper III

Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E. Feasibility of a Digital Patient-Provider Communication Intervention to Support Shared Decision-Making in Chronic Health Care, InvolveMe: Pilot Study. Journal of Medical Internet Research. Formativ Research. 2022;6(4):e34738.

Summary

Background

Living with a chronic health condition often causes a variety of symptoms that negatively affect health related quality of life. It is dependent on individual variations in symptoms, symptom frequency and the extent to which the symptoms bother the individual. It can be difficult for both patient and health care providers (HCPs) to identify the patient's symptoms and informational needs, how this affects the patient's life, manage their emotions and concerns, and to elicit patient's preferences. Symptoms that remain unaddressed can worsen and lead to complications, as well as unnecessary suffering and overuse of health care services. An increasing number of studies show benefits of using digital interventions, such as symptom assessment and secure messaging, in the follow-up of patients with chronic health conditions. The use of digital interventions has shown to improve patient-provider communication, facilitate shared decision making (SDM) and improve quality of life for the individual. Despite the benefits, widespread adoption of such digital interventions in specialist health care services has not occurred. This may be caused by existing interventions not meeting the demands of stakeholders. Thus, there is a need for developing interventions tailored to suit the contexts and challenges experienced by patients and HCPs, as well as to facilitate the patients and HCPs to collaborate better to understand and resolve the patient's situation.

Aim

The primary aim of this dissertation was to develop and evaluate a digital patient-provider communication intervention, *InvolveMe*, to facilitate SDM in chronic health care settings. Participants were patients with non-functioning pituitary adenomas or renal transplant recipients and HCPs involved in the patients' treatment. The specific objectives of the three studies for the dissertation were:

1) To map patients' symptoms and needs, then use this information to design and develop a digital patient-provider communication tool providing patients with an opportunity to self-report symptoms and preferences for care prior to visits, and to use secure messaging between visits.
2) Explore HCPs understanding of what constitutes potential facilitators and barriers to the use of the intervention, and to use this information to tailor the intervention to the intended context and identify key aspects for an implementation plan.

3) To assess feasibility by exploring acceptability, demand (i.e., system use), and limited efficacy of the *InvolveMe* intervention.

Methods

The United Kingdom's Medical Research Council (MRC) framework for developing and evaluating complex interventions was used to guide the development process and was supplemented with other approaches for design and development. An exploratory research design was used, entailing a combination of qualitative and quantitative methods of data collection. This included interviews (Study I), focus groups (Study I, II and III), workshops (Study I and II), project steering group committee meetings (Study II), system log data (Study III) and patient-reported measures in a pre-post feasibility pilot study (Study III). Qualitative data were analyzed using thematic analysis (Study I, II and III) and quantitative data were analyzed using descriptive statistics and dependent paired t-tests (Study III).

Results

In **Study I**, 14 patients were interviewed and 11 HCPs participated in two focus groups. The results highlighted patients' symptoms and challenges, the need to master a new life, as well as suggestions and input for the digital tool. This knowledge was used in the development of the content and system in workshops, where six patients and six HCPs participated.

Study II identified facilitators and barriers for using a digital intervention through focus groups, workshops and project steering group committee meetings with 14 HCPs and two patient representatives. This knowledge was used to tailor the intervention to the local context and to identify key aspects for an implementation plan.

Study III evaluated the use of *InvolveMe* in clinical practice by including 23 patients with non-functioning pituitary adenomas in a pre-post feasibility study and a focus group with four HCPs. Patients were given access to the intervention and answered outcome measures at baseline and at three months. In addition, information was obtained from 16 patients who declined study participation. There was a predominance of male patients in the study and, among those, a third needed technical support to complete the study requirements. The results indicated a user-friendly and feasible intervention, where the use of assessments, secure messaging, and outcome measures (questionnaires) worked well. The completed assessments provided insights into patients' current situations, including physical symptoms and informational needs. Patients who declined to participate were older than participating patients, and they declined mainly due to not having a smartphone or that participating would

be too demanding. Results from the outcome measures were mixed and inconclusive. Findings from the focus group with HCPs supported the potential for SDM using assessments and secure messages.

Conclusions

This dissertation contributes to the field about how an intervention can be developed based on existing knowledge and tailored to stakeholders (i.e., patients and HCPs) needs, and how an intervention can be developed to identify patients' challenges and preferences (i.e., symptoms and needs). The identification of patients' challenges and preferences may provide important information about their current situation and priorities. *InvolveMe* has the potential to foster conversations about patients' challenges along with possible actions to resolve them, in line with the patient's preferences, and thus facilitate SDM.

Sammendrag

Bakgrunn

Å leve med kronisk sykdom kan være krevende, og redusere livskvaliteten. Det er vanlig med store individuelle variasjoner i symptomer, symptomfrekvens og i hvilken grad den enkelte plages av de. Det kan være utfordrende for både pasient og helsepersonell å finne ut hva som er mest plagsomt for pasienten, hvordan dette påvirker pasientens liv, håndtere følelser og bekymringer og å få tak i pasientens preferanser. Symptomer som forblir uadressert kan forverres og føre til komplikasjoner, samt unødvendig lidelse og økt bruk av helsetjenester. Stadig flere studier viser fordeler ved bruk av digitale løsninger, slik som symptomkartlegging og sikker epost, i behandling og oppfølgning av pasienter med kronisk sykdom. Blant annet kan bruken av slike løsninger forbedre kommunikasjon mellom pasient og helsepersonell, fremme felles beslutningstaking og forbedre livskvalitet for den enkelte. Til tross for fordeler så benyttes det i liten grad digitale løsninger i oppfølgning av pasienter med kronisk sykdom i spesialisthelsetjenesten, noe som kan skyldes at eksisterende intervensjoner ikke er godt nok tilpasset utfordringene pasienter og helsepersonell opplever. Det er behov for å utvikle løsninger som kan bidra til at pasient og helsepersonell jobber bedre sammen for å forstå og håndtere pasientens situasjon best mulig.

Mål

Overordnet mål for avhandlingen var å utvikle og evaluere en digital intervensjon, *InvolverMeg,* for å styrke den kliniske kommunikasjonen og fremme felles beslutningstaking i oppfølgningen av pasienter med kronisk sykdom. Pasientene i prosjektet hadde ikke-hormonproduserende hypofyseadenom eller hadde gjennomgått en nyretransplantasjon. Også helsepersonell involvert i behandlingen av disse pasientgruppene deltok. Delmål for de tre studiene som inngår i avhandlingen var:

1) Utforske pasienters (og helsepersonells) erfaringer relatert til symptomer og behov, og å bruke denne informasjonen for å designe og utvikle en løsning som gir mulighet for selvrapportering av symptomer og preferanser samt benytte sikker epost mellom konsultasjoner.
2) Utforske helsepersonells forståelse av hva som potensielt kan fremme eller hemme bruk av en slik løsning, og så å bruke denne informasjonen for å tilpasse løsningen til kontekst, samt å identifisere elementer til en implementeringsplan.
3) Vurdere gjennomførbarhet av *InvolverMeg* ved å utforske brukervennlighet systembruk, studierutiner og preliminær effekt.

Metode

United Kingdoms' Medical Research Council (MRC) rammeverk for utvikling og evaluering av komplekse intervensjoner ble benyttet for å guide utviklingsprosessen, og ble supplert med andre tilnærminger for design og utvikling. Det ble benytte et utforskende forskningsdesign med en kombinasjon av kvalitative og kvantitative data innsamlingsmetoder. Dette inkluderte intervjuer (Studie I), fokusgrupper (Studie I, II og III), workshop (Studie I og II), styringsgruppemøter (Studie II), system bruksdata (Studie III) og pasientrapporterte endepunkt i en pre-post pilotstudie (Studie III). Kvalitative data ble analysert ved hjelp av tematisk analyse (Studie I, II og III) og kvantitative data ble analysert ved deskriptiv statistikk og t-tester (Studie III).

Resultater

I **Studie I** ble 14 pasienter intervjuet og 11 helsepersonell deltok i to fokusgrupper. Resultatene synliggjorde symptomer og utfordringer, samt behov for å mestre et nytt liv, i tillegg til forslag og innspill til en digital løsning. Denne kunnskapen ble benyttet i videreutviklingen av innhold og system i workshops, hvor seks pasienter og seks helsepersonell deltok.

Studie II identifiserte fremmere og hemmere for bruk av en digital løsning gjennom fokusgrupper, workshop og prosjektstyringsgrupper hvor 14 helsepersonell og to pasienter deltok. Kunnskapen om fremmere og hemmere ble benyttet for å optimalisere og tilpasse løsningen til lokal kontekst og for å identifisere elementer viktige for en implementeringsplan.

Studie III evaluerte bruken av *InvolverMeg* i klinisk praksis over tre måneder ved å inkludere 23 pasienter med ikke-hormonproduserende hypofyseadenom i en pre - post pilot studie og inviterte fire helsepersonell som benyttet løsningen, til fokusgruppe. I tillegg ble det innhentet enkelte opplysninger fra 16 pasienter som takket nei til å teste løsningen.

Det var en overvekt av mannlige pasienter som deltok, og en tredjedel måtte ha teknisk støtte for å utføre studiekrav. Resultat synliggjorde en brukervennlig og gjennomførbar intervensjon, hvor bruken av kartlegginger, epost og spørreskjema fungerte godt. Bruk av kartlegginger synliggjorde pasientens nåværende situasjon, inkludert fysiske plager, informasjons behov. De som takket nei til å delta var eldre enn de som deltok, og de takket hovedsakelig nei fordi at de ikke hadde smarttelefon, eller fordi de trodde at det ville være for krevende å delta. Resultat fra psykososiale utfallsmål var blandet og inkonklusivt. Resultat fra fokusgruppe med helsepersonell synliggjorde at bruk av kartlegginger og epost har potensiale for å gi støtte til prosesser som innebærer felles beslutningstaking.

Konklusjon

Denne avhandlingen bidrar med kunnskap om hvordan en digital løsning kan utvikles basert på eksisterende kunnskap og samtidig tilpasses brukeres (pasienter og helsepersonell) behov. Avhandlingen bidrar med kunnskap om hvordan en digital løsning kan utvikles for å synliggjøre pasienters utfordringer (symptomer og behov) og preferanser. Kartlegging av pasientens utfordringer kan frembringe viktig informasjon om nåværende situasjon og synliggjøre hva som er viktig å få snakke med helsepersonell om. Det har potensiale til å fremme samtaler om pasientens utfordringer, og med det mulige løsninger og bidra til felles beslutningstaking i tråd med pasientens preferanser.

Abbreviations & definitions

Abbreviations

CFIR: Consolidated Framework for Implementation Research

EHR: Electronic health record

FHIR®: Fast Healthcare Interoperability Resources

GRIPP2: Guidance for Reporting of Patients and Public Involvement

HADS: Hospital anxiety and depression scale

HCP: Health care providers

HL7®: Health level 7

HLQ: Health Literacy Questionnaire

HRQoL: Health related quality of life

MRC: Medical Research Council

NFPA: Non-functioning pituitary adenomas

PVO: Department for Data Protection and Information Security

RTX: Renal transplant

REK: Regional Committee for Medical and Health Research Ethics

SDM: Shared decision making

SUS: System usability scale

TSD: Services for Sensitive Data

Frequently used terms and definitions

Acceptability refers to the extent to which the *InvolveMe* intervention is judged as suitable, satisfying, or attractive to program deliverers and program recipients (i.e., stakeholders) (1).

Adoption refers to the initial decision or action to try to employ an innovation or evidence-based practice. Adoption may also be understood as 'uptake' (2).

Approach refers to guidance, theories, methodologies, and frameworks that have influenced intervention development, such as a shared decision-making approach.

Demand refers to the extent to which the *InvolveMe* intervention is used (i.e., the assessment feature and the secure message feature) (1).

Determinants are facilitators and barriers that may influence the implementation outcome (3).

Digital (patient-provider) communication intervention refers to the use of a digital tool in the intended context for information exchange between patients and providers via mobile phone, computer, or tablet.

Digital tool refers to the actual technological features in this dissertation (i.e., the assessment and secure messaging).

Context is understood as the conditions or surroundings in which something exists or occurs and is an important mediator of change and innovation in a health care organization (3). The term includes the outpatient setting which the intervention is intended to suit, and the characteristics associated with that setting.

Digital assessment tool refers to a tool which is used by patients to remotely share information with health care providers (HCPs) about their current situation with regards to symptoms, needs and preferences for care prior to planned consultations.

Feature is a distinct trait or part of a tool, such as the digital assessment feature or the secure message feature.

HL7® FHIR® is a standard that defines how health care information can be exchanged between different computer systems regardless of how it is stored in those systems (4)

Implementation refers to the extent an innovation, program or process can be successfully delivered to intended participants in a defined context (1).

(Health) Information and communication technology are tools and resources used to access, share- and exchange information, process and store, that seek to prevent- and treat disease, and manage chronic disease. Information and communication technology allows for remote care (5).

Intervention tailoring refers to an implementation strategy where findings from the identification of determinants are used to address barriers, leverage facilitators and to fit the context (6).

Limited efficacy refers to the exploration of potential effects (1) from RAND 36, HADS and HLQ.

Patient portal is a digital health system, which provides patients with secure online access to their own health information: HCPs notes and medication lists; care services such as appointment booking and reminders, and communication with their HCPs via secure messaging (7).

Shared decision making refers to a process where patients and HCPs work together to identify and develop a shared understanding about patients' challenges, which entails recognizing patients' feelings and resolving or changing patients' situations by suggesting or making decisions regarding possible actions in line with patient preferences and relevant evidence (8, 9).

Secure messages refers to the secure, asynchronous communication between patients and HCPs through patient portals (smartphone messaging or email) (10).

Stakeholder(s) refers to anyone who may influence or be influenced by the digital communication intervention (e.g., patients, HCPs, research and development team).

List of tables and figures

Tables

Figures

1. Introduction

Chronic health conditions are common and demanding, often causing a variety of symptoms that negatively affect health related quality of life (HRQoL) (11-14). Attention to symptom management is important and recommended for patients with chronic health conditions (15, 16). However, patient-provider communication and interaction concerning symptoms may be challenging (17-24). Shared decision making (SDM) may carry the potential to improve patient-provider communication and interaction (25, 26) regarding symptom management (27, 28).

SDM usually takes place in physical patient-provider encounters and has mostly been confined to supporting patients in decisions to do with single treatments or screening (27-30) and not chronic care situations (8). However, researchers in Norway developed an intervention in 1999 based on SDM to be delivered on-site using a handheld computer to help patients with chronic health conditions to report symptoms, problems, and care preferences to their health care providers (HCP) (28, 31-35). This intervention was significantly beneficial to patient care and outcomes, including improved symptom management, patient-provider communication and HRQoL (31-33, 35). The work described in this dissertation is influenced by this intervention. Since then, technology has evolved and provided new types of care for chronic care situations (27, 36). For example, the use of secure messages through patient portals can improve patient-provider communication (37, 38), and engage patients and HCPs in SDM (39, 40), which may thus improve follow-up of patients with chronic health conditions. Digital health care services, such as the use of patient portals for patient-provider communication, are important to ensure sustainable and high-quality health care services (41).

The Norwegian government highlights SDM and the use of digital health care services to improve patient-provider communication (42). However, when this dissertation was conducted at Oslo University Hospital in Norway research and evidence on the implementation of SDM or digital patient-provider communication, concerning symptom and needs assessments and secure messages, was limited and at times found to be lacking. For example, several barriers to its implementation exist, including issues with integration into daily workflow (43, 44) and user-friendliness (45, 46). To ensure implementation success, it is important to tailor interventions to suit the local context (47). However, limited stakeholder involvement (e.g., patients and HCPs) in the design and development process is a known challenge for the implementation of digital interventions (46, 48, 49), even though stakeholders can provide important input for such intervention tailoring (47). This dissertation

aims to develop and evaluate an intervention by drawing on the existing evidence and theory, and tailor the intervention to suit the local context in line with the United Kingdom's Medical Research Council (MRC) approach for developing and evaluating complex interventions (50, 51). The limited use of digital patient-provider communication (i.e., symptom assessments and secure messages), and new opportunities provided by technology, call for updated approaches and further research on the development and evaluation of digital patient-provider communication interventions to support SDM in chronic care situations.

1.1 This dissertation

This dissertation seeks to contribute to understand how a digital patient-provider communication intervention can be developed and evaluated to facilitate SDM within care for patients with chronic health conditions. This dissertation centers around the development and evaluation of the digital communication intervention *InvolveMe* (Norwegian Nurses Association, grant #847382). It specifically explores how an intervention supplementing the care of patients with chronic health conditions could be developed and evaluated to facilitate SDM in support of the needs of patients and HCPs in a meaningful, useful, and effective way. To address issues raised by existing research, Study I describes the design and development of a digital assessment tool, concerning symptoms and preferences for care, presented in Paper I. Study II identifies facilitators and barriers to be used in implementation preparations of the intervention, presented in Paper II. Study III explores acceptability, system use and limited efficacy of the intervention in a feasibility pilot, presented in Paper III.

1.2 Dissertation structure

In this dissertation, the introduction (1) is followed by the background (2) to provide an overview of the literature within the research topics included. The background provides the rationale for the three studies included. In primary aim and specific objectives (3), the aim, objectives and research questions addressed are presented. In methods, design and development approaches (4), conceptual frameworks, research design and methodology are presented, including ethical considerations. Results (5) presents a summary of the findings from each of the three studies included, while the discussion (6) explores methodological considerations, synthesizes findings and discusses them in light of the existing research. The discussion section ends with contributions to practice and science, and recommendations for future research. Finally, the conclusion (7) concludes the dissertation findings.

2. Background

Chronic health conditions are conditions that last one year or more and require ongoing medical attention, limit activities of daily living, or both (52). Chronic health conditions include prevalent conditions such as cancer, respiratory disease, heart disease and diabetes (52, 53), as well as less prevalent conditions such as non-functioning pituitary adenomas (NFPA) or end-stage renal disease provided with renal transplant (RTX), which are the conditions this dissertation focuses on. Globally, including Norway, people are living longer with chronic health conditions, and a considerable portion of the population over 60 years old live for a long time with one or more chronic health conditions (53, 54). A chronic health condition may cause challenges that affect multiple aspects of the life of the individual and thus research exploring what matters most to patients living with a chronic health condition is needed.

2.1 Living with chronic health conditions

Although the nature and consequence of chronic health conditions varies depending on the condition and the individual circumstances, most conditions cause various challenges for the individual (15, 16). A common challenge is dealing with symptoms that negatively affect the person (11-14), for example, keeping up with work tasks and demands (55), or making necessary lifestyle adjustments. Common symptoms for patients with various chronic health conditions are fatigue, pain, sleeping problems, stress, as well as emotional challenges such as anger, anxiety and frustration (16, 56, 57). As symptoms are a subjective indication of a disease or a change in condition (58), patients are an important source of information for understanding their situation. There are large variations in what symptom experiences involve, including what symptoms are recognized or experienced, as well as the frequency, severity and extent to which patients are bothered by them (16). As patients may experience a variety of symptoms, and these symptoms interact, the effect on the individual's life is also varied (16).

Living with a chronic health condition may be a barrier to employment and workforce participation (55), because it impairs a patient's ability to work (59). This may affect education, hours worked, job turnover, cause early retirement, as well as affect wages, and position reached (55). It has been proposed that efforts to improve education and employment could help to improve health and subsequently reduce social inequalities in health (54). Social inequalities in health are linked to communication inequalities (60), which affect patients'

capacity to understand and apply the information they receive from HCPs (17, 60-62). There may be a considerable gap between what HCPs assume patients understand, and what patients truly understand (63). Informational needs are often overlooked by HCPs, which may relate to that HCPs underestimate patients' informational needs (64), and many patients report that their informational and emotional needs remain unmet in consultations with HCPs (65-67). In addition, patients may also find it difficult to voice their informational needs (68). For example, sensitive topics such as sexual concerns are seldom addressed (69). Patients may believe that providers would address such a topic if it was considered important, and when they do not, patients do not want to burden the provider (69). HCPs should also provide attention to emotional cues, as this significantly increases patients' total information recall (70), which implies that communication outcomes are enhanced when HCPs attend to patients' emotional needs.

Despite symptom management being an integral part of chronic health care, there is a lack of research including symptoms and needs and patient-provider communication for some chronic health conditions.

2.2 The chronic health care setting of this dissertation

In this dissertation, patients living with chronic health conditions are represented by patients with NFPA or RTX recipients, from either an endocrine or a nephrology outpatient clinic at a large university hospital in Norway. HCPs in this dissertation were represented by HCPs from the endocrine and nephrology outpatient clinic responsible for care and follow up of patients with NFPA or RTX recipients. The Norwegian health care system is publicly financed and the population coverage is universal, which offers high levels of social and financial protections (71). Income inequality is low and gender equality is high in Norway, however, there are increasing socioeconomic inequalities in health (71), especially related to educational groups (72). A higher educational level is associated with better health and longer life expectancy (72). Much attention has been dedicated towards improving care quality in the Norwegian health care system (71), and the initiative for improvement of care for the two patient groups in this dissertation came from HCPs and the management at the participating outpatient clinics.

Both patient groups commonly experience a long period of slow deterioration in their health status before receiving surgery. Even though surgery improves HRQoL, patients are confronted with a life with condition-related symptoms that interfere with their daily living (56, 57). After surgery, both groups are followed for a long period in specialist health care at

outpatient clinics. As there is high individuality and variability in symptom experience within both patient groups, planning of time and resources needed at consultations is important for both patients and HCPs. There was no digital patient-provider communication available when this dissertation was planned, and patient-provider contact was restricted to phone, letter, or face-to-face meetings. Frequent phone contacts as well as many unplanned consultations in between planned visits were common for both patient groups due to various symptoms and concerns. Altogether, this implicated the potential for improvements of patient-provider communication and interaction in follow-up.

2.2.1 Non-functioning pituitary adenomas (NFPAs)

Pituitary adenomas account for approximately one third of all intracranial tumors, and NFPAs are the most common pituitary adenoma (73). Epidemiologic data on NFPAs is limited due to variation in study methods and registers used (73, 74). However, in one Swedish study, the incidence (2001-2011) of NFPAs was found to be 1.8 cases/100.000 inhabitants, and NFPAs were more frequent in men (58%) than women (42%) (74). NFPAs are benign tumors, but because of their location and the proximity to the pituitary gland, they may cause challenges such as impaired vision, headache, or affect pituitary hormonal secretion (73, 75). The treatment is primarily surgery and complication rates after surgery are low (76). However, there are many long-term challenges, including: fear of recurrence; persisting distressful thoughts; problems with an altered personality; anger; jealousy; sadness; frustration; difficulties communicating about the disease; fatigue; sleeping difficulties, and decreased HRQoL (56). So, there is a potential for improving care.

2.2.2 Renal transplant (RTX) recipients

Chronic kidney disease is a common disease with a global prevalence of 9.1% (700 million); patients experience a range of symptoms such as fatigue, depression, pain, poor sleep, muscle cramps, dry skin, itching, and decreased HRQoL (57). RTX is generally accepted as the preferred treatment when patients with chronic kidney disease progress into end stage kidney disease (77-79). In 2019, 258 RTXs were conducted in Norway at Oslo University Hospital, and 3665 RTX recipients were living with the condition (79). Most RTX recipients are men, 64%, (79), and RTX recipients experience increased HRQoL (80) and fewer symptoms after the RTX (57). However, RTX recipients have considerably poorer HRQoL than the general population (57, 81), so there is a need for improving HRQoL and care even after RTX.

2.2.3 The call for a more patient-centered approach

Chronic health conditions not only affect the individual's health but have social implications and incur a financial cost to society (82). These affect the infrastructure of the health care services through an increased demand on resources (55, 83). Changes in health care services with increased demand on HCPs time may also negatively affect patient-provider communication and interaction (59, 84). Increased demand on HCPs may arise from the pressure to see more patients in less time and additional administrative tasks (59, 84). This provides limited time for providers to gather relevant information, understand patients' situations, and explore patients' preferences, values and needs (59).

The increasing prevalence of chronic health conditions creates a challenge for the health care system of not curing but managing these conditions, by preventing the impairment of functioning and maintaining HRQoL for as many years as possible (85). This challenge has called for a more patient-centered care approach that is respectful of and responsive to individual patient preferences, needs, and values (86), which underlines the importance of patient-provider communication and interaction. Assessment of patients' symptoms should be prioritized to better understand the patient's experience and to provide the needed treatment (87), and research to develop interventions to meet patients' needs is warranted. However, such interventions should provide HCPs with insight into the patient's current situation, including psychological and physiological functioning, whilst not increasing the demand on HCPs.

2.3 Shared decision making (SDM)

SDM is central in patient-centered care (86) and has traditionally been explained as a collaborative approach where HCPs share the best available evidence with the patient in the process of decision making, and patients are encouraged to consider benefits and harms of available options and to communicate their informed preferences (88, 89). Despite research and policy support, widespread adoption of SDM into routine practice has not occurred (90-92).

2.3.1 A brief history of SDM in the perspective of chronic health care

The concept of SDM in health care first arose about 40 years ago (93). However, its underlying model of mutual participation was already described in 1956 as a give-and-take relationship between the patient and the HCP, based on equality and respect (94). This approach was considered particularly useful in the management of chronic health conditions

(94), because patient involvement in behavioral, psychosocial and lifestyle interventions could affect health beyond the impact of biomedical interventions (95). SDM differentiates from a paternalistic approach where HCPs make the decisions and an informed approach where patients make the decision (96). SDM lies between these two approaches, which both are characterized by a one-way information exchange, while essential for SDM is the two-way information exchange (96).

In 1997, Charles and colleagues provided a framework to clarify the meaning of SDM with the key components: involvement of both patient and provider, information exchange, build a consensus about preferred choice and decision making (97). This framework was intended to suit situations concerning life-threating illnesses with limited time to consider choices of treatment and decisions that implied serious and irreversible consequences to the patient (26, 97). Montori and colleagues (2006) suggested adding the component 'ongoing partnership' to suit the chronic care situation and include an emphasis on the patient-provider relationship (26). These frameworks underline the importance of patient-provider communication, and an international statement on SDM from 2010 called on patients and HCPs to work together through the appropriate provision of two-way communication (98). However, the statement did not provide a firm definition of SDM and was silent with respect to patients with chronic health conditions (98).

SDM research and implementation in clinical practice at this point are often conducted by using a generalized SDM approach (e.g., focus on weighing pros, cons, and preferences regarding different treatment options) supplemented with decision aids (8, 9). Existing evidence suggests that a generalized SDM approach may not be the most efficient for resolving patients' challenges in living with chronic health conditions (8, 9, 99). Research examining decision aids in chronic health conditions highlights that they are mostly designed to 'transfer information' about options and the harms and benefits of these, but do not promote patient-provider communication and interaction (30). Additionally, the use of decision aids may make little or no difference to the number of HCPs adhering to SDM as a recommended clinical practice (100).

Patient involvement has been a part of the Norwegian government policy since 2001 (101). SDM, which was considered a promising approach to strengthening patient involvement, was coined with the Norwegian term 'samvalg' in 2015 (102). 'Samvalg' cannot be translated directly into English as shared decisionmaking, in contrast to other Scandinavian countries where the chosen term is a direct translation (i.e., 'fælles beslutningstakning', 'delat beslutsfattande'). After 'samvalg' became the official Norwegian translation of SDM, SDM

was promoted through government policy as a recommended clinical practice (103). The generalized approach for SDM in Norway (i.e., 6 Steps To SDM) (104, 105) was mainly promoted for use in situations with a defined problem that had several treatment options and a limited time to decide. Less attention was given to situations where patients were living with a chronic health condition and managing various challenges as they emerged or evolved over time.

2.3.2 Patient preferences

Patient preferences relates to patients' values, originating from their cognition, experience, and reflection, and can be defined as the individual's evaluations and inputs to the care process, implying that preferences are judgments that can influence health care choices (106). Adherence to chronic disease management requires evaluation of patient preferences (107), and as each individual patient is unique, it is important to ask for their preferences, views, and values.

Patients have expert knowledge about their life, challenges they have experienced, and what matters most to them in their present situation (26, 108). It is important that patients share this information with their providers, and providers share sufficient information about available options with patients to allow them to participate in the decision making process (26). How to make the best decision will vary with the patient's experience and their preferences (8). However, access to patients' preferences can be complex as they may find them difficult to articulate (109). Patient preferences may not be elicited as much as they are constructed in conversations between patients and providers, and patients may need support to understand and clarify what they need (109). A review highlighted five practice recommendations for HCPs to facilitate meaningful patient-provider interactions: 1) prepare with intention before seeing the patient; 2) listen intently and completely; 3) agree on what matters most; 4) connect with patient story, and 5) explore emotional cues (84). Interactions that incorporate these recommendations may identify patients' preferences more easily (84).

SDM is often concerned with obtaining patient preferences with regards to available treatment options, rather than identifying and integrating their preferences into the management of challenges that patients with chronic health conditions experience in daily life over time (28, 30). The latter is particularly relevant because management of chronic health conditions constitutes a large part of chronic health care (28, 72), affecting multiple value-laden dimensions of patients' lives (28) where the scientific and clinical knowledge of HCPs may not provide adequate direction (110). The importance of patient values in decision

making is undisputed, yet much of the focus in SDM research and implementation so far has primarily focused on a technical approach, such as taking the right steps in the correct sequence at the right time, assuming that this is the best way forward for the individual (110, 111). Less effort has been made to investigate methods to bring forth patient values and learn how to integrate these values into the decision making process (110). Nevertheless, when patients and HCPs interact and communicate with each other they are likely to develop a shared understanding that can improve decision making and quality of care (112).

2.3.3 An adapted SDM approach to resolve patient challenges

The approach to SDM that guides this dissertation, here referred to as the adapted SDM approach, has a particular focus upon the collaborative work between patients' and HCPs as they identify patient challenge and develop a shared understanding about how the challenge affects the patient's daily life, recognize the patient's feelings about the challenge and resolve or change the patient's situation by suggest or make decisions regarding possible actions in line with the patient's preferences and relevant evidence (8, 9, 99). In contrast with a generalized SDM approach that tend to focus on single treatment decisions, focus here is on supporting the information exchange in a SDM process which focus on the daily life challenges of living with a chronic health condition over time.

It has been proposed that the need to choose between options is only one situation where SDM is appropriate and that there are other situations that require SDM (8, 9, 26). Indeed, some claim that every time patients and HCPs work together to determine a course of action for a patient's situation, they are performing SDM (8, 9). It is the patient's specific situation that determines the approach to SDM and which tools may be useful (8, 9). The context of patients living with chronic health conditions also requires SDM as living with a chronic health condition comes with challenges and care for patients should respond to these challenges (26, 99). When applying the adapted SDM approach in the contexts explored in this dissertation, NFPAs and RTX patients, a tool is needed that can support the decision making process and should assess patients' challenges, including symptoms and needs (99). Assessing patients' challenges may be useful, although identifying such challenges can be difficult (16). There are however, indications that assessing patients' symptoms and needs may be associated with improved patient outcomes (32, 33, 113-117), improved patient-provider communication and interaction, and may promote SDM in follow-up (116). Interventions where patients provide information about themselves, such as health status, concerns, and needs prior to a consultation have also been demonstrated to improve HCPs

clinical practice (100). Assessing patients' symptoms, needs, and preferences for care prior to an outpatient visit may thus be used to facilitate SDM in consultations (27). Offering options for communicating through secure messaging may also supplement and support the specific situation as it may help provide a joint understanding of the challenges that patients face. However, research exploring the potential of SDM in managing challenges that come from living with chronic health conditions is still at an early stage (8).

2.4 The potential of digital communication in chronic health care

Information and communication technology has the potential to bridge the gap between patients' and provider's perspectives by creating the opportunity to focus on the clinical encounter (118). There is an increasing need for health care services that facilitate patients' opportunities for involvement in their own care, and digital patient-provider communication mediated through patient portals may provide such opportunities to explore long-term follow-up of patients with chronic health conditions.

Patient portals have become an increasingly important access to health information and care (10, 119), and the use of patient portals has been shown to facilitate patient-provider communication and engage patients and providers in SDM (39). Patient portals can support information sharing and improve visit preparation and patient-provider communication (39). Secure messaging is a common patient portal feature, while digital assessment tools that provide patient data are a less frequent feature (39). Both are identified as features for fostering patient-provider relationships (120).

Few studies have explored the impact and feasibility of using features such as secure messages and digital assessment tools in relation to outpatient visits (118). Research that encompasses integrated systems, such as patient portals integrated with digital assessment features, is scarce, and subsequently there is limited evidence regarding improvement of care and outcomes (121). However, the use of secure messages and digital assessment tools has the potential to make health care services more accessible and better distributed (122), which could enhance the quality of follow-up of patients with chronic health conditions.

2.4.1 Secure messages

The use of secure messages provides patients and HCPs with multiple opportunities for contact, and research shows that patient-provider communication may benefit from using secure messages (45, 123, 124). For example, the use of secure messages is described to improve patient outcomes and quality of care among patients with chronic conditions compared to a standard follow-up (125), and can contribute to improved patient-provider relationships (120). Furthermore, the use of secure messages significantly improved survival rates among cancer patients and reduced treatment-related admissions as well as emergency visits (126). However, the use of secure messages also increased the number of face-to-face meetings and phone calls with HCPs (126).

The main causes of patients using secure messaging are provider accessibility, self-management, and unmet needs (38). The speed and ease of such communication, as well as direct access to a HCP, are described as motivational factors for the use of secure messages (10). HCP's main reason for using secure messages is to provide patient education (38). Research examining secure messages between patients and HCPs shows that patients mostly seek information, and subsequently HCPs messages are a response to patients' questions (127). Patient-provider interaction through messages has also shown improved communication efficiency and is described to provide HCPs with a better understanding of patients' needs (38). In addition, such messaging is described to support coordination of care (10).

It has been proposed that secure messages can facilitate goals of patient-centered care by enhancing communication through recognizing expressions of emotions (127). For example, a study analyzing secure messages for patterns in patient-provider communication identified three significant themes for patients and providers: 1) information management, such as information exchange and problem solving; 2) uncertainty management, such as relationship building and sense making, and 3) patient safety and patient engagement (128). Patient engagement can improve patient outcomes and health (129), thus the use of secure messages have the potential to improve follow up of patients with chronic health conditions.

2.4.2 Digital assessment tools

Capturing a patient's current situation can facilitate the patient and provider working together to identify the patient's challenge, and collaborating to resolve the challenge according to patient preferences (25, 130). The use of digital assessment tools to accurately present a patient's current situation can encourage patient-provider communication and interaction, which may improve consultation efficiency and effectiveness (120, 130, 131).

The intervention, which this dissertation was influenced by, provided patients with opportunity to report symptoms using a digital assessment tool, and patient completed assessments were printed out on paper and delivered in-hand to HCPs (28, 31-33, 35). The practice showed a beneficial effect in multiple studies examining patient care and outcomes: more symptoms were addressed (31, 32); symptom distress decreased (31); patient care was more consistent with patient preferences (35); the patients were more active (32), and patients need for support in symptom management was reduced (31). Furthermore, the use of this intervention showed that patients expressed significantly more feelings and concerns in consultations compared to a control group (33, 132). These findings are supported by other studies using digital assessment tools, describing benefits like improved information sharing about patients HRQoL and social aspects (27), as well as improved symptom detection, HRQoL, and physical functioning (115, 133, 134).

Patients received more information when they used a digital assessment tool prior to a consultation, which is explained by the use of the intervention providing patients with an opportunity to ask their HCP about topics they otherwise would have forgotten (32). Patients' informational needs are rarely reported to be included in digital assessment tools and were not included as a part of the digital assessment tool, which influenced this dissertation. However, it is worth noting that interventions aiming to help patients address their informational needs are more likely to succeed than interventions aimed at HCPs (68).

Information and communication technology today also provides opportunities to remotely collect data. The use of tools to remotely collect patient data have been described to reduce patients' symptom burdens (113, 114, 134), decrease emergency visits and reduce in-hospital admissions (115). The remote use of digital assessment tools may be especially important for people with chronic health conditions as patient data prior to a consultation can inform patient care (121). Completing assessments from home may also be less stressful for the patients as a hospital setting may be experienced as busy and hectic. However, patient data is infrequently collected in routine clinical practice (131) and sharing of data prior to hospital visits is scarce (121). Patient data could, however, present patients' views and supplement the traditional

method of medical history acquisition and physical examination, thus providing information to support SDM (131). In addition, the remote use of digital assessment tools may provide benefits to HCPs clinical workflow by not requiring patients to complete paper-based assessments in waiting rooms or within the limited time of a consultation with HCPs (131).

2.4.3 Implementation aspects to consider in intervention development process

Research that encompasses the development and evaluation of digital patient-provider communication interventions to facilitate SDM for patients with chronic health conditions is scarce (36). However, digital communication interventions have been shown to provide opportunities for patient to communicate symptoms, needs and preferences for care (33, 123, 135, 136), and thus facilitate SDM (27). Such interventions may aid HCPs in eliciting patient preferences for care and provide individually tailored follow-up (31, 40, 45, 135, 137). Research suggests that few existing interventions share patient data prior to hospital visits (121, 138), and few interventions describe offering both data sharing prior to consultations and secure messaging between consultations. Although there is increasing evidence of benefits from using digital patient-provider communication, implementation into clinical practice is still challenging (44, 49, 139-143). This is why attention should be given to implementation during the development and evaluation of digital interventions (144). Specific determinants can act as facilitators as well as barriers that influence implementation outcome (3), which implies that a facilitator in one setting may be a barrier in another setting. This may explain why similar interventions may be introduced in various ways in different settings (145).

Patient portals can provide features such as secure messaging and assessments, and thus have the potential to contribute to improved patient-provider communication and facilitate SDM in chronic health care (27, 39, 45, 124). However, concerns have been raised around both patient and HCP barriers to adoption of digital communication interventions (37, 49, 118). Patient barriers are related to lack of internet access, lack of portal user-friendliness and technical support, lower education levels, and increased age (37, 49). Patient barriers for use of secure messages through patient portals include technological difficulties, and confusion about what constitutes an appropriate ‘non-urgent’ message (10). Barriers for using digital assessment tools are related to low health literacy and lack of comfort with or access to digital technology (e.g., not having a smartphone) (118).

HCP barriers to adoption are related to workflow changes, as single systems such as digital assessment tools or patient portals without integration into electronic health records may

increase data entries and work tasks for HCPs (118). In addition, HCPs have negative experiences with the use of secure messages increasing their workload, poor system functionality, and insufficient training and resources (147). Barriers concerning use of digital assessments perceived by HCPs are delivery of assessments too often, assessments becoming too lengthy, patients revealing too many concerns to be discussed within the restrains of a consultation time, and subsequently an increased workload (148). Furthermore, a lack of infrastructure and time affects HCPs ability to engage with a digital assessment tool (149). This suggests that there is a need to carefully plan how such tools can be incorporated into the existing system used by the organization (149). Barriers related to system capability and system integration should also be carefully considered in the development process to avoid an increase in HCPs workload (118).

There is limited guidance concerning which implementation strategies may be effective in implementing digital communication interventions (150). However, research highlights some promising strategies that increase the likelihood of implementation success (144, 150, 151). These include stakeholder involvement (47), identification of facilitators and barriers (151, 152), and to develop an implementation plan (151, 153). User-friendly software, summaries of patient data and system integration into electronic health records, and training and support of both patients and HCPs have been acknowledged as important for successful implementation (39, 118, 142, 143, 148, 149). Identifying and involving all potential stakeholders early in the development process is important, such as engaging end-users in the design process (118). In this dissertation, both patients and HCPs are included in intervention development as important stakeholders.

Contextual barriers may be modifiable if addressed, which is why identification of stakeholder's facilitators and barriers can provide important knowledge to be used in intervention tailoring (151, 152). As such, stakeholder involvement may reduce intervention complexity, increase intervention acceptability and increase the likelihood of implementation success (47).

3. Primary aim and specific objectives

The primary aim of this dissertation was to develop and evaluate a digital patient-provider communication intervention to facilitate SDM in chronic health care settings.

3.1 Specific objectives

The specific objectives investigated in the three studies for the dissertation were:

I: To map patients' (i.e., patients with a non-functioning pituitary adenoma (NFPA) or renal transplant recipients (RTX)) symptoms and needs in preparation for the development of a digital patient-provider communication tool, *InvolveMe.* Then, to design and develop the tool to suit each patient's situation and preferences concerning symptom management in outpatient chronic health care settings by providing them with the opportunity to: 1) self-report symptoms and preferences for care prior to visits, and 2) use secure messaging for patient-provider communication between visits.

II: To prepare the implementation of a digital patient–provider communication intervention, *InvolveMe*, into the daily workflow at two outpatient clinics where patients with chronic health conditions are treated. To identify potential facilitators and barriers to implementation, using the Consolidated Framework for Implementation (CFIR) as the conceptual framework in order to: 1) tailor the *InvolveMe* intervention to the intended context, and 2) identify key aspects for an implementation plan.

III: To assess feasibility by exploring acceptability, demand (i.e., system use), and limited efficacy of the *InvolveMe* intervention.

3.2 Research questions

The overall aim and specific objectives were guided by the research questions presented below.

Research questions in Study I:

- What are the symptoms and needs of patients living with NFPA or RTX?
- What are the experiences and preferences of patients and HCPs concerning information and communication technology?
- How can a digital tool suit the needs and preferences of patients and HCPs?

Research questions in Study II:

- What are the potential facilitators and barriers for use of a digital communication intervention?
- How can the intervention be tailored and adapted to overcome potential barriers?
- How can the intervention be prepared for feasibility testing?

Research questions in Study III:

- Acceptability: To what extent is *InvolveMe* judged as suitable, satisfying, or attractive?
- Demand: How is the *InvolveMe* intervention used, and what are the HCPs' experiences with use?
- Limited efficacy testing: Does the tool show promise of being successful with the intended population?

4. Methods

This section presents an overview of the design and development approaches influencing this dissertation, as well as details about the specific data collection methods used in each of the three studies conducted.

4.1 Design and development approaches

The main approach that influenced this dissertation was the MRC framework for developing and evaluating complex interventions (50). This approach was, however, supplemented with input from other approaches, such as participatory design (154), the Guidance for Reporting Involvement of Patients and the Public (GRIPP) (155), the CFIR (156), and Bowen's ideas on the design of feasibility studies (1). The combination of explorative qualitative and quantitative research approaches, as well as iterative and collaborative design approaches, provided input for the intervention development and evaluation process. The rationale behind the combination of approaches was for the approaches to complement each other and identify ideas that may not otherwise have been considered.

4.1.1 The Medical Research Council (MRC) framework

Complex interventions can be explained as interventions which contain several interacting components (50). The MRC approach presents phases of development, evaluation, and implementation (50). The MRC's development phase consists of identifying existing evidence, identifying and developing theory, and modeling the process and outcomes (50). Identifying existing evidence means discovering what is already known of similar interventions, whereas identifying and developing theory involves developing a theoretical understanding of the anticipated process of change by using existing evidence and theory (50). The modeling process and outcomes involves providing information essential to understanding the effect the components have, how this may vary among participants and between sites, then to use this information to refine the design (50). The evaluation phase regards the provision of important insights about the developed intervention through feasibility testing, and the implementation phase concerns assisting future implementation (50). This dissertation primarily centers around the development (Study I and II) and evaluation (Study III) phases.

4.1.2 Participatory design

The MRC's approach recommends using appropriate evidence and theory in the development of interventions (50). A participatory and iterative approach was therefore also chosen for this dissertation, inspired by participatory design, which was deemed appropriate as it is widely used in relation to information and communication technology (157). One of the underlying principles in participatory design is that the people who perform a specific activity know the most about how the activity is done (157). Participatory design methods imply an ethical motivation to enhance and support how people can engage with others and acknowledge the importance of including all stakeholders in the design process. Another principle in participatory design centers on the processes and tools, which enable the technology users, designers, and stakeholders to learn from each other by understanding one another's perspectives (157). This also alludes to the ethical stance that to make the design process genuinely participatory, various voices need to be heard and understood (157). Inspired by the perspective of participatory design, this dissertation considered both patients and HCPs as stakeholders, as well as members of the research and development team (157). Participatory design often involves workshops where prototypes and various design games are used (154), such as the conducted tool development workshops in Study I presented in Section 4.3.3.

4.1.3 The guidance for reporting of patients and public involvement (GRIPP2)

The GRIPP2 was used in this dissertation as a strategy to increase patient involvement by actively planning their inclusion (155) throughout the development and evaluation process. The plan for patient involvement was developed in close collaboration with an experienced patient representative using the GRIPP2 long-form, which consists of eight check points: 1) abstract of paper; 2) background of paper; 3) aim of paper; 4) methods of paper; 5) capture of measurement of involvement impact; 6) economic assessment; 7) study results, and 8) discussion and conclusions (155). As GRIPP2 is developed to be used as a check list for the reporting of patient involvement in research, not all check points were applicable to this dissertation. However, the use of GRIPP2 influenced our awareness of the theoretical underpinnings, concepts and theory in the development phase, such as participatory design and SDM, as well as the design and choice of methods in the development process in Study I and II, like including patient representatives to provide input on the process.

4.1.4 The Consolidated Framework of Implementation Research (CFIR)

The MRC's approach recommends paying attention to the context which the intervention is supposed to take place in to identify possible implementation problems (50). CFIR was applied in Study II to identify contextual facilitators and barriers to inform tailoring the intervention and implementation planning (156, 158, 159). CFIR includes five domains with 39 specific constructs within those domains that aim to aid the identification and combination of relevant constructs, as well as to provide a comprehensive understanding of facilitators and barriers influencing implementation (156). Italics are used to highlight domains and constructs of CFIR in this dissertation.

The CFIR domain of *Intervention Characteristics* relates to how aspects of the intervention affect the implementation, such as perceived complexity of the intervention and the adaptability of the intervention to suit a local context (156). The *Outer Setting* domain refers to the organizations knowledge about the patients' needs and resources and the extent to which this is considered regarding the intervention. The *Inner Setting* domain relates to elements within the organization and includes structural characteristics like network and communication, culture, tension for change, and leadership engagement. The domain of *Characteristics of Individuals* focuses on the individual knowledge and belief in the intervention, while the domain *Process* includes the practical elements of the implementation process, like planning, execution, evaluation, and recruitment of resource persons (156). Knowledge provided from the use of CFIR in Study II was used to tailor the intervention to suit the context and identify the key aspects for an implementation plan.

4.1.5 The design of feasibility studies

The MRC's approach recommends feasibility testing to evaluate the developed intervention (50), and the description on how to design feasibility studies by Bowen and colleagues (1) was used to conduct the evaluation part in Study III. Feasibility studies are intended to determine whether an intervention is appropriate for further testing, and Bowen and colleagues (1) propose eight areas to focus on in feasibility studies: acceptability; demand; implementation; practicality; adaption; integration; expansion, and limited-efficacy testing. Study III focused on the exploration of acceptability, demand, and limited efficacy testing. So, conducting a feasibility study was considered essential as few studies have been published using comparable interventions, and prior studies were performed in other settings (31, 32).

4.2 Research design and overview of studies

A combination of explorative qualitative and quantitative research designs was chosen to enable a thorough exploration of the topics in this dissertation (160). Qualitative methods were used to elicit descriptions and provide insights into participant's ideas on the research questions (Study I, II, III). To complement the insights, research questions in Study III were explored with quantitative methods.

In Study I, the data collection approach and participant inclusion were based on individual interviews with patients and focus groups with HCPs, followed by four separate tool development workshops conducted with patients or HCPs. Study II was based on focus groups and workshops with HCPs, as well as written minutes from the project steering committee meetings with HCPs and patient representatives. Study III included patients' actual system use, as well as patient data from psychosocial outcome measurements, and a focus group with HCPs.

Interviews were chosen to obtain an understanding of patients' everyday lives with various chronic symptoms and challenges (161). Focus groups were employed for exploring experiences, opinions, and perceptions among HCPs through group dynamics and discussions (162). Workshops were conducted to engage stakeholders, gather their ideas and perspectives in the design and development of both the tool and the intervention (163). They were also used for tailoring the content and system of the tool, to ensure input, and to share insights and experiences between the participating outpatient clinics. A project steering committee was established and meetings were conducted to promote leadership and stakeholder engagement, including patient involvement, as well as ensure input to the intervention tailoring process. Psychosocial outcome measures were collected to evaluate the potential effectiveness of the intervention, and data on actual system use was collected to attain insights about the intervention delivery and use in clinical practice. For an overview of the study design, participants, data collection, development activities and data analyses, see Table 1.

Table 1. Overview of study design, participants, data collection and development activities, and data analysis

Study	Study design	Participants	Data collection and development activities	Data analysis
I	Qualitative	Patients (n=14) HCPs[a] (n=11)	Interviews Focus groups Content and software development - Tool development workshops - Software iterations	Thematic analysis
II	Qualitative	HCPs (n=14) Patients (n=2)	Focus groups Project steering committee meetings Workshops Tailoring of the intervention to context	Thematic analysis
III	Pre-post, single arm feasibility pilot study	Patients (n=23) HCPs (n=4)	System use (i.e., assessments and messages) Psychosocial outcome measures Focus group	Descriptive statistics Exploratory analysis Thematic analysis

[a]HCP: health care providers

4.2.1 The research and development team

The research and development team in this research project consisted of: i) the principal investigator and senior scientist (i.e., EB), who has 15 years of experience as a registered nurse and leader in a chronic care setting, she also has worked and published in the field of eHealth for over 10 years; ii) a senior scientist and a registered nurse (i.e., CV), who has worked and published in the field of implementation of eHealth for over 10 years; iii) the head of department, adjunct associate professor and a licensed clinical psychologist (i.e., LSN), all of whom were experienced in conducting qualitative analysis, and two experienced in quantitative analysis; iv) myself, the PhD candidate, project administrator, and author of this dissertation, a registered nurse and lecturer with approximately 20 years of experience in health care (i.e., BS); v) the tech lead and system developer with a master's degree in software engineering, and vi) a digital designer experienced in design, visual communication and animation, both v and vi have 15 years of experience with developing solutions and systems to be used in the health care service. All team members were employed at the Department of Digital Health Research, Division of Medicine at Oslo University Hospital. BS was responsible for coordinating and conducting all research phases and development activities under supervision of EB. The team met regularly throughout the project to discuss various aspects of the research process.

4.3 Participants, data collection and development activities

Participants in this dissertation were patients and HCPs from either an endocrine or a nephrology outpatient clinic at a large university hospital in Norway. To be eligible for study participation, patients had to be diagnosed with a NFPA or be RTX recipients, 18 years or older and able to read and speak Norwegian. In addition, patients in Study III had to have access to a smartphone, tablet or personal computer, and have access to internet with a secure access key (BankID). The HCPs were registered nurses, physicians, and health support personnel, either responsible for care of NFPA patients or for RTX recipients. Most participants were invited to participate in more than one data collection and development activity, as their experiences and involvement in previous activities were considered to have potential for enhancing the design and development discussions. See Table 2 for details.

Table 2. Overview of participants, data collection and development activities.

	Individual interviews	Focus groups	Tool development workshops	Steering group committee meetings	Workshops	Outcome measures	System use	Focus group
Study	I	I, II	I	II	II	III	III	III
Patients (NFPA[a])	n=5		n=3	n=1		n=23	n=23	
Patients (RTX[b])	n=9		n=3	n=1				
HCPs[c] (NFPA[a])		n=5	n=3	n=2	n=4			n=4
HCPs[c] (RTX[b])		n=6	n=3	n=2	n=3			

[a]NFPA: non-functioning pituitary adenomas, [b]RTX: renal transplant recipients, [c]HCP: health care providers

The two patient groups (NFPA and RTX) were separated and focus groups and tool development workshops were conducted according to diagnosis to develop diagnostically separate assessment tool. In addition, to tailor the intervention to suit each context (i.e., each outpatient clinic), the project steering committee meetings were also separated.

4.3.1 Individual interviews (Study I)

Five patients with NFPAs agreed to be contacted about the study and all agreed to participate in the study. Eleven RTX recipients agreed to be contacted about the study, while nine of these participated. The data material was collected through individual interviews and a background questionnaire related to age, sex, diagnosis, time since diagnosis and education. Eight interviews were conducted in-person. Six interviews were conducted by phone, at the patients' requests. The interviews were directed by a semi-structured interview guide

containing open ended questions reflecting the studies research questions presented in Section 3.2 and related topics of interest, see Appendix 1. To ensure easily understandable and appropriate questions, a patient representative gave feedback on background questions as well as the interview guide. The interview guide focused on topics such as daily life with a chronic health condition; symptom management; follow-up from health care services; use of technology, and requirements and expectations of a digital tool. These topics intended to provide an understanding of the context including patients' needs, challenges, and priorities (50, 156, 157). The first two interviews were conducted by BS in collaboration with EB. The remaining interviews were conducted by BS. All interviews were audio recorded and transcribed verbatim.

4.3.2 Focus groups (Study I, II, III)

12 HCPs were provided with written information about Study I and II, and eleven agreed to participate. Two focus groups (diagnostically separated) were conducted with five HCPs from the endocrine outpatient clinic and six from the nephrology outpatient clinic, and HCPs also completed a background questionnaire related to age, sex, and years of work experience within specialist health care. Four HCPs from the endocrine outpatient clinic participated in a focus group for Study III. Two of those HCPs had participated in preceding data collection activities and two were "naïve" participants.

Focus groups for Study I and II were conducted in-person at HCPs' workplace, while the focus group for Study III was performed via secure a video link. Resource use and logistics concerning gathering HCPs for in-person groups were reasons for collecting data for Study I and II in the same focus group, and for using the video link to conduct the focus group in Study III. Focus groups were performed using a semi-structured interview guide with open-ended themes reflecting the research questions, see Appendix 2. The interview guide for HCPs in Study I were similar in composition and topics to the individual interviews with patients. Interview guides for Study II were influenced by the five domains of CFIR (156), see Appendix 3. The interview guide for Study III consisted of open-ended questions, reflecting acceptability and demand inspired by Bowen and colleagues (1) descriptions of how to design feasibility studies, see Appendix 4. The focus groups provided an understanding of the context, in addition to a focus on future implementation (50, 156). The focus groups were conducted by BS and EB, and were audio recorded and transcribed verbatim.

4.3.3 Content and software development including tool development workshops (Study I)

Data collection from patient interviews and focus groups with HCPs, in combination with findings from existing literature including SDM evidence and theory, informed the content and software development of the intervention. In addition, knowledge of the existing Norwegian context influenced the development.

Content development

The content development process utilized input on the organization of the assessment feature (i.e., to suit each patient group) from the tool development workshops. All patients from individual interviews were asked if they could be contacted for workshop participation. Those who agreed to participate were invited and two tool development workshops were conducted, each with three patients. The HCPs, which also participated in focus groups, were provided with written information about the tool development workshop and agreed to be contacted and asked for participation. Those who agreed to participate were invited and two workshops, each with three HCPs, were conducted. In the nephrology workshop one HCP from the previously conducted focus group and two “naïve” HCPs participated.

Preparation prior to the workshops consisted of printing meaningful units identified in the preceding interviews with patients and focus groups with HCPs, such as "I feel fatigued" or "my job exacerbates me". Then, these units were attached to a card to be used in a card sorting exercise in the workshops. Also, findings from the literature that were not represented among the meaningful units from patients and HCPs were printed and attached to cards (e.g., sleeping disturbances or sexual dysfunctions). The cards were initially grouped under suggested themes based on previous research (28, 31-35, 132), and presented in the tool development workshops.

Cards with meaningful units and the suggested themes were first presented in patients’ workshops where patients gave feedback and sorted the cards, then this feedback was incorporated and presented in HCPs workshops. Brief notes were made on and pictures were taken of the sorted cards from all workshops. Based on feedback from these development workshops, initial records of content were drafted for each patient group and discussed among the research and development team, focusing on using plain language and shortening the record of content. The revised record of content was implemented in a prototype and input on content and language was solicited. This input was used to further refine the content.

Software development

The software development was conducted by the Section of System Development at the Department of Digital Health Research, in collaboration with the study research and development team. The hospital's patient portal had an existing option for secure messaging, however, as of 2018 when the study was conducted, it was not yet implemented into clinical use. Software development therefore focused on developing an assessment feature to be distributed through the existing secure message feature in the hospital patient portal. Through an iterative process, using simple sketches to illustrate various ideas, an initial paper prototype was developed and iteratively refined based on feedback from the research and development team. A high-fidelity technical prototype was then built to suit a smartphone format as well as tablet or a computer for the patient user-face. This prototype was tested by stakeholders, who provided feedback on the software. Finally, the assessment feature was developed according to a standard for health care interoperability (4). A final refinement of the content and system was conducted based on stakeholder feedback.

4.3.4 Project steering committee meetings (Study II)

Two of the patients who participated in Study I were contacted by HCPs at the outpatient clinics and asked if they could be contacted for steering committee meeting participation. They represented each patient group, and both agreed to participate in the study. Four HCPs (i.e., two from each outpatient clinic, including the head of the clinic) who had previously participated in other data collection or development activities were asked if they were interested in participating and agreed to. The project steering committee meetings were conducted diagnostically separated.

Project steering committee meetings were established to provide stakeholders with access to relevant information and possibilities to participate in the process of decision making, which is in line with requirements of using a participatory approach (164). Involving stakeholders in the design and development of the intervention is important to gather information about the context. Every health care setting has unique needs and the intervention must be adapted to fit the setting and the people involved (164). To prepare the stakeholders, each committee meeting began with a short presentation of the project status prepared by BS. This aimed to put the stakeholders in a better position to evaluate and think creatively. The presentation was followed by questions related to how things work and why, to facilitate group discussions. Themes discussed in meetings ensured input on the process of tailoring the intervention to the context. BS initiated a phone conversation before each meeting with the

patients, to prepare them, explain the process of the meeting, and again afterwards to check whether the patients had felt free to voice their thoughts and reflections in the meeting.

4.3.5 Workshop (Study II)

Seven HCPs participated in one joint workshop, where three HCPs were from an endocrine outpatient clinic and four were from a nephrology outpatient clinic. Six had previously participated in other data collection or development activities, and one was "naïve".
The workshop focused on enhancing knowledge about potential end-users and the context where the intervention would be used. A thematic guide based on the five domains of CFIR was used to facilitate the workshop, see Appendix 5. The five domains were first introduced to the HCPs by the BS, followed by group discussions in two diagnostically separate groups within the workshop, before the groups presented group reflections for discussion in plenum. A member from each group wrote down the group's suggested facilitators and barriers for each domain on post-it notes.

4.3.6 Tailoring to context (Study II)

As a part of the analysis process findings from Study II were discussed among BS, EB, CV and LSN. Considerations regarding whether or not various CFIR constructs were facilitators, barriers, or key aspects to include in an implementation plan were conducted in these discussions. A card sorting exercise where meaningful units were attached to cards facilitated these discussions, which were of an iterative and cyclical nature rather than linear, see Section 4.4.1. BS had visited the two outpatient clinics on several occasions, making brief notes of observations and impressions of context, which were then incorporated into these discussions. Discussions of how to tailor the intervention to suit the local contexts at the two outpatient clinics were also conducted.

4.3.7 Feasibility pilot study (Study III)

Of 39 eligible patients with NFPA who were invited to participate, 23 agreed, 12 declined and four did not complete the study requirements. Data collection started in April 2020 among NFPA patients, while data collection among RTX recipients was put on hold due to the COVID-19 pandemic. Data related to sociodemographic and disease-related measures from patients were collected at baseline, and data from HCPs were limited to sex and profession. An unexpected incident led to the closure of the hospital patient portal in October 2020 and caused a subsequent closure of the study before the planned study period completion.

Data related to *acceptability* included experiences from introducing patients to the intervention and a measurement of system usability (i.e., the System Usability Scale, SUS) (165) at a three months follow-up. Data from non-participants were also collected to explore acceptability.

To explore *demand*, messages and assessments were extracted from the hospital patient portal. These data included number and content of messages sent by patients, number of invitations sent from HCPs to patients to complete assessments, number of completed assessments from patients and assessment content. Patients who did not send messages or complete assessments were categorized as non-users. In addition, both acceptability and demand from the perspective of HCPs was explored in a focus group, as described in Section 4.3.2.

To explore *limited efficacy*, patients completed digital self-reported outcome measures at baseline before gaining access to the intervention, and again after having access to the intervention for three months. The following outcome measures were collected: anxiety and depression by the Hospital Anxiety and Depression Scale (HADS) (166); health-related quality of life (HRQoL) by the non-commercial SF 36 Short-Form Health Survey (RAND 36 version) (167, 168), and health literacy by the Health Literacy Questionnaire (HLQ) (169).

4.4 Analysis

4.4.1 Qualitative analysis

We used thematic analysis informed by Braun and Clarke (170) to analyze transcripts from individual interviews and focus groups, written minutes from project steering committee meetings and workshops, and secure messages (i.e., written text). Braun and Clarke's methods of analysis consist of six steps that are designed to be reflexive rather than linear, implying a process where subsequent steps may prompt returning to earlier steps (171). A theme is explained as a patterned response or meaning generated from the data (170), which informs the research question (171). The first step in the analysis was familiarizing ourselves with the transcripts, next was initial coding. Then, main themes were generated and refined, subthemes were identified, the wording of each theme and the overall analysis were clarified, and finally, compelling quotes were selected.

Study I As recommended by Braun and Clarke (170), familiarization was the first step of analysis. BS conducted the interviews, completed 75% of the transcript work (the remaining were transcribed professionally), as well as read through the entire data set several times.

Summaries of each interview were made, and from these a main summary based on all interviews was produced, which served as an opportunity to become even more familiar with the material and facilitate early identification of potential themes. The summaries were later compared with the results of the analysis. The analytic software NVivo 11 (QRS International, Victoria, Australia) was used to organize and analyze the data material. The analysis was conducted in weekly discussions among BS, EB, CV and LSN, and proceeded into broad initial codes, which primarily sought to organize the material into meaningful units to subsequently be further analyzed. Codes were developed and modified throughout the analysis. Next, the codes were grouped into themes and subthemes. To explore themes and subthemes and how these were connected, a thematic map was developed (170). The map was used to reexamine and refine based on similarities and differences within and across themes, which led to the reorganization and identification of new themes and subthemes. Each theme and subtheme were discussed among BS, EB, CV and LSN as described above, which provided an opportunity to focus on coherence within and across themes and subthemes. Themes and subthemes from Study I were presented with illustrating quotes in the published Paper I.

Study II The data material in Study II were transcripts from focus groups, meeting minutes and post-it notes, which were stepwise thematically analyzed, informed by Braun and Clarke (170). The data material was deductively analyzed as one data set based on CFIR; codes were pre-defined as constructs, and themes as domains. BS led the analysis process, which included weekly meetings for discussions with EB and CV. Familiarization with the data set included BS writing early impression of the initial codes in the data set. A decision was made to use colors to mark data based on their source before the data was coded into an Excel spreadsheet. Then, the initial codes and revisions of those were made. Next, the codes were discussed and revised by BS, EB, and CV. Then, the coded meaningful units were printed and attached to cards, before being grouped under themes (i.e., the five CFIR domains) on large A3 sheets of paper which were mounted onto the wall to visualize themes/domains and codes/constructs. This visualization was used to identify variations and similarities within the material which were then discussed by BS, EB, and CV, and based on the consensus, we re-evaluated and re-sorted codes/constructs and themes. Themes from Study II were presented with illustrating quotes in the published Paper II.

Study III Secure messages from patients were extracted from the patient portal, and data from the focus group with HCPs was transcribed verbatim by BS. After reading through the data set for familiarization, the data from the secure messages was inductively coded into two codes. The data from the focus group with HCPs were deductively coded into two the predefined codes acceptability and demand. These broad initial codes were explored, and new codes were developed and organized into subthemes and themes. Data was coded by BS, and discussed with EB, before further discussions with CV and LSN. Quotes to illustrate the secure messages from patients and the themes and subthemes from focus groups with HCPs were chosen and presented in Paper III.

4.4.2 Quantitative analysis

Study III Statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS, version 25, IBM Corp, Armonk, NY). Descriptive statistics, such as medians with ranges and proportions with percentages were calculated. To analyze pre-post intervention changes in outcome measures, dependent paired t-test were used. All tests were 2-sided, and P-values <.05 were considered statistically significant.

4.5 Ethical considerations

The three studies in this dissertation were performed in accordance with the Helsinki Declaration (172), including recruitment, study execution (i.e., data collection and analysis), risk assessment and final presentation, and were approved by the Department for Data Protection and Information Security (PVO, equivalent to an institutional review board, at Oslo University Hospital (20178/9223), see Appendix 6 and 7. Due to the design and development emphasis of Study I and II, the need for approval by the Regional Committee for Medical and Health Research Ethics for Southeast Norway (REK) was waived, see Appendix 8. Study III was approved by REK (2018/2201, 2020/15893), see Appendix 9-12, and registered at ClinicalTrials.gov (NCT04218721). As a part of preparation for the application to REK, the study's sociodemographic and disease-related questions and outcome measurements (i.e., HADS, RAND, HLQ) were tested by a patient representative to explore time for completion and user-friendliness.

4.5.1 Study recruitment considerations

Potential patient participants were asked if they wanted information about the study in question (Study, I, II or III) from their HCPs. Those who were interested received written information and the HCPs provided the names and contact information of the interested patients to the research team. The majority of interested patients were contacted by BS by phone after 1-3 days, receiving verbal and written information. If patients did not answer, one additional call was made, and if patients still did not answer, a text-message was sent. No further attempts for contacts were made if the text message was unanswered. In two cases, the HCPs told me that the interested patients preferred to be contacted with a text message before conversation by phone. All text messages mentioned above were sent with no identifying information, for example hospital name or diagnosis. The information provided involved details about study participation and potential risk or consequences associated with participation. Also, interested patients were provided with an opportunity to ask questions before deciding to participate.

HCPs were recruited through selection by the heads of the clinics, through projects presentations at the outpatient clinics in question, and by already collaborating HCPs. Potential participants were provided with verbal and written information about the study and study participation. The consent forms were formulated broadly, which meant that participants could choose to participate in more than one data collection and development activity if they wished to.

Written informed consent was obtained from all participating patients and HCPs. All participants in all studies were informed about the nature of the study in question, that participation was voluntary and about their right to withdraw at any time without providing any reason. In addition, potential patients were informed that withdrawal would have no consequence for the medical treatment and follow-up. All participants were provided with a copy of the consent form to keep. Patients in Study I were offered a gift certificate (with a value of approximately US $30 dollars) as compensation for their time and travel expenses. Patient representatives in Study II were compensated for hours spent. For more details about information and consent forms, see Appendix 13-18.

4.5.2 Data protection

Material from the data collection were protected by separating all individually recognizable information (i.e., audio recordings and transcripts) from the code list containing project ID numbers, which is in accordance with the Helsinki Declaration (172), REK and PVO

requirements and the General Data Protection Regulation (European Parliament and the Council of the European Union, 2016). All individually recognizable information and the code list were stored separately at secure servers and in locked rooms or cabinets under the responsibility of the principal investigator (EB). All personal identifiable information in the transcribed material was removed before analysis. Also, steps were taken to ensure that quotes could not be used to identify or traced back to the participants. The consent forms for patients in Study III and patient measurements were approved to be stored digitally in a secure area at Services for Sensitive Data (TSD) at the University of Oslo. Messages and completed assessments were approved to be stored anonymized on a secure server for storage of research data at Oslo University Hospital with access restricted to BS, EB, CV and LSN.

5. Results

Results from the three studies included in this dissertation are summarized and presented below.

5.1 Results from Study I

Most of the interviewed patients (n=14) were male (8/14), and the age ranged from 37–67 years (median 54.5). Five patients had NFPA and nine were RTX recipients. Most of the HCPs in focus groups (n=11) were female (8/11) and registered nurses (6/11) followed by physicians (4/11) and health support personnel (1/11). HCPs ages ranged from 31–61 years (median 49) and they had between 2-30 years of clinical experience in specialist health care. Data from interviews with patients and focus groups with HCPs was analyzed and organized into three main themes: 1) *Making symptoms and challenges visible*, 2) *Mastering a new life*, and 3) *Digital opportunities in follow-up*. The first two themes gave input on the content of the digital assessment tool, see Paper I, Table 2 for a thematic overview of content. The third theme provided input for the software development, see Paper I, Table 3 for an overview of the software functionalities. The development of content and software are presented in Section 5.1.4.

5.1.1 Making symptoms and challenges visible

Findings illustrated that patients were experiencing symptoms they felt were invisible to HCPs and revealed topics HCP's patients would ask about in consultations. Two sub-themes were identified:

Bodily symptoms: Patients described their experience with the physical aspects of their condition, which they felt were invisible to their HCPs, for example sleeping difficulties or fatigue. Some of the symptoms the patients described were diagnostic specific, while most symptoms were common among both patient groups. HCPs described questions regarding symptoms often raised by patients, for example weight change, which were barely mentioned in interviews with patients.

Psychosocial challenges: Patients described experiences related to their change of roles and negative impact on QoL. Also, patients described struggling with emotions such as feeling alone, lack of support, changes in life and the acceptance of those changes. HCPs described anxiety to be common in both patient groups.

5.1.2 Mastering a new life

This theme illustrated the challenges that may occur after a diagnosis, and that patients needed to learn how to manage new aspects of their condition. Two sub-themes were identified:

The need for work-related support: The patients described wanting to live a "normal" life, where those able to work wanted to work despite experiencing limitations due to their illness and circumstances. Several patients described being unable to remain in a physically demanding job, while other participants with office jobs were able to work. The patients also described that they at times needed practical support from HCPs related to managing their job situation. The need for work-related support was also brought up in focus groups with HCPs.

The need for information: Most patients described wanting to make lifestyle changes and felt they needed information to do so. Some described receiving information from HCPs as not useful because of "poor timing" or it not being tailored to their individual needs. HCPs described that they were uncertain about if all patients were able to find relevant information independently.

5.1.3 Digital opportunities in follow-up

This theme illustrated challenges experienced by patients in navigating the health care system and potential opportunities for digital interaction. Two sub-themes were identified:

Navigating the health care system: Some patients reported not always receiving adequate support from the health care system in managing various symptoms and challenges and stated that HCPs were busy and difficult to contact by phone. Patients described uncertainty about where to find relevant health information, and that it was common to forget questions, challenging to know who to ask, or what questions to ask. HCPs described their daily work as very hectic, which sometimes caused forgetting to document patient contact by phone. Some HCPs said that they sometimes shared their private phone number with patients so that they could get in contact.

Digital possibilities for interaction: Most patients described that it would be reassuring to use digital communication to contact HCPs, stating that such communication with HCPs would allow them to share what was important to them. Most of the HCPs reported wanting to communicate digitally with their patients, anticipating that such communication could potentially reduce patients' anxiety and be helpful for information recall. In addition, they stated that a "digital symptom list" would be useful for providing insight into patients' needs and expectations prior to hospital visits. HCPs expressed the importance of using existing clinical systems for such communication.

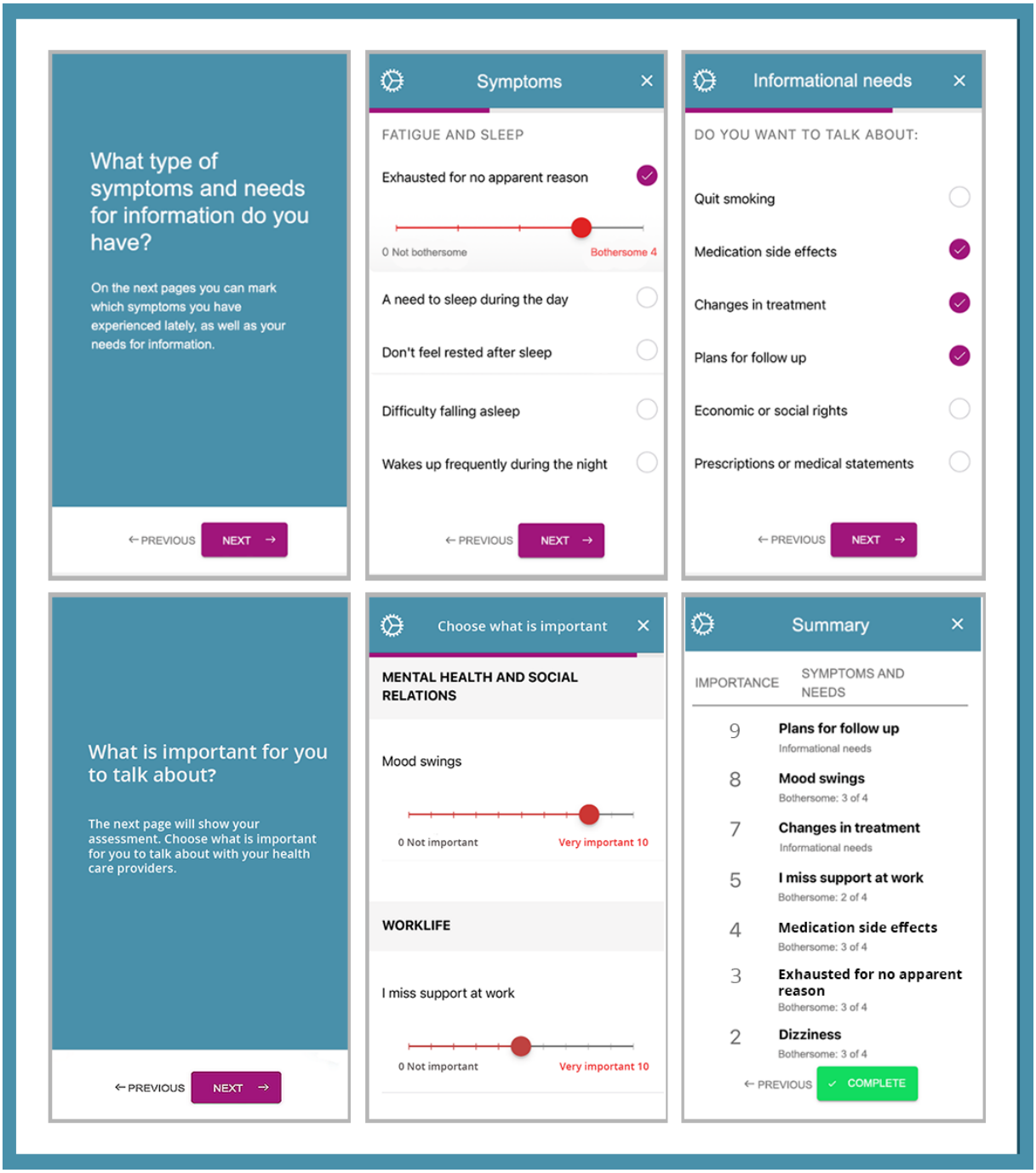
5.1.4 Content and software development

The tool development workshops ensured that topics from existing literature or briefly mentioned in interviews or focus groups were not left out.

The software development was also influenced by the content development process as the included content affected which features should be built. The assessment feature was developed as a Single Page Application (i.e., web-technology) in line with the Health Level-7 Fast Healthcare Interoperability Resources (HL7 FHIR) standard (ref fhir.org). This allowed for integration with the hospital patient portal, and the assessment to be sent as an attachment via the existing secure message functionality, which suited hospital computers and the HCPs' interface. This also provided the opportunity for patients to use it from home settings prior to hospital visits, and for HCPs to use the assessments in consultation preparation. The assessment feature contained functionality for rating how bothersome symptoms were experienced and for prioritizing topics important for patients to discuss in the upcoming consultation with HCPs, see Figure 1. Assessment completion generated a summary that was sent to HCPs.

The category 'need for information' was added to the assessment feature. It was decided not to use the Norwegian term of SDM (i.e., 'samvalg') in relation to wordings in the assessment feature, but to elicit patients' preferences in the wording of the prioritization part of the assessment feature (e.g., "What is important for you to talk about?").

Figure 1. Screenshots from patients' interface of the *InvolveMe* tool.



5.2 Results from Study II

The HCPs (n=14) were mostly female (10/14), ages ranging from 28-63 years (median 49.5) and had from 2-38 years of clinical experience from specialist health care. The two patients were female. Data were examined and analyzed into 18 CFIR constructs relevant to the study purpose. The constructs are presented by the five domains of CFIR: *Intervention characteristics, Outer setting, Inner setting, Characteristics of individuals*, and *Process*. A short description of considerations regarding tailoring of the *InvolveMe* intervention to the intended context, and identification of key aspects for the implementation plan, follows in Section 5.2.6.

5.2.1 Intervention characteristics

Intervention source. The intervention was developed within the hospital where HCPs were involved in development activities to prepare the content and system development. The HCPs expressed a perception of intervention ownership.

Relative advantage. Most HCPs perceived that the intervention`s approach for assessing symptoms could be an advantage compared with current practice with no such option. The HCPs described that the interventions approach had raised awareness about the patients' perspectives, patient-provider communication, patient satisfaction and HRQoL; thus having the potential for increased patient safety. In addition, HCPs described that using such communication could potentially reduce the number of phone calls from patients.

Adaptability. The HCPs shared their opinions on how they thought the intervention could fit into existing workflows. They perceived that it was beneficial with integration of the intervention in the hospital patient portal. Some HCPs expressed concern that the intervention could introduce additional work tasks, such as if patients completed extensive assessments and expected everything to be addressed in the consultation.

Trialability. HCPs were positive about participating in a clinical trial to test the intervention. However, they raised concerns about carrying out the planned trial without a pilot test in advance.

Complexity. The HCPs stated that the digital tool had to be intuitive and easy for them to use. Although it could be integrated into the hospital patient portal, the HCPs expressed concern that it likely would not be allowed to be integrated with the electronic health records because of data protection and privacy regulations. HCPs were worried about an increased workload if the regulations required that paper printouts of the completed assessments be manually scanned into the electronic health records. The participating physicians raised

concerns about receiving secure messages directly to an individual mailbox without some form of triage, or that the use of the message functionality might become more like a chat, with ongoing messages between patients and HCPs.

5.2.2 Outer setting

Patient needs and resources. The HCPs explained that they perceived patients as most anxious earlier on in the disease trajectory. They described a structured system for patient follow-up that had room for improvement. HCPs described that they thought most patients would be motivated to use the intervention and that such use could improve patient-provider communication. In addition, such use could serve as a secure channel where patients knew that they could get in contact with HCPs. The HCPs raised concerns about various aspects of patient acceptance, such as how some patients might be afraid of losing in-person contact with HCPs, or that digital communication might not suit all patients. They also stated that the intervention could require a level of digital competence, which some patients would lack. Adding to the HCPs input, patients in this study supplemented the patient input from Study I and strengthened the patients' voices by providing direct comment on the intervention. Patients were positive toward the intervention and viewed that such communication would improve patient follow-up.

5.2.3 Inner setting

Structural characteristics. The two included outpatient clinics described staff stability but were organizationally different. One clinic had several health support personnel that organized much of the patient administrative work for registered nurses and physicians. The other clinic included a small HCP group, which they perceived as an advantage in terms of intervention implementation.

Network and communication. Both clinics had weekly meetings for activity planning where research projects, including this study, were discussed.

Culture. HCPs reported that they were generally interested in innovations, and most HCPs saw the potential for improved symptom management through the use of *InvolveMe.*

Tension for change. HCPs described receiving many phone calls from patients which they suggested could be answered digitally.

Leadership engagement. The heads of the participating clinics were positive and engaged members of the project steering committee, as well as supportive and involved in the research project.

5.2.4 Characteristics of individuals

Knowledge and beliefs. Mostly the HCPs expressed a positive attitude toward using this type of intervention to improve clinical practice. The positive attitude was also expressed by believing that such an intervention could make patients feel safe and cared for.

5.2.5 Process

Planning. HCPs stated that a lack of information and assignment of intervention responsibility could potentially reduce their motivation for intervention use and highlighted the importance of providing information and guidance to everyone involved. It was suggested that joint project steering committee meetings could exchange information on implementation strategies during the implementation process, as well as availability of the research team for technical support and training.

There was definite *Engagement* in the planned intervention in this study. For example, some HCPs initiated writing abstracts to present study details at local and national conferences. Heads of clinics (i.e., physicians) were described as filling an *Opinion Leader* role, and HCPs from the project steering committee were considered to be *Implementation Leaders*. Registered nurses involved in the research project were seen as potential *Champions* and drivers of the implementation. BS and EB potentially influenced and facilitated the intervention as *External Change Agents*. In addition, HCPs suggested that a facilitator from the research team be available to the clinic staff members for support during the implementation process.

5.2.6 Tailoring of the *InvolveMe* intervention to the intended context

The knowledge generated from focus groups highlighted some differences in the size of the outpatient clinics and workflow. This contributed to reflections and considerations about potential facilitators and barriers, and how to tailor the intervention based on this knowledge. Presented in Tables 2-6 in Paper II are descriptions and considerations regarding the tailoring of the intervention to the intended context, as well as identification of key aspects for an implementation plan which were made in discussions around findings within CFIR domains.

5.3 Results from Study III

Of the 39 patients with NFPA who were assessed for eligibility, 23 (59%) agreed to participate and 16 (41%) declined or did not meet the study requirements for the pilot study, see Figure 4, Recruitment flowchart, Paper III. The 23 patients that were included in the study completed baseline measures and received the *InvolveMe* intervention. Of these, 19 patients completed the three month follow-up outcome measures. Due to technical issues with the hospital patient portal, the pilot study had to close after six months, which meant that the four last included patients had limited time (1 to 4 weeks) to use the intervention and were therefore not invited to complete the three month follow-up outcome measures. One of the four patients completed an assessment, but none of the four sent secure messages during the time that they had access. Patients (N=23) had a median age of 54 years (range 26-78) at inclusion and 17 (74%) had completed surgery. Patients were mostly male (14/23, 61%) and almost half (10/23, 44%) noted elementary school as their highest level of education. The non-participants that declined to participate or did not meet the study requirements were mostly male (12/16, 75%) with a median age of 73 years (range 55-80). HCPs (N=4) were all female and registered nurses working at the outpatient clinic.

5.3.1 Acceptability

Among the 23 patients receiving the *InvolveMe* intervention, seven (30%) needed additional technical support and assistance during study inclusion to be able to complete the study requirements. At the three month follow-up, the System Usability Scale mean score was 72.2 (SD 14.6), which demonstrates good system usability (165). Of the 16 non-participants, four (25%) were positive towards participating, but did not complete the study requirements. The main reason for declining to participate was described as not having a smartphone (7/16, 44%), others stated that it could be challenging to participate in a digital intervention, and some were not familiar with certain technological terms such as smartphone. Findings from the focus group with HCPs regarding Acceptability generated two subthemes, *Intervention Attractiveness* and *Intervention Suitability.*

Intervention Attractiveness: HCPs described the availability that the intervention provided for the patients as favorable, especially to patients with complex health issues or heavy symptom burden. They expressed that they would like to use the intervention for a longer period than that of the study period, as well as in a potential future clinical trial. The HCPs described patients as interested and easy to recruit.

Intervention Suitability: The HCPs were satisfied with the intervention because it provided a secure channel for patient-provider communication. They highlighted that their preceding involvement in the process of the intervention development was an important factor to ensure that the intervention suited the purpose. Based on experiences from recruiting patients to the pilot study, the HCPs were not convinced that the intervention was suitable for all elderly patients who sometimes lacked necessary equipment like a smartphone.

5.3.2 Demand (system use)

During the three month study period, 43% (10/23) patients used the intervention (i.e., secure messages and assessments). Four used secure messages, sending a total of 17 secure messages. HCPs responded to all messages mostly with messages, but sometimes by phone or in-person in the upcoming consultation. The content of the messages from patients were sorted into two codes: (1) *Patient administrative matters*, and (2) *Symptoms and challenges*.

Patient Administrative Matters: Nine secure messages mainly concerned change of scheduled time for hospital appointment, prescriptions of medications or other practical matters.

Symptoms and challenges: Eight secure messages concerned various symptoms and challenges experienced by patients. The messages concerned a need for guidance on how to manage various symptoms.

HCPs sent 13 invitations to complete assessments prior to upcoming consultations and of those eight were completed prior to a scheduled hospital visit, see Figure 2 and 3. The categories *Bodily symptoms* and *Need for information* were marked in all assessments. The most prevalent need for information was about disease trajectory, marked by seven (7/8, 88%) patients. The number of marked symptoms and needs varied from three to seventeen (median 6.5). Reasons for not completing the assessment varied (e.g., rescheduled appointments, lack of notification).

Findings from the focus group with HCPs regarding Demand generated two subthemes, *Elements of SDM* and *Intervention challenges and opportunities*.

Elements of SDM: HCPs described how the assessment aided patients in sorting their thoughts, and thus provided information about common symptoms and needs. Also, completed assessments provided opportunities for HCPs to address sensitive topics in conversations with patients. Patients' prioritization of topics important to them were described to contribute to a patient-provider conversation that revolved around those topics. Patients completed assessments that contributed to changing HCPs perspective on what was important

to discuss with patients. Also, use of secure messages provided a channel for support and contact for patients in the aftermath of surgery.

Intervention challenges and opportunities: The intervention was initially described by HCPs to be time consuming. However, after having learned to use the system, they described that it could be executed in between other daily tasks. Message replies were subject for discussion among HCPs before answering patients, which were described as positive, potentially contributing to improved care. It was suggested that the assessment potentially could support HCPs that had little prior knowledge about the patient group. HCPs also described that the access to the intervention was valued, even by participants who did not utilize it (patients).

Figure 2. Invitation to complete the assessment, from patients' interface.

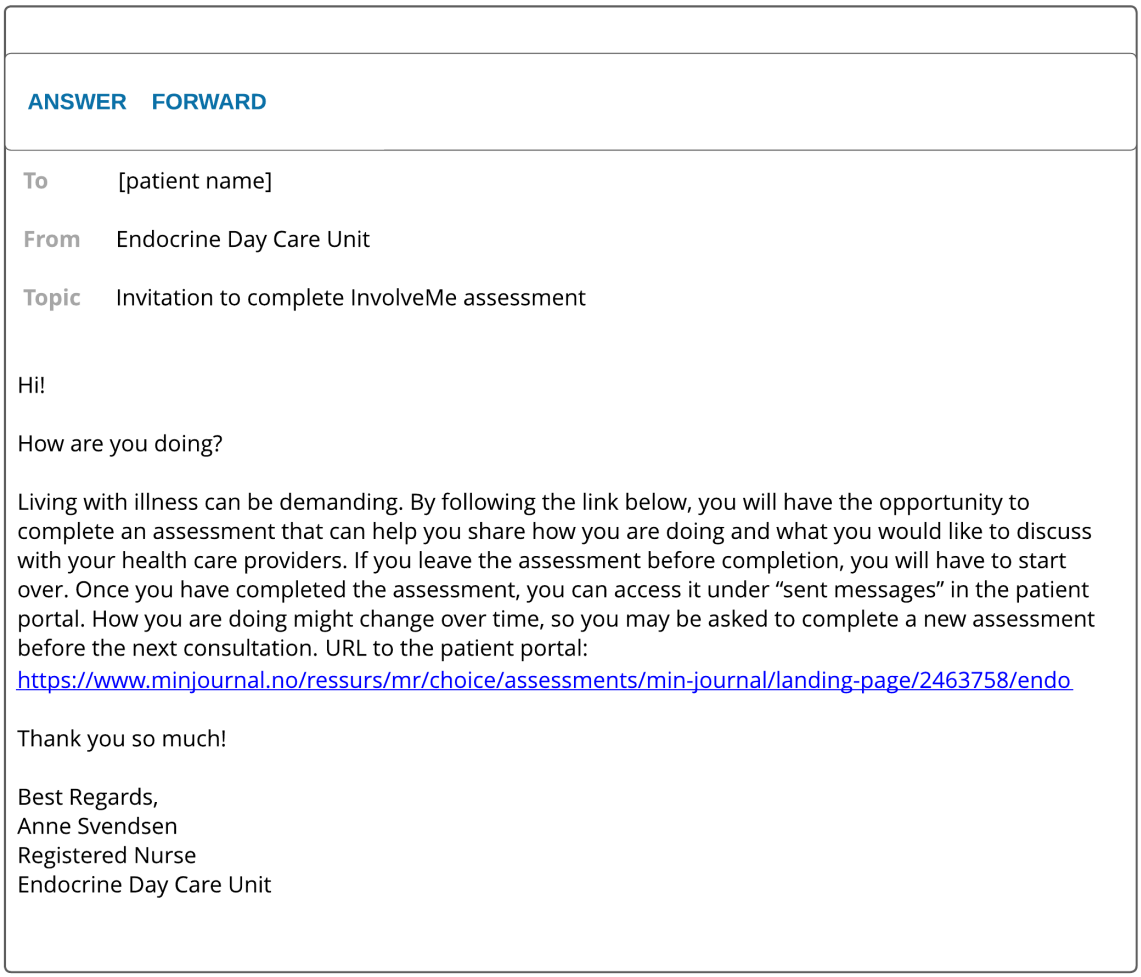
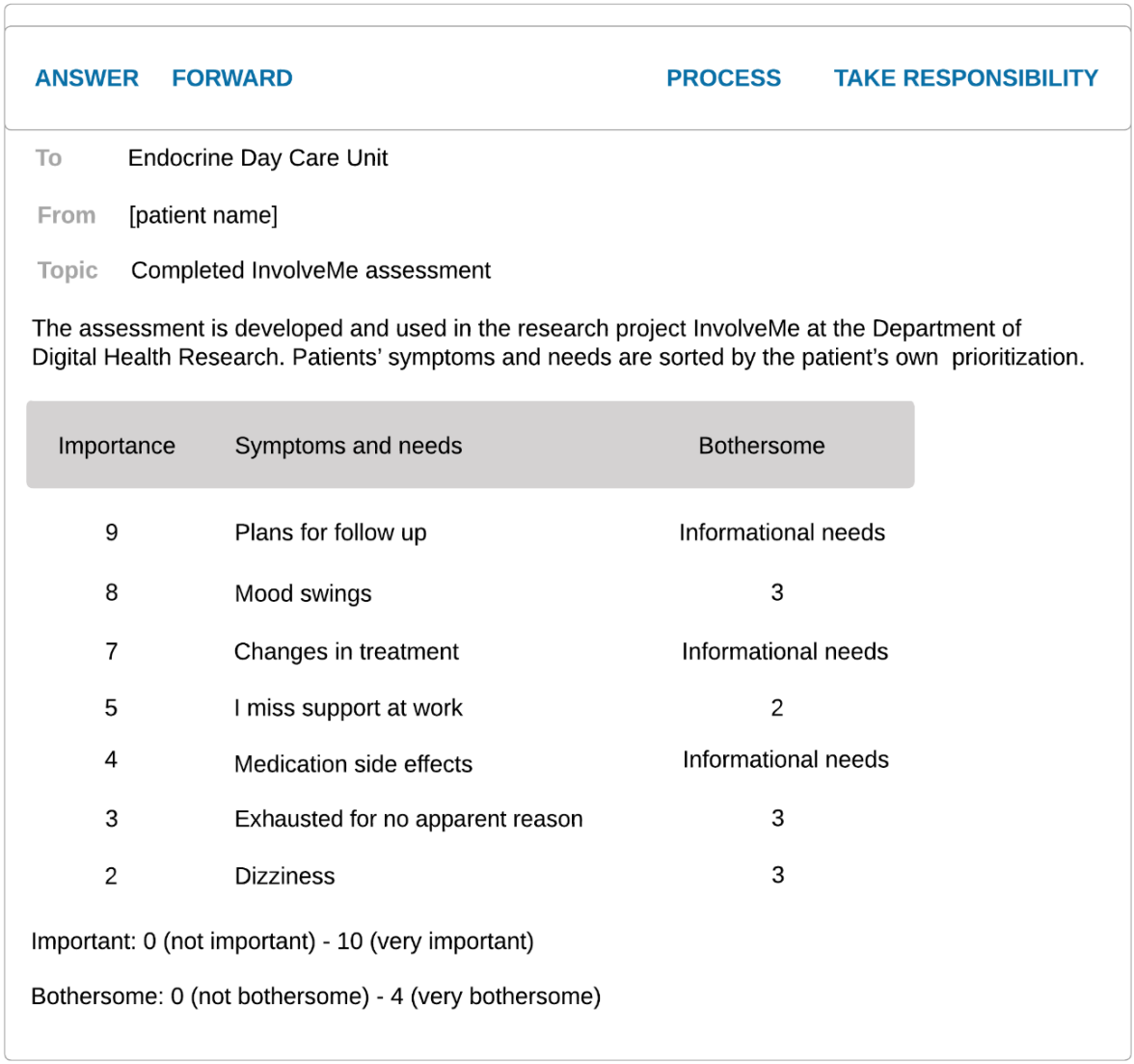


Figure 3. Summary of completed assessment, from HCPs' interface.



5.3.1 Limited efficacy testing

Preliminary pre-post intervention findings at follow-up revealed statistically significant increases in symptoms of anxiety (Mean difference (MD) 3.9; 95 % Confidence interval (CI) 2.3 to 5.5) and depression (MD 2.7; CI 0.9 to 3.8) for the participating patients. HRQoL findings indicated statistically significant improvement for the "Role Physical" subscale (MD 25.0; CI 3.0 to 47.0), but not for other subscales. There was a large variance in data and subsequent broad CIs for the HRQoL subscales. Health literacy measures remained stable from baseline to follow-up.

6. Discussion

The three studies of this dissertation constitute the development and evaluation of *InvolveMe*, a digital patient-provider communication intervention. The dissertation includes aspects of development, implementation preparations (i.e., intervention tailoring and identification of key aspects for an implementation plan), and evaluation (i.e., feasibility testing). The following discussion includes elaborations surrounding the main findings and considerations. Strengths and limitations are discussed in methodological considerations, followed by the dissertation's contribution to science and implications for practice, as well as recommendations for future research.

6.1 Main findings and considerations

There is a growing body of literature concerning digital patient-provider communication in health care services. However, there were limited availability and use of digital patient-provider interventions including assessment and secure messages in specialist health care in Norway.

The dissertation's overall aim was to develop and evaluate a digital patient-provider communication intervention to facilitate SDM in chronic health care settings. This included using opportunities provided by technology to identify challenges related to living with a chronic health condition (i.e., NFPA and RTX recipients), as well as integration of evidence and theory, so that patients and HCPs would find the intervention acceptable.

Results from the three studies in this dissertation present the complexity and impact of living with chronic health conditions, such as NFPAs and RTX, but also highlighted many common experiences and needs across the two diagnostic groups. Findings also illustrate the potential that the *InvolveMe* intervention has to provide insight into patients' current situations and identify important topics for patient-provider conversations. In addition, the overarching results provide knowledge and suggestions on how a digital patient-provider communication intervention could be developed, tailored, and evaluated to facilitate SDM to meet the needs of patients and HCPs in chronic health care settings. This dissertation also attempts to address the limitations of a generalized SDM approach in chronic health care by deploying an adapted SDM approach to suit the situations these studies focus on. The adapted SDM approach may help patient-provider conversations to be individualized and responsive to the challenges patients face.

The following discussion includes elaborations and considerations surrounding three topics: 1) the potential an intervention like *InvolveMe* may have to facilitate SDM for patients living with chronic health conditions; 2) the use of identified facilitators and barriers to tailor interventions to context, and 3) the potential a digital intervention like *InvolveMe* may have for a variety of patient groups with chronic health conditions. Methodological considerations regarding the dissertation, as well as the contribution to science, implications for practice and recommendations for future research will also be discussed.

6.1.1 The potential an intervention such as *InvolveMe* may have to facilitate SDM

Through the development process in Study I and II, the research and development team sought to adapt and present content material in a digital format through iterations, and system development and tailoring followed by evaluation in Study III with actual users. The development process also sought to incorporate evidence and develop theory from the field of SDM and chronic health conditions, in addition to evidence from the use of digital assessments tools and secure messages in Study I and II. This is in line with the recommendations in the MRC approach for developing complex interventions (50, 51). The result of this process was *InvolveMe*, a digital patient-provider communication intervention to facilitate SDM in the follow-up of chronic health conditions.

Specific considerations were made regarding SDM barriers as a part of the intervention development process in Study I and II to increase the likelihood that the developed intervention would facilitate SDM, as barriers may be modifiable if they are addressed. For example, the Norwegian term for SDM (i.e., 'samvalg') was relatively new and not widely adopted among patients and HCPs at the time of the intervention development (2018-2020). In addition, the generalized approach of SDM (6 Steps To SDM) (104, 105) that was promoted at the time was not considered to suit the situation of living with a chronic health condition. SDM is widely promoted by policy makers, yet the term and practice may be unclear about which steps that are essential and which decisions that demand SDM (173). As a new term in Norway, its promotion could affect the attention given to improve the lives of those with a chronic health condition. Introducing a new term, an adapted SDM approach, and the digital aspect of the intervention at the same time was considered to increase the complexity of the intervention, as described in CFIR (156, 174), thus creating a barrier. This was the main reason for not using the term 'samvalg' in meetings with patients and HCPs or in the developed assessment feature. Previous research highlights considering context specific

facilitators and barriers to SDM (92), and the MRC approach points out that interventions may have the potential to work if adapted to the local context (50, 51).

The focus of this thesis is the challenges of living with a chronic health condition, like symptoms and needs as mapped in Study I, and a generalized SDM approach was considered not to be appropriate to this situation. Hargraves and colleagues claim that any time that patients and HCPs work together to solve patients' problematic situations they are engaging with SDM (8, 9, 99). Living with a chronic health condition demands this collaboration between patients and HCPs over time. Therefore, chronic health conditions require an adapted SDM approach and a tool that could aid the identification of the specific challenges that the patients' experience, like symptoms and needs. It also needed to provide clarity on what the HCPs prioritize in discussions with patients to help resolve their issues. This is in line with new approaches to explore and understand SDM, which highlight that SDM approaches need to vary with patients' situations and the purpose they pursue (8, 9, 99). It has been suggested that the slow adoption of the generalized SDM approach is due to HCPs not considering it as relevant for situations and problems they routinely face with patients (8). Therefore, a SDM approach adapted to suit situations HCPs and patients commonly face may have the potential to facilitate SDM (99), as well as increase its adoption. A review highlights that interventions like *InvolveMe*, where information is obtained from patients about their health concerns prior to a clinical encounter, improve clinical practice by increasing HCP adherence to recommended practice guidelines (100).

Findings from Study III showed that patients used the assessment feature and the secure message feature to communicate challenges they experienced, including bothersome emotions and sensitive topics. Although it was not explored in Study III, this approach may present the potential for meaningful patient-provider conversations about emotions and sensitive topics, which are important as existing SDM interventions have been criticized for not contributing to creating empathic patient-provider conversations (111). Existing research suggests that sexual concerns are not currently addressed in clinical encounters, and that patients do not ask for help even though they are interested in receiving it (69). The provision of information about patients' current situations, including their prioritization and preferences of topics for what matters most to discuss with HCPs may enable patients and HCPs to work together to find suitable actions to help resolve these issues (8, 25, 28). The assessment feature of *InvolveMe* contributes to the understanding that patients believe that the topics listed in the assessment are of interest for the HCP, and thus raise these topics for discussion. This is in line with SDM

principles, as a focus on individual needs and what matters most is a central consideration (9, 97, 99).

During the development process of Study I, an information category was added to the *InvolveMe* assessment feature to encourage patients to ask for information that they needed. The reason for adding the information category was based on findings regarding patients' needs and experiences with making lifestyle changes in Study I. As patients may find it challenging to voice their informational needs (69, 175, 176), assessing them may provide support to the patient and be significant to meeting these needs. Providing information is an important part of care for patients (177), and may thus aid SDM. In Study III, all patients that completed assessments requested information. This provided an opportunity for HCPs to provide information that is congruent with patients' individual informational needs, however this was not explored further in Study III. HCPs in Study III described that information exchange about patients' situations facilitated a more individualized follow-up. Existing research underlines that HCPs provision of information tailored to patients' needs might affect anxiety and depression levels, and HRQoL (66). In addition, information tailored to individual needs may enhance the information processed by the patient, and thus encourage patients to make lifestyle changes at their own pace. Providing features to support lifestyle changes may strengthen preventive aspects, which may reduce the use of traditional health care services (178, 179). In Study III, patients were provided with the opportunity to remotely describe their current situation by using the *InvolveMe* assessment feature. Research on digital interventions combining secure messages and remote symptom and needs assessments mediated by patients' portals to facilitate SDM is scarce (36). However, research highlights that digital assessment tools are of importance for patients with chronic health conditions because they may support the patient-provider relationship and provide care that aligns with patient preferences (27). The assessment feature may support patient-provider conversations and a decision making process concerning the identified challenges from a completed assessment. Both the assessment feature as well as the secure message feature may play a supporting role in resolving patients' challenges, and thus facilitate SDM. Experiences of remote monitoring of patients with chronic health conditions found that remote monitoring increased SDM; patients described that being able to discuss their data empowered them to become an equal partner in their own care and allowed them to be more engaged with HCPs (180). *InvolveMe* represents an intervention that suits the purpose of identifying patients' challenges. The *InvolveMe* assessment feature can contribute to the development of a shared understanding and may aid HCPs in giving an empathetic response when resolving or

changing a patient situation. This may carry the potential to facilitate SDM in chronic health care (99) and is in line with Hargraves and colleges (9) call for SDM practices and tools that suit the contextual purpose (9). The extent to which *InvolveMe* can facilitate SDM needs further exploration, as Study III did not explore how the use of the intervention affected patient-provider conversations.

The *InvolveMe* intervention aims to be suitable for patients living with a chronic health condition by providing an opportunity for them to describe their current situation, including informational needs, sensitive and emotional topics, and patient preferences, therefore facilitating more meaningful patient-provider conversations.

6.1.2 Using facilitators and barriers to tailor interventions to their context

The development phase of the MRC's approach consists of identifying existing evidence, identifying or developing theory, and modeling the process and outcome (50). The gathered evidence is to be used in developing a theoretical understanding of the process of change (181). However, existing evidence does not provide information about the actual context where the interventions are supposed to be delivered. Thus, stakeholders (i.e., HCPs and patients) may provide important contextual information which can be used to refine and tailor the intervention before proceeding to the evaluation phase (i.e., feasibility testing) (181). It was considered useful to supplement the MRC approach with the CFIR approach in Study I to provide such information about the context.

The use of CFIR in Study II generated knowledge about potential facilitators and barriers for implementation to be used in tailoring the intervention to the context (156). The generated knowledge was used to address barriers and to leverage facilitators as key aspects to include in an implementation plan. The research approach of Study II provided multiple opportunities for input from stakeholders and seemed particularly appropriate for the context for several reasons. Firstly, conducting focus groups with HCPs ensured engaged stakeholders, captured their knowledge of the local outpatient context and their reflections about how the *InvolveMe* intervention could be an advantage in comparison to current practices. Secondly, involving patients from Study I in the project steering committee meetings (Study II) ensured the patient perspectives were included. The inclusion of the patient perspective was important because, for example, HCPs expressed concerns about patient acceptance of digital communication, while the participating patients expressed a positive attitude towards use of digital communication. Therefore, including both stakeholder groups perspectives allowed for clarification of the perceived versus the actual barriers. Thirdly, the workshops provided the

opportunity for HCPs to share their reflections and expectations with each other, which allowed further explorations regarding potential facilitators and barriers. For example, HCPs shared concerns about additional work and physicians raised concerns about receiving secure messages directly to an individual mailbox.

Adoption into clinical practice requires that both patients and HCPs find the intervention to be useful, valuable, relevant, and easy to use (142, 143). If, conversely, interventions are unhelpful, burdensome and irrelevant, adoption into clinical practice is unlikely to occur (142, 143). To ensure adoption into clinical practice, stakeholder involvement, such as patients and HCPs experiences and views, is significant to the intervention development and evaluation (51). The research approach of Study II ensured that the research and development team were provided with stakeholder input, which was used to develop and refine the intervention, as well as to make considerations about which implementation strategies would be feasible and suit the contextual needs. In addition, this research approach allowed for stakeholders' preferences and practice context to be incorporated into the development process.

Developing a digital intervention such as *InvolveMe*, which requires a patient interface, a HCP interface, and to be integrated into the hospital patient portal, was acknowledged to be highly complex. The MRC's approach for developing and evaluating complex interventions guides the development process in making methodological and practical decisions (50). However, it was considered that supplementing the MRC's approach with the CFIR approach would provide a comprehensive development procedure that would contribute additional knowledge to increase and enhance the intervention to suit clinical practice. Therefore, the CFIR approach was integrated throughout the research process in Study II, including study design, data collection and analysis, which is in line with the recommendations for its use (159). For example, for the intervention to suit clinical workflow, data was needed regarding intervention adaptability, trialability and complexity (the constructs of CFIR), which are not systematically addressed in the MRC's approach. These CFIR constructs were explored in focus groups and a workshop in Study II. This approach to the integration of CFIR into the study design are in line with the updated CFIR and new tools provided on its website (i.e., cfirguide.org) (174). Damshroder and colleagues published the updated CFIR based on a literature review (174) before Paper II was published in 2022, and the CFIR website (i.e., cfirguide.org) now provides a template for an interview guide, as well as a matching tool for barriers and implementation strategies.

The identification of barriers early in the development process and addressing them are also in line with the key principles of the MRC approach, which highlights that intervention

developments are dynamic, iterative, open to change, as well as keeping in mind future evaluation and implementation (182). These principles were addressed with actions throughout the development and evaluation process. This was not a sequential process, rather it was undertaken in parallel and revisited, which meant that actions and insights interacted with each other and insights gained from one action influenced plans for other actions as the intervention was developed (182). One identified barrier (i.e., adaptability) concerning the assessment feature entailed actions to condense the assessment feature and make refinements to present the assessment summary. Another barrier (i.e., complexity) concerning worries around messages being sent directly to physicians required actions to set up a shared email inbox with a dedicated triage moderator (see Paper II). This exemplifies how insights influenced actions alongside the process of intervention development. The identification of barriers allowed for considerations to be made and barriers to be addressed. This ensured the reach of target stakeholders (i.e., HCPs), as well as minimized concerns and disruptions to existing clinical workflow while assuring intervention delivery to patients.

Even though the integration and use of CFIR is recommended for the complete research process, it is not to my knowledge promoted to assist the development of interventions (156, 159, 174). However, using information of identified facilitators and barriers is described as an important step to tailoring interventions in implementation preparations to promote intervention transferability (183). This implies that CFIR may serve as a meaningful tool for tailoring interventions, and thus have relevance for intervention transferability (183).

While this dissertation cannot evaluate the actual implementation of *InvolveMe,* the identification of facilitators and barriers and the consideration and integration of them into the development process, as well as the feasibility testing of the intervention, did prepare the intervention for further evaluation and implementation (48, 150, 184).

6.1.3 The potential of a digital intervention such as *InvolveMe*

The involvement of stakeholders (i.e., patients and HCPs) in the design process of Study I to ensure that the developed intervention met the needs of its intended users, was essential for this dissertation. The approaches of participatory design (157) and GRIPP2 (155) were applied in Study I to identify stakeholders' experiences, needs and preferences in the development process. Research underlines the importance of stakeholder involvement, as representing the target group can provide important input to reduce intervention complexity and increase system acceptability (47, 184, 185). However, it may be questioned if the experiences and the identified needs of the patients in this dissertation can be considered

representative for each diagnostic population: can five NFPA or nine RTX be representative of each adult population that are living with these conditions in Norway today? Can the identified challenges from these conditions be representative across diagnostic groups?

The two patient groups involved in the development of *InvolveMe* in Study I shared most challenges, which is the case for many chronic health conditions (11-14, 16). There may be larger individual differences in experienced symptoms within a diagnostic group than across different diagnostic groups (16). However, the use of assessments prior to consultations, as in Study III, may help identify patients' challenges and thus provide individual care that addresses the variability in symptoms. Such an approach therefore has the potential to work across diagnostic groups. In addition, the use of assessments prior to consultations may serve as a way to gather information about patients' current situations, and to use this information to start outpatient conversations about the challenges that the patients' experience the most. This approach can work for many patient groups with different conditions. This is also in line with SDM as it facilitates care that is tailored to patients' preferences and needs (9, 99). Such an approach need not be reinvented for each patient group. However, the timing of the assessment completion should be explored, as this may influence the patient response.

Another aspect that is not linked to diagnosis is the identification of the actual challenge. Lorig and colleagues (16) highlight this as a difficult but important task, as the identification is important to help patients resolve experienced challenges. People with different chronic health conditions may experience similar challenges, for example fatigue or sleeping problems (15, 16). Symptoms may interact with other symptoms and make the condition worse (16), which can influence education, employment, income, and social support networks (72). In addition, patients with the same condition with similar challenges may have very different responses to resolve the challenges (16). Given the potential for a negative impact on the individual as well as for the health care services, new and easily accessible options to supplement the care of patients with chronic health conditions and to enhance patient-provider communication are vital. Similar challenges across chronic health conditions imply that the ways in which they can be resolved may be similar as well (16).

Chronic health conditions are a major source of disease burden and demand on resources in health care services (54), which has led to an increased focus on patients managing their own condition, their involvement in decision making, and a focus on HCPs providing support and care suited to individual situations (186). Specialist health care in Norway does for the most part, to my knowledge, develop and offer diagnostic specific programs for self-management. The reason for this may be related to uncertainty about whether a generic approach to self-

management may interfere with diagnostic specific management. However, generic approaches have been developed for self-management of chronic health conditions with success. One example is the Chronic Disease Self-Management Program, which has shown to improve overall health, health care utilization and self-efficacy for individuals participating in the program (187, 188). Previous research on a similar intervention to *InvolveMe* for cancer patients also provides support for the potential such an intervention may have for other patient groups (32, 33, 132).

In Study III there was a modest use of secure messages. However secure messages have been evaluated by patients in previous studies to be useful and supportive (38, 45, 123, 124). Providing opportunities to communicate with HCPs seems to be an important feature across different patient groups. Previous research also suggests that secure messages appeal to patients with high levels of symptom distress and low social support, potentially due to a need for support (189). A way of tailoring support for those patients could be to identify challenges, as offered in *InvolveMe*. More research is needed to gain further insight into this topic.

6.2 Methodological considerations

This dissertation was influenced by multiple design and development approaches, as presented in Section 4., which provided input for the data collection and development activities carried out. In the following section, considerations related to stakeholders, the use of multiple design and development approaches, and analyses are discussed.

6.2.1 Aspects of stakeholder involvement

In the three studies in this dissertation, there was a total of 54 stakeholders, including 37 patients and 17 HCPs. In addition, data were collected from 16 non-participants in Study III, as presented in Section 4.3. Despite recommendations from influential approaches such as the MRC's (50, 51) stakeholders are infrequently involved in the development of digital interventions (190, 191). In this dissertation, potential stakeholders were identified early, and steps were taken to assure stakeholder involvement by applying inspiration from participatory design (157) and GRIPP2 (155). Recent research highlights that the use of approaches such as GRIPP2 can work as a strategic tool for patient involvement and engagement in the development of health care services (185). The stakeholder involvement and data collection methods in this dissertation provided multiple perspectives and opportunities to explore

intervention development topics, in line with recommendations from the MRC's approach (50, 51).

To develop a digital communication intervention to suit the patient with NFPA or RTX recipients, the intention was to include a heterogenous group of patients in terms of age, sex and education. Of the 37 patients included in the three studies, 59% were male, and the median age was 54 years (range 26-78). The sample patients being predominantly male was probably because the prevalence of NFPA and RTX is higher in males than in females (74, 79), and may therefore indicate that the study population is representative of the patient populations. Patients were required to speak and read Norwegian, which may have excluded patients with a minority background. Also, there were few young or elderly patients. This might imply that the intervention is best suited to the age groups included in the development and evaluation of the intervention. One should carefully consider the intervention transferability to groups not represented among the study population. However, there is evidence that essential core elements of the intervention (i.e., assessments and secure messages) could be useful for a variety of groups (10, 27, 38, 45, 113, 121, 125, 126, 131). Evidence is an important aspect of assessing transferability (183). A more diverse patient population might have created different results, which could have contributed to further tailoring of the intervention for a more varied patient group.

Patients in Study III were generally familiar with technology, as most patients had searched for health-related information on the internet and had high health literacy scores. However, several patients in Study I were uncertain about where to find relevant health information. Research indicates that people with chronic conditions are more likely to use the internet to find health related information compared with the general population (192, 193). However, there are health equity disparities in patient portal use, which implies that patients with chronic health conditions use portals less often (194). Further, elderly patients, patients with low health literacy, and patients with low socioeconomic status are described to use portals less (194). Even though technology is a natural part of many people's lives and many report using the internet (195), the reasons for this internet usage are not specified and are therefore not comparable with targeted digital health behavior. For example, to complete specific health related tasks and to apply health related information into their own self-care.

Another aspect to consider is time since surgery and time living with the chronic health condition. There were indications that a more recent diagnosis and surgery entailed a greater need for contact and opportunities for digital patient-provider communication. For example, some patients in Study I expressed experience with anxiety and informational needs most

frequently early on in their trajectory; this was also expressed by HCPs in focus groups. A future clinical trial may provide further insight into this.

The health literacy scores among patients in Study III were high, which may indicate that the intervention was most accepted among those with existing knowledge and digital skills. Intervention acceptability may also be related to patients' age. Data from the 16 non-participants in Study III (who declined to participate or did not meet study requirements) added an additional perspective on the acceptability of the developed intervention. They were mostly male with a median age of 73 years (range 55-80). Research shows that increased age contributes to lower levels of digital skills (196) which may be a barrier to the use digital services (197). However, research on digital interventions to improve social connectedness in elderly people shows that study designs that incorporated digital training and support are effective (198). Research highlights the need for targeted training and education to overcome barriers and increase digital skills in older people (197). This also indicates that the non-participant perspective could be of importance to explore further in future clinical trials, to provide knowledge on how to design and develop digital health services to suit older people. A future trial should consider offering training and support specifically targeted to older people to increase digital skills and minimize the digital divide.

The 17 HCPs in this dissertation were registered nurses, physicians and health support personnel from the participating outpatient clinics and were mostly female. Digital interventions may be difficult to implement with regards to interoperability, integration with existing systems, or disruption of patient-provider interaction (47). Therefore, involving HCPs is important for identifying facilitators and barriers, and for understanding the application context (199). As there was no access to digital patient-provider communication when the intervention was developed, the HCPs envisioned how they thought a digital communication intervention might provide opportunities and voiced their concerns with using a digital communication intervention. This provided important input for the use of and integration into existing systems, and for tailoring the intervention to minimize disruptions in clinical workflow. Stakeholder involvement early in the implementation process is highlighted as an important implementation strategy (47, 199). There are examples of interventions being developed only to discover that it needed to be tailored to suit the context (50, 51). Tailoring of digital interventions may be time consuming and costly, which can lead to attempts to tailor the context instead of the intervention and could explain the absence of implementation success. In this dissertation, however, the HCPs perspectives were included in all three studies to provide input on the development and evaluation of the intervention to ensure successful

intervention delivery and use, whilst keeping in mind future implementation into clinical practice.

The internal stakeholders in the research and development team represented a multidisciplinary team, including many of whom were licensed HCPs, with four having expertise in follow-up of chronic health conditions and five with expertise in communication and information technology. The research and development team made decisions on how to integrate input throughout the development process, including final decisions around content and software. However, BS made frequent contact with HCPs and patient representatives to update them on the ongoing research and development process and to maintain a relationship. This may also have contributed to decreased effects of power inequalities and thus provided a space to share reflections regarding various aspects of the development process.

6.2.2 Combining approaches for intervention development and evaluation

The development and evaluation process of this dissertation were influenced by the MRC approach for developing and evaluating complex interventions (50) and grounded in a SDM approach (8, 9, 26, 28, 35). A participatory design approach (154) was supplemented with the use of GRIPP2 to plan user involvement (155). CFIR were used to inform the intervention tailoring (156), and Bowen and colleagues' descriptions of designing feasibility studies (1) influenced the evaluation process.

The combination of approaches was useful in the development and evaluation of the intervention. This provided flexibility and created options for supplementing each other. For instance, the development phase is briefly outlined in the MRC approach (50) and it was considered appropriate to complement this approach. For example, the participatory design approach and the GRIPP2 approach informed the development (i.e., design and development activities), and the SDM approach influenced the development of theoretical understanding of the intervention in Study I. Study I provided important information about the design of the intervention, and Study II used CFIR to provide information to refine and tailor the intervention, as well as the evaluation (i.e., pilot feasibility study/Study III). This is in line with the MRC approach (i.e., modelling process and outcomes) (50). More recently, the development phase of the MRC approach has been elaborated on, in which the suggested key actions are involve stakeholders, bring together a team, understand context, attend to future implementation, and design and refine (182). This elaboration supports the rationale behind how the intervention development was carried out in this dissertation.

Bowen and colleagues' (1) approach for designing feasibility studies was used in Study III to guide the evaluation of the intervention, in line with the MRC approach (50). The evaluation of the intervention in Study III centered around acceptability, demand, and limited efficacy testing (1), which provided input for refining the recruitment process and suggesting that a support person should be available for patients and HCPs.

It was initially planned to pilot test the assessment feature of *InvolveMe* prior to the clinical trial. While conducting Study I and II, the need to test the complete *InvolveMe* intervention was raised and discussed in workshops with HCPs, and then further discussed among the researchers. It was considered useful to broaden the scope and to conduct a feasibility pilot study to test the complete intervention (i.e., use of assessments and secure messages) in the local context and not only the assessment tool. However, there were several uncertainties. For instance, we were unsure if the participating outpatient clinics would agree with the change of plans, and which aspects of the intervention would be useful to explore in a feasibility pilot study. The MRC approach highlights that a pilot study should examine uncertainties identified during development, and that complex interventions work best when tailored to the local context (50). However, the MRC approach does not outline in detail how to tailor interventions or how to design pilot studies, so the approach of CFIR (156) was applied to Study II to examine the issues regarding uncertainties, and the Bowen and colleagues' approach (1) was applied to Study III in designing the feasibility pilot study. Using the CFIR approach to explore facilitators and barriers to the local context provided stakeholders with opportunities to be involved in decision making. For example, the decision to conduct a feasibility pilot test of the intervention in the local context was agreed upon by all stakeholders and aspects to explore in a pilot study were revealed. These aspects provided input for the subsequent design of the pilot study, which illustrates how insights gained from one action influenced plans for other actions as the intervention evolved (182).

The decision to combine multiple approaches seemed to be appropriate for this dissertation but was also challenging. For instance, the approaches of MRC, CFIR and Bowen and colleagues are widely cited and used, but there is no consensus on how these approaches should be applied. However, the MRC approach was recently updated and elaborated on (51), including descriptions of intervention development (182) and evaluation (200). Such descriptions and elaborations could make these approaches easier to apply. It is worth noting that the MRC's approach emphasizes that it does not intend to be prescriptive but rather supportive, aiming to help researchers make choices regarding methodological and practical issues (50). This provided flexibility to use the MRC approach in combination with other

approaches, and flexibility may be useful for developing and tailoring an intervention to suit the context.

6.2.3 Qualitative analyses

The qualitative data from the three studies in this dissertation were analyzed using thematic analysis, informed by Braun and Clarke (170). Thematic analysis is a useful and widely used method for analyzing qualitative data (171). Inductive as well as deductive approaches can be employed to identify themes using thematic analysis (170). In this dissertation an inductive approach was employed to the collected material in Study I, a deductive approach was employed to the analysis in Study II, and a combined approach to analysis in Study III.

An inductive approach was considered appropriate for the collected data of Study I as they were rich and detailed. The individual interviews with patients and focus groups with HCPs were conducted to understand experiences, preferences, and context, and to use their perspectives to map each patient's symptoms and needs, as well as preferences for a digital tool. The chosen approach allowed for an in-depth exploration of the perspectives of the participants, viewing similarities and differences, and generated themes that provided insight into the collected data. BS, who led the analysis process, was considered to bring a naïve perspective to the analysis process with no prior experience or "ownership" of the intervention that *InvolveMe* builds on. Findings from the analysis did not differ much from the early intervention but provided some new information which was used in the content and software development. The new information may suggest that the inductive approach chosen for Study I was adequate for further development of a pre-existing intervention. Findings from the analysis in Study I were used to provide input to be discussed by stakeholders in tool development workshops for the content and software development.

A deductive approach was considered appropriate for the data collected in Study II as the CFIR approach guided the data collection focusing on identifying facilitators and barriers to be used in intervention tailoring (156), in addition to guiding the data analysis. The use of CFIR provided both codes (i.e., constructs) and themes (i.e., domains). However, some constructs are abstract and not intuitive to use and apply, which introduces a risk of overlooking topics because of uncertainties about whether or not an item is a construct.

A combined approach was considered appropriate in Study III given the less complex material (i.e., one focus group) involving assessing feasibility through concepts of acceptability and demand (1). The deductive part of the analysis was conducted by applying

two broad codes of acceptability and demand to sort the data material, before new codes and subthemes were developed within each initial code using an inductive approach.

The use of existing approaches for Study II and III seemed useful to understand data in the context of the chosen theory (170). It is worth noting that a deductive and a combined approach to analysis seemed more rapid to conduct, which may be useful in iterative development processes that sometimes require rapid feedback. However, the more rapid analyses of Study II and III may be due to BS being more experienced at this time, and that the data material was less rich and complex in comparison to Study I.

The findings from the three studies illustrate that drawing influence from Braun and Clarkes thematic analysis was appropriate when seeking to understand experiences and thoughts across data sets (201).

6.2.4 Quantitative analysis

The quantitative data from Study III were collected digitally through outcome measures and system use data. Measurement of anxiety and depression (i.e., HADS), and HRQoL (i.e., RAND) were considered relevant for Study III, as symptoms and their impact affect follow-up of patients. Health literacy (i.e., HLQ) was considered a relevant outcome measurement for measuring patient-provider communication and interaction, as health literacy and digital skills are connected (202). In addition, the chosen outcome measurements (i.e., HADS, RAND, HLQ) were considered practical and acceptable to patients, as the measures were tested (e.g., time to complete and user-friendliness) as a part of the study preparations. All patients that received a three month follow up completed the questionnaires which suggests that completing digital questionnaires from home is practical and acceptable to patients. For analyses regarding anxiety and depression, HRQoL and health literacy, results from unadjusted tests are presented. How potential confounders such as sex, age, marriage, education, employment status, and income impacted the results were not adjusted, taking the limited sample size into account.

Study III also collected data on patients' use of secure messages and assessments, as the collection of system use is recognized as important to understanding participants' digital behavior (203). System use was collected to explore and understand digital patient-provider communication and interaction. However, due to few participating patients, a short study period and limited use of secure messages and assessments, the analyses only give an indication of the use of *InvolveMe*.

6.3 Evaluating the research quality

Evaluating the quality of research is important, especially if findings are planned to be used in practice and integrated into health care delivery (204). Despite ongoing discussions about whether concepts from quantitative research are appropriate to evaluate qualitative research, there are most commonly used different concepts to evaluate the quality of quantitative and qualitative research (204-206). In this dissertation, the concept of trustworthiness is applied to the qualitative research findings (Study I, II, III), whereas considerations related to the concepts of reliability and validity are applied to the quantitative data in Study III.

6.3.1 Assessing research quality by the concept of trustworthiness

The concept of trustworthiness refers to the evaluation of quality in qualitative research (160) by using the criteria of credibility, conformability, dependability and transferability (160, 207). To ensure trustworthiness, the design, context, participants, data collection and development activities, and analysis are described in detail in Section 4. of this dissertation. Actions conducted to improve the trustworthiness of these studies are the presentation of quotes in the results section of Paper I, II and III, a combination of several methods, discussion of results among the research team, and the use of influential approaches to guide the design and research process.

Also important for establishing trustworthiness is reflexivity (160), which implies critical self-reflections, including own biases, personal preconceptions, and preferences (160). I started out as a novice researcher with limited knowledge about the patient groups in this dissertation. However, I had experience with family members living with chronic health conditions, as well as long clinical experience in caring for other patient groups in need of long-term follow-up, and in-depth knowledge about patient involvement, including SDM. I had no previous knowledge of the field of digital health but was curious and open-minded about exploring new possibilities provided by technology. At the same time, I view the human nature to be concerned with belonging, implying that attention, acceptance and support are important in all human relationships. Being naïve and open-minded could potentially provide new questions and perspectives to be explored. Conversely, the lack of experience and knowledge of a field could lead to missing important clues. However, the research in this dissertation was conducted in close collaboration with an experienced research and development team, as well as stakeholders, which allowed sharing of experiences.

Credibility refers to the confidence in how well data and the processes of data analysis (interpretation) address the intended focus (160). Several strategies were applied to the

improve the credibility of the findings, in line with recommendations from Lincoln and Guba (207). For instance, the research and development team devoted time to becoming familiar with and understanding the studied context (i.e., patients, HCPs). This dissertation also applied method triangulation (i.e., several methods of data collection) in all three studies, as well as investigator triangulation (i.e., several researchers involved in research and analysis) and data triangulation (i.e., several sources of data) (160). Data triangulation refers to data collection from the same participants at different times and from different perspectives (i.e., patients, HCPs) (160).

In addition, this dissertation included theory triangulation (i.e., the use different theories to analyze and interpret data) (208) such as SDM, the MRC approach and CFIR. The triangulation strategies may have contributed to a broad understanding of the studied topics by inclusion of perspectives that otherwise may have been overlooked. For example, the HCP perspective in Study III highlights elements of SDM that otherwise would not have been uncovered. As such, the triangulation strategies applied in this dissertation could increase credibility. Credibility was also ensured by audio recording interviews and focus groups, followed by verbatim transcriptions, providing analyses to be conducted from written text.

Conformability refers to the degree of neutrality in a study, meaning that the findings reflect participants' voices and not the researcher (160, 207), while dependability concerns the stability of data over time, meaning that data can be replicated or repeated (160, 207). Both aspects rely on the researcher's skills and abilities in the research process (207). In this dissertation, three researchers participated in the analysis in addition to myself. As such, this supported investigator triangulation which contributes to reducing researcher biases and thus strengthening conformability and dependability. Two of the researchers did not participate in the data collection process and contributed to necessary impartiality in the development of the interview guides, coding, themes and subthemes, and analysis and interpretation of the data; thus further strengthening conformability and dependability. In addition, to illustrate themes and subthemes, quotes were included in the published papers to increase transparency of analysis and findings.

Transferability refers to the extent the findings can be transferred to other settings or contexts (207). The context of this dissertation is described in detail, which allows the reader to assess transferability. To increase transferability of the interpretation, themes and subthemes were included in the published papers. Although the patient groups had diagnostic specific symptoms there were also several common challenges that may be linked to living with a chronic health condition, possibly suggesting that more generic assessments could suit

several conditions. The transferability of this dissertation's findings is reflected upon and discussed in the main findings, methodological considerations and in implications for practice and research, see Section 4.

6.3.2 Assessing research quality by the concepts of reliability and validity

The concept of reliability refers to the accuracy and consistency of information in a study, and the concept of validity refers to the extent to which an interference in a study is unbiased and well-founded (160). In this dissertation, these concepts are applied to the quantitative data in Study III.

To ensure reliability, a thorough and accurate description of the research process is described in Section 4., which includes the chosen psychosocial outcome measures, and how they are collected and analyzed (160).

The psychosocial outcome measures used in Study III, HADS (166), RAND-36 (167, 168), and the HLQ (169) were validated measures in Norway and were primarily included to test feasibility of the measures (e.g., are the measures easy to answer digitally), in addition to measure the limited efficacy. HADS and RAND were chosen based on a literature review on outcomes for the patient groups and findings from Study I regarding symptoms and needs. HLQ were chosen due to health literacy's importance in patient-provider communication (i.e., low health literacy may be a barrier for SDM) (209), and health literacy's link to digital health behavior/skills (202). HADS, RAND and HLQ are also generic measures, which may allow comparison to normative populations.

There were no missing data in the pilot study outcome measurements due to a mandatory setting for measurement completion. This may have masked possible difficulties patients experienced completing the measurements (e.g., were the measures understandable?). However, none of the patients that participated requested support with completing measures at baseline or at the three month follow-up, and all 19 participants receiving the three month follow-up completed the measures. This may indicate that patients found the measures relevant and easy to complete. It also suggests that the measurements were easy to administer digitally to patients and easy to return, as well as deemed acceptable.

The use of the System Usability Scale (165) at the three month follow-up indicated good system usability. However, the patients completing the scale most likely rated all the features included in the patient portal and not only the specific features of *InvolveMe*. This may indicate that the use of the System Usability Scale to assess integrated features did not provide acceptable reliability and validity in this context.

One aspect of validity is referred to as external validity, which relates to the extent to which study results can be generalized to other samples or settings (160). However, due to the research design of Study III as a feasibility pilot study, this was not possible, nor is it the primary goal of feasibility studies in general (160). The aim of feasibility studies is to provide findings to help determine if an intervention should be recommended for efficacy testing (1). Another aspect of validity is referred to as internal validity, which relates to the extent to which it can be inferred that an intervention caused the observed effects on the outcome (160). It was expected that patients in Study III would experience stable (i.e., not worsened) or potentially improved outcome measures in terms of anxiety and depression, HRQoL and health literacy. Unexpectedly, symptoms of anxiety had worsened at the three month follow-up. However, this might not be ascribed to the intervention, but rather be explained by a national increase in Covid-19 cases at the time of the follow-up. This displays that a pre-post designed study with one group has its limitations when events occur between pre-test and post-test, and that such design can threaten internal validity (210). A study design with a control group would minimize such a threat (210). However, this is not the aim of feasibility studies either, and the study period was too short and the sample too small for statistical analysis to provide meaningful results.

The developed assessment feature of *InvolveMe* does not aim to be an instrument to measure change. It's purpose is to support patient-provider communication by sharing information about patients' situation and eliciting patient preferences as preparation and support for conversations regarding patients challenges and care in an outpatient context. The use of the assessment feature was provided with indications of positive impact by positive comments in Study I, including being able to complete the assessment at home, as well as positive statements from patients and HCPs in Study III.

6.4 Implications for practice and research

The overall aim of the dissertation was to develop and evaluate a digital patient-provider communication intervention to facilitate SDM in chronic health care settings. The studies focus on patients with NFPA and RTX recipients, although RTX recipients were not included in Study III due to the Covid-19 pandemic. This thesis specifically aimed to explore a SDM approach for resolving patients' challenges in living with a chronic health condition, which entailed identifying patients' challenges to support the decision making process. In this process, the dissertation sought to adapt and explore a generalized SDM approach to suit the situation of patients living with a chronic health condition. To the best of our knowledge,

InvolveMe is the only Norwegian intervention with an adapted SDM approach specifically targeted at patients living with chronic health conditions. The development and evaluation process of *InvolveMe* introduced additional contributions and implications for practice and research, which are briefly summarized below.

First, findings from Study I contribute to the knowledge about diagnostic specific challenges, as well as shared challenges and needs among patients with NFPA and RTX recipients. This knowledge will be relevant for HCPs caring for these patient groups, and to people working with health care research concerning digital patient-provider communication (36). This dissertation also contributes to the knowledge about the needs and requirements of information and communication technology for patients with NFPA and RTX recipients, as well as for HCPs caring for the two patient groups. Further, it contributes to how such knowledge could be used to develop a digital communication intervention to suit the contextual needs of both patients (214) and HCPs.

Second, findings from Study II provide knowledge about intervention tailoring through identifying and addressing facilitators and barriers to suit contextual needs and contributes to refining and optimizing an intervention before feasibility testing. Specifically, Study II provides knowledge about how CFIR could be used to assist the development of interventions by identifying facilitators and barriers to tailor interventions. This could be used to further the development of the CFIR approach and help advance implementation science, as well as inform those interested in the development of complex digital interventions (211, 212). Findings provide insight into how tailoring of digital communication interventions can be carried out according to contextual needs, which could inform systematic and targeted development of such interventions.

Third, findings from Study III provide insights for improvement of the recruitment process and further tailoring of the intervention to prepare for implementation. Because of the software development according to the HL7 FHIR standard, there are ongoing efforts to integrate *InvolveMe* with the national patient portal (i.e., helsenorge.no) and electronic health records. *InvolveMe* has relevance to chronic care follow-up, as well as the potential to supplement advanced hospital care in patients' home settings. This dissertation has contributed insight and considerations related to how technology, theory and evidence can provide tools to support patient-provider conversations and thus facilitate SDM in a chronic health care context. The acquired insights from the development and evaluation of *InvolveMe* have already been integrated into the development of a communication intervention targeting

family caregivers of patients admitted to intensive care units (213), which are currently being tested in randomized controlled trials.

Finally, this dissertation may serve as an example of how a generalized SDM approach can be adapted to suit the situation of patients living with a chronic health condition by identifying patients' challenges and preferences on topics to discuss with HCPs. This illustrates the potential *InvolveMe* may have to foster conversations which facilitate SDM. The findings of these studies contribute to knowledge about how an intervention may be designed, developed and evaluated using multiple design and development approaches, and how to use existing evidence and theory to guide this process. The inspiration from the chosen design and development approaches contributed to knowledge and experience in how to integrate the input they provided and explore potential outcomes. As such, this dissertation provides knowledge that can give guidance to others developing similar interventions.

6.5 Recommendations for future research

The development and evaluation process have contributed to refinement and optimization of the *InvolveMe* intervention, both of which are important to implementation success (47, 50, 51, 184). The evaluation did establish feasibility and future research should examine efficacy findings as well as explore the elements of this dissertation's adapted SDM approach for patients living with chronic health conditions: identify patient challenge and develop a shared understanding, recognize patient's feelings, resolve or change patient's situation (8, 9, 99). The adapted SDM approach may represent a framework for digital SDM in chronic care management. Future research should evaluate the adapted SDM approach and its contribution to patient-provider conversations. Focus should be directed towards how its elements contribute to eliciting patient preferences, as well as how to provide well informed decisions for the challenges that patients experience.

The call for a more patient-centered care approach and the limited availability of communication interventions highlight the importance of supplementing standard care with remote support and care for patients living with chronic health conditions. By using technology as a tool and SDM as the process, technology may offer opportunities to explore how SDM can contribute to resolving challenges of patients living with a chronic health condition. Future research should also continue to explore the perspectives of intervention non-participants and non-users, as their perspective can identify potential barriers for use of digital communication interventions. Such knowledge may be especially useful for the development of more user-friendly and accepted digital communication interventions, as well

as developing useful and targeted implementation strategies to increase equity and diversity in the use of such interventions.

This dissertation was influenced and guided by several design and development approaches. Future research should draw on the provided information to further develop and refine the approaches used in this dissertation. For example, this dissertation employed several approaches to involve stakeholders with different perspectives in the intervention development and evaluation. Future research should build on this information and expand this evidence base (185). According to participatory design, one should reflect upon potential users not included or represented in the development process (157). In the future for *InvolveMe*, this could mean further evaluating the need for tailoring the intervention specifically for younger and elderly users. Even though there was a focus during the development process on providing content in plain language, one should also consider the need for tailoring specifically focusing on user's health literacy, as low health literacy is linked to low digital skills in the Norwegian population (202). There is also a need to tailor interventions to suit a diverse population by providing it in several languages.

This dissertation used the CFIR approach to identify potential facilitators and barriers for implementation, which were used to tailor the intervention to suit contextual needs during its development. Future studies should aim to understand how the use of CFIR can inform intervention development and refinement, and as such impact the implementation outcome.

Even though the *InvolveMe* intervention cannot be implemented as planned, it can be applied in a future clinical trial due to the use of standards in the software development. Future research should apply established standards in the development of software features and systems to reduce research waste.

7. Conclusions

To address the call for a more patient centered approach, and the limited availability of digital communication interventions in chronic health care settings, this dissertation sought to develop and evaluate a digital patient-provider communication intervention to facilitate SDM for patients living with a chronic health condition, specifically patients with NFPA and RTX recipients.

This dissertation provides a comprehensive example of a development process, first by identifying existing evidence, then identifying and developing theory, before modeling processes and outcomes, and then conducting the actual evaluation. Drawing from existing design and development approaches, this dissertation offers an extensive exploration of the challenges of patients living with a chronic health condition from their own perspective as well as from the perspective of HCPs responsible for care. Potential facilitators and barriers for system use were also explored and identified to address and overcome barriers and maintain facilitators in the process of intervention tailoring. Aiming to identify and address challenges with digital SDM interventions, as well as SDM theory, the development process entailed adapting a generalized SDM approach to suit the situation of living with a chronic health condition. A generalized SDM approach can be developed and extended to facilitate SDM for different situations. Drawing on the adapted SDM approach, an intervention such as *InvolveMe* has the potential to facilitate conversations where patients and HCPs identify challenges that matter, along with possible ways of resolving them.

Findings from this dissertation highlight how identifying patients' challenges (i.e., symptoms and needs) can provide information about patients' current situations and elicit patient preferences that are of importance to discuss with HCPs. Interventions such as *InvolveMe* have the potential to support SDM and impact future care delivery for patients living with chronic health conditions.

References

1. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med. 2009;36(5):452-7.
2. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.
3. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10:53.
4. HL7 FHIR Foundation [Internet]. Health Level Seven International Fast Health Interoperability Resources. [Accessed March 2022]. Available from: Welcome to the HL7 FHIR Foundation
5. Talking HealthTech. [Internet]. What is Health Information and Communication Technologies? 2020. [Accessed July 2023]. Available from: What is Health Information and Communication Technologies (ICT)? (talkinghealthtech.com)
6. Powell BJ, Beidas RS, Lewis CC, Aarons GA, McMillen JC, Proctor EK, et al. Methods to Improve the Selection and Tailoring of Implementation Strategies. J Behav Health Serv Res. 2017;44(2):177-94.
7. The National Coordinator for Health Information Technology (ONC). [Internet]. What is a patient portal? 2017. [updated Sept 9 2017]. [Accessed March 2022]. Available from: What is a patient portal? | HealthIT.gov
8. Hargraves IG, Montori VM, Brito JP, Kunneman M, Shaw K, LaVecchia C, et al. Purposeful SDM: A problem-based approach to caring for patients with shared decision making. Patient Educ Couns. 2019;102(10):1786-92.
9. Hargraves IG, Fournier AK, Montori VM, Bierman AS. Generalized shared decision making approaches and patient problems. Adapting AHRQ's SHARE Approach for Purposeful SDM. Patient Educ Couns. 2020;103(10):2192-9.
10. Hefner JL, MacEwan SR, Biltz A, Sieck CJ. Patient portal messaging for care coordination: a qualitative study of perspectives of experienced users with chronic conditions. BMC Fam Pract. 2019;20(1):57.
11. Burstrom K, Johannesson M, Diderichsen F. Health-related quality of life by disease and socio-economic group in the general population in Sweden. Health Policy. 2001;55(1):51-69.
12. Saarni SI, Harkanen T, Sintonen H, Suvisaari J, Koskinen S, Aromaa A, et al. The impact of 29 chronic conditions on health-related quality of life: a general population survey in Finland using 15D and EQ-5D. Qual Life Res. 2006;15(8):1403-14.
13. Heyworth IT, Hazell ML, Linehan MF, Frank TL. How do common chronic conditions affect health-related quality of life? Br J Gen Pract. 2009;59(568):e353-8.
14. Wu M, Brazier JE, Kearns B, Relton C, Smith C, Cooper CL. Examining the impact of 11 long-standing health conditions on health-related quality of life using the EQ-5D in a general population sample. Eur J Health Econ. 2015;16(2):141-51.
15. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health. 2014;104(8):e25-31.
16. Lorig K, Holman H, Sobel D. Living a Healthy Life with Chronic Conditions: Self-Management of Heart Disease, Arthritis, Diabetes, Depression, Asthma, Bronchitis, Emphysema and Other Physical and Mental Health Conditions: Bull Publishing Company; 2012.
17. May CR, Cummings A, Myall M, Harvey J, Pope C, Griffiths P, et al. Experiences of long-term life-limiting conditions among patients and carers: what can we learn from a meta-review of systematic reviews of qualitative studies of chronic heart failure, chronic obstructive pulmonary disease and chronic kidney disease? BMJ Open. 2016;6(10):e011694.
18. Aiyegbusi OL, Kyte D, Cockwell P, Marshall T, Gheorghe A, Keeley T, et al. Measurement properties of patient-reported outcome measures (PROMs) used in adult patients with chronic kidney disease: A systematic review. PloS One. 2017;12(6):e0179733.
19. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Improving access to supportive cancer care through an eHealth application: a qualitative needs assessment among cancer survivors. J Clin Nurs. 2015;24(9-10):1367-79.

20. Basch E, Iasonos A, McDonough T, Barz A, Culkin A, Kris MG, et al. Patient versus clinician symptom reporting using the National Cancer Institute Common Terminology Criteria for Adverse Events: results of a questionnaire-based study. Lancet Oncol. 2006;7(11):903-9.
21. Basch E, Jia X, Heller G, Barz A, Sit L, Fruscione M, et al. Adverse symptom event reporting by patients vs clinicians: relationships with clinical outcomes. J Natl Cancer Inst. 2009;101(23):1624-32.
22. Laugsand EA, Sprangers MA, Bjordal K, Skorpen F, Kaasa S, Klepstad P. Health care providers underestimate symptom intensities of cancer patients: a multicenter European study. Health Qual. 2010;8:104.
23. Vistad I, Cvancarova M, Fossa SD, Kristensen GB. Postradiotherapy morbidity in long-term survivors after locally advanced cervical cancer: how well do physicians' assessments agree with those of their patients? Int J Radiat Oncol Biol Phys. 2008;71(5):1335-42.
24. Friis K, Lasgaard M, Osborne RH, Maindal HT. Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29,473 Danish citizens. BMJ Open. 2016;6(1):e009627.
25. Hargraves I, LeBlanc A, Shah ND, Montori VM. Shared Decision Making: The Need For Patient-Clinician Conversation, Not Just Information. Health Aff. 2016;35(4):627-9.
26. Montori VM, Gafni A, Charles C. A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes. Health Expect. 2006;9(1):25-36.
27. Wickramasekera N, Taylor SK, Lumley E, Gray T, Wilson E, Radley S. Can electronic assessment tools improve the process of shared decision-making? A systematic review. Health Inf Manag. 2020; 72-86.
28. Ruland CM, Bakken S. Developing, implementing, and evaluating decision support systems for shared decision making in patient care: a conceptual model and case illustration. Journal of biomedical informatics. 2002;35(5-6):313-21.
29. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:Cd001431.
30. Wieringa TH, Rodriguez-Gutierrez R, Spencer-Bonilla G, de Wit M, Ponce OJ, Sanchez-Herrera MF, et al. Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. Syst Rev. 2019;8(1):121.
31. Ruland CM, Holte HH, Roislien J, Heaven C, Hamilton GA, Kristiansen J, et al. Effects of a computer-supported interactive tailored patient assessment tool on patient care, symptom distress, and patients' need for symptom management support: a randomized clinical trial. J Am Med Inform Assoc. 2010;17(4):403-10.
32. Heyn L, Finset A, Eide H, Ruland CM. Effects of an interactive tailored patient assessment on patient-clinician communication in cancer care. Psycho-Oncol. 2013;22(1):89-96.
33. Heyn L, Ruland CM, Finset A. Effects of an interactive tailored patient assessment tool on eliciting and responding to cancer patients' cues and concerns in clinical consultations with physicians and nurses. Patient education and counseling. 2012;86(2):158-65.
34. Ruland CM. Decision support for patient preference-based care planning: effects on nursing care and patient outcomes. J Am Med Inform Assoc. 1999;6(4):304-12.
35. Ruland CM. Handheld technology to improve patient care: evaluating a support system for preference-based care planning at the bedside. J Am Med Inform Assoc. 2002;9(2):192-201.
36. Hartasanchez SA, Heen AF, Kunneman M, García-Bautista A, Hargraves IG, Prokop LJ, et al. Remote shared decision making through telemedicine: A systematic review of the literature. Patient Educ Couns. 2021;105(2):356-365.
37. Scott Kruse C, Argueta DA, Lopez L, Nair A. Patient and provider attitudes toward the use of patient portals for the management of chronic disease: a systematic review. J Med Internet Res. 2015;17(2):e40-e.
38. Shang L, Zuo M, Ma D, Yu Q. The Antecedents and Consequences of Health Care Professional-Patient Online Interactions: Systematic Review. J Med Internet Res. 2019;21(9):e13940.
39. Antonio MG, Petrovskaya O, Lau F. The State of Evidence in Patient Portals: Umbrella Review. J Med Internet Res. 2020;22(11):e23851.

40. Johansen MA, Berntsen GK, Schuster T, Henriksen E, Horsch A. Electronic symptom reporting between patient and provider for improved health care service quality: a systematic review of randomized controlled trials. part 2: methodological quality and effects. J Med Internet Res. 2012;14(5):e126.
41. Carini E, Villani L, Pezzullo AM, Gentili A, Barbara A, Ricciardi W, et al. The Impact of Digital Patient Portals on Health Outcomes, System Efficiency, and Patient Attitudes: Updated Systematic Literature Review. J Med Internet Res. 2021;23(9):e26189.
42. Meld. St. 7 (2019-2020). Nasjonal helse- og sykehusplan 2020-2023. Helse- og omsorgsdepartementet; 2020.
43. Varsi C, Ekstedt M, Gammon D, Børøsund E, Ruland CM. Middle Managers' Experiences and Role in Implementing an Interactive Tailored Patient Assessment eHealth Intervention in Clinical Practice. Comp Inform Nurs. 2015;33(6):249-57.
44. Børøsund E, Ruland CM, Moore S, Ekstedt M. Nurses' experiences of using an interactive tailored patient assessment tool one year past implementation. Int J Med Inform. 2014;83(7):e23-e34.
45. Scott Kruse C, Bolton K, Freriks G. The Effect of Patient Portals on Quality Outcomes and Its Implications to Meaningful Use: A Systematic Review. J Med Internet Res. 2015;17(2):e44.
46. Keyworth C, Hart J, Armitage CJ, Tully MP. What maximizes the effectiveness and implementation of technology-based interventions to support healthcare professional practice? A systematic literature review. BMC Med Inform Decis Mak. 2018;18(1):93.
47. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci. 2016;11(1):146.
48. Granja C, Janssen W, Johansen MA. Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature. J Med Internet Res. 2018;20(5):e10235.
49. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: A systematic review. J Telemed Telecare. 2016;24(1):4-12.
50. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
51. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021;374:n2061.
52. National Center for Chronic Disease Prevention and Health Promotion. [Internet]. About Chronic Diseases. [Accessed May 2022]. 2022. Available from: https://www.cdc.gov/chronicdisease/about/index.htm
53. World Health Organization. [Internet]. Noncommunicable diseases: World Health Organization. [Accessed March 2023]. 2022. Available from: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.
54. Øverland S KA, Vollset SE, Kinge JM, Skirbekk V, Tollånes MC. Disease Burden in Norway 2016. Results from the Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016]. 2018;17-36. Bergen/Oslo. Norwegian Institute of Public Health.
55. OECD. The labour market impacts of ill-health. In Health at a Glance: Europe 2016: State of Health in the EU Cycle. OECD Publishing. Paris.
56. Andela CD, Scharloo M, Pereira AM, Kaptein AA, Biermasz NR. Quality of life (QoL) impairments in patients with a pituitary adenoma: a systematic review of QoL studies. Pituitary. 2015;18(5):752-76.
57. Fletcher BR, Damery S, Aiyegbusi OL, Anderson N, Calvert M, Cockwell P, et al. Symptom burden and health-related quality of life in chronic kidney disease: A global systematic review and meta-analysis. PLoS Med. 2022;19(4):e1003954.
58. Anderson DM, Keith J, Novak PD, Elliot MA. Mosby's Medical, Nursing, & Allied Health Dictionary: Mosby; 2002.
59. Drossman DA, Ruddy J. Improving Patient-Provider Relationships to Improve Health Care. Clin Gastroenterol Hepatol. 2020;18(7):1417-26.
60. Häfliger C, Diviani N, Rubinelli S. Communication inequalities and health disparities among vulnerable groups during the COVID-19 pandemic - a scoping review of qualitative and quantitative evidence. BMC Public Health. 2023;23(1):428.

61. Kamimura A, Higham R, Rathi N, Panahi S, Lee E, Ashby J. Patient-Provider Relationships Among Vulnerable Patients: The Association With Health Literacy, Continuity of Care, and Self-Rated Health. J Patient Exp. 2020;7(6):1450-7.
62. Nouri SS, Rudd RE. Health literacy in the "oral exchange": an important element of patient-provider communication. Patient Educ Couns. 2015;98(5):565-71.
63. Graham S, Brookey J. Do patients understand? Perm J. 2008;12(3):67-9.
64. Christalle E, Zill JM, Frerichs W, Härter M, Nestoriuc Y, Dirmaier J, et al. Assessment of patient information needs: A systematic review of measures. PloS One. 2019;14(1):e0209165.
65. King A, Hoppe RB. "Best practice" for patient-centered communication: a narrative review. J Grad Med Educ. 2013;5(3):385-93.
66. Husson O, Mols F, van de Poll-Franse LV. The relation between information provision and health-related quality of life, anxiety and depression among cancer survivors: a systematic review. Ann Oncol. 2011;22(4):761-72.
67. Fröjd C, Von Essen L. Is doctors' ability to identify cancer patients' worry and wish for information related to doctors' self-efficacy with regard to communicating about difficult matters? Eur J Cancer Care (Engl). 2006;15(4):371-8.
68. Kinnersley P, Edwards AGK, Hood K, Cadbury N, Ryan R, Prout H, et al. Interventions before consultations for helping patients address their information needs. Cochrane Database Syst Rev. 2007(3).
69. Reese JB, Sorice K, Beach MC, Porter LS, Tulsky JA, Daly MB, et al. Patient-provider communication about sexual concerns in cancer: a systematic review. J Cancer Surviv. 2017;11(2):175-88.
70. Westendorp J, Stouthard J, Meijers MC, Neyrinck BAM, de Jong P, van Dulmen S, et al. The power of clinician-expressed empathy to increase information recall in advanced breast cancer care: an observational study in clinical care, exploring the mediating role of anxiety. Patient Educ Couns. 2021;104(5):1109-15.
71. World Health Organization. Regional Office for Europe. European Observatory on Health Systems and Policies.Sperre Saunes I, Karanikolos M & Sagan, A. 2020. Norway: health system review. World Health Organization. Regional Office for Europe. Avaliable from: https://apps.who.int/iris/handle/10665/331786
72. Norwegian Institute of Public Health. Public Health Report: Health Status in Norway 2018. Oslo. 2018. Available from: Health status in Norway 2018 - NIPH (fhi.no)
73. Øystese KA, Evang JA, Bollerslev J. Non-functioning pituitary adenomas: growth and aggressiveness. Endocrine. 2016;53(1):28-34.
74. Tjörnstrand A, Gunnarsson K, Evert M, Holmberg E, Ragnarsson O, Rosén T, et al. The incidence rate of pituitary adenomas in western Sweden for the period 2001-2011. Eur J Endocrinol. 2014;171(4):519-26.
75. Joustra SD, Thijs RD, van den Berg R, van Dijk M, Pereira AM, Lammers GJ, et al. Alterations in diurnal rhythmicity in patients treated for nonfunctioning pituitary macroadenoma: a controlled study and literature review. Eur J Endocrinol. 2014;171(2):217-28.
76. Halvorsen H, Ramm-Pettersen J, Josefsen R, Ronning P, Reinlie S, Meling T, et al. Surgical complications after transsphenoidal microscopic and endoscopic surgery for pituitary adenoma: a consecutive series of 506 procedures. Acta Neurochir. 2014;156(3):441-9.
77. Liem YS, Bosch JL, Arends LR, Heijenbrok-Kal MH, Hunink MG. Quality of life assessed with the Medical Outcomes Study Short Form 36-Item Health Survey of patients on renal replacement therapy: a systematic review and meta-analysis. Value Health. 2007;10(5):390-7.
78. Amro A, Waldum-Grevbo B, von der Lippe N, Brekke FB, Miaskowski C, Os I. Symptom Clusters From Dialysis to Renal Transplantation: A Five-Year Longitudinal Study. J Pain Symptom Manage. 2016;51(3):512-9.
79. The Norwegian Renal Registery. Annual Report 2019. Oslo: Oslo University Hospital; 2019.
80. Avramovic M, Stefanovic V. Health-related quality of life in different stages of renal failure. Artificial organs. 2012;36(7):581-9.
81. von der Lippe N, Waldum B, Brekke FB, Amro AA, Reisaeter AV, Os I. From dialysis to transplantation: a 5-year longitudinal study on self-reported quality of life. BMC nephrology. 2014;15:191.

82. Hessel F. Burden of Disease(s). In: Kirch W, editor. Encyclopedia of Public Health. Dordrecht: Springer Netherlands; 2008. p. 94-6.
83. McPhail SM. Multimorbidity in chronic disease: impact on health care resources and costs. Risk Manag Healthc Policy. 2016;9:143-56.
84. Zulman DM, Haverfield MC, Shaw JG, Brown-Johnson CG, Schwartz R, Tierney AA, et al. Practices to Foster Physician Presence and Connection With Patients in the Clinical Encounter. JAMA. 2020;323(1):70-81.
85. World Health Organization. Multimorbidity: World Health Organization. Geneva; 2016. Avaliable from: https://apps.who.int/iris/handle/10665/252275.
86. Barry MJ, Edgman-Levitan S. Shared Decision Making - The Pinnacle of Patient-Centered Care. NEJMe. 2012;366(9):780-1.
87. Christensen VL, Rustøen T, Thoresen M, Holm AM, Bentsen SB. Stability of distinct symptom experiences in patients with chronic obstructive pulmonary disease (COPD). Respir Med. 2022;201:106944.
88. Elwyn G, Frosch D, Volandes AE, Edwards A, Montori VM. Investing in deliberation: a definition and classification of decision support interventions for people facing difficult health decisions. Med Decis Making. 2010;30(6):701-11.
89. Stiggelbout AM, Weijden TVd, Wit MPTD, Frosch D, Légaré F, Montori VM, et al. Shared decision making: really putting patients at the centre of healthcare. BMJ. 2012;344:e256.
90. Maskrey N. Shared decision making: why the slow progress? BMJ. 2019;367:l6762.
91. Joseph-Williams N, Lloyd A, Edwards A, Stobbart L, Tomson D, Macphail S, et al. Implementing shared decision making in the NHS: lessons from the MAGIC programme. BMJ. 2017;357:j1744.
92. Waddell A, Lennox A, Spassova G, Bragge P. Barriers and facilitators to shared decision-making in hospitals from policy to practice: a systematic review. Implement Sci. 2021;16(1):74.
93. *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient–Practitioner Relationship.* Washington, DC, USA: US Government Printing Office; v. 1; 1982. President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research.
94. Szasz TS, Hollender MH. A Contribution to the Philosophy of medicine: The Basic Models of the Doctor-Patient Relationship. AMA Archives of Internal Medicine. 1956;97(5):585-92.
95. Gionfriddo MR, Leppin AL, Brito JP, Leblanc A, Shah ND, Montori VM. Shared decision-making and comparative effectiveness research for patients with chronic conditions: an urgent synergy for better health. J Comp Eff Res. 2013;2(6):595-603.
96. Gafni A, Charles C. Shared decision-making, decision aids, and the role of values in treatment decision-making. In: Kissane DW, Bultz BD, Butow PN, Bylund CL, Noble S, Wilkinson S, editors. Oxford Textbook of Communication in Oncology and Palliative Care: Oxford University Press; 2017. p.23-27.
97. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med. 1997;44(5):681-92.
98. Salzburg Statement on Shared Decision Making. BMJ. 2011;342:d1745.
99. Montori VM, Ruissen MM, Hargraves IG, Brito JP, Kunneman M. Shared decision-making as a method of care. BMJ Evidence-Based Medicine. 2022; bmjebm-2022-112068.
100. Fønhus MS, Dalsbø TK, Johansen M, Fretheim A, Skirbekk H, Flottorp SA. Patient-mediated interventions to improve professional practice. Cochrane Database Syst Rev. 2018; 11;9(9).
101. Lov om pasient- og brukerrettigheter. (Pasient og brukerrettighetsloven). LOV-1999-07-02-63. Accessed: May 10. 2022. Avaliable from: Lov om pasient- og brukerrettigheter (pasient- og brukerrettighetsloven) - Lovdata
102. Nylenna M. [About shared decision making and other related words]. Tidsskr Nor Laegeforen. 2015;135(2):149.
103. Meld. St. 11 (2015-2016). Nasjonal helse- og sykehusplan (2016–2019). Helse og omsorgsdepartementet; 2016.
104. Kasper J, Hoffmann F, Heesen C, Köpke S, Geiger F. MAPPIN'SDM – The Multifocal Approach to Sharing in Shared Decision Making. PloS One. 2012;7(4):e34849.

105. Kienlin S, Stacey D, Nytrøen K, Grafe A, Kasper J. Ready for SDM- evaluation of an interprofessional training module in shared decision making – A cluster randomized trial. Patient Educ Couns. 2022;105(7):2307-14.
106. Brennan PF, Strombom I. Improving health care by understanding patient preferences: the role of computer technology. J Am Med Inform Assoc. 1998;5(3):257-62.
107. Losi S, Berra CCF, Fornengo R, Pitocco D, Biricolti G, Federici MO. Drug Target Insights. 2021;15:13-20.
108. Zimmermann C, Del Piccolo L, Bensing J, Bergvik S, De Haes H, Eide H, et al. Coding patient emotional cues and concerns in medical consultations: the Verona coding definitions of emotional sequences (VR-CoDES). Patient education and counseling. 2011;82(2):141-8.
109. Epstein RM, Peters E. Beyond Information: Exploring Patients' Preferences. JAMA. 2009;302(2):195-7.
110. Kelly MP, Heath I, Howick J, Greenhalgh T. The importance of values in evidence-based medicine. BMC Medical Ethics. 2015;16(1):69.
111. Kunneman M, Gionfriddo MR, Toloza FJK, Gärtner FR, Spencer-Bonilla G, Hargraves IG, et al. Humanistic communication in the evaluation of shared decision making: A systematic review. Patient Educ Couns. 2019;102(3):452-66.
112. Kennedy BM, Rehman M, Johnson WD, Magee MB, Leonard R, Katzmarzyk PT. Healthcare Providers versus Patients' Understanding of Health Beliefs and Values. Patient Exp J. 2017;4(3):29-37.
113. Maguire R, McCann L, Kotronoulas G, Kearney N, Ream E, Armes J, et al. Real time remote symptom monitoring during chemotherapy for cancer: European multicentre randomised controlled trial (eSMART). BMJ. 2021;374:n1647.
114. Mooney KH, Beck SL, Wong B, Dunson W, Wujcik D, Whisenant M, et al. Automated home monitoring and management of patient-reported symptoms during chemotherapy: results of the symptom care at home RCT. Cancer Med. 2017;6(3):537-46.
115. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2016;34(6):557-65.
116. Graupner C, Kimman ML, Mul S, Slok AHM, Claessens D, Kleijnen J, et al. Patient outcomes, patient experiences and process indicators associated with the routine use of patient-reported outcome measures (PROMs) in cancer care: a systematic review. Support Care Cancer. 2021;29(2):573-93.
117. Ruland CM, Andersen T, Jeneson A, Moore S, Grimsbo GH, Børøsund E, et al. Effects of an internet support system to assist cancer patients in reducing symptom distress: a randomized controlled trial. Cancer Nurs. 2013;36(1):6-17.
118. Gandrup J, Yazdany J. Using Health Information Technology to Support Use of Patient-Reported Outcomes in Rheumatology. Rheum Dis Clin North Am. 2019;45(2):257-73.
119. Van den Bulck SA, Hermens R, Slegers K, Vandenberghe B, Goderis G, Vankrunkelsven P. Designing a Patient Portal for Patient-Centered Care: Cross-Sectional Survey. J Med Internet Res. 2018;20(10):e269.
120. Wannheden C, Åberg-Wennerholm M, Dahlberg M, Revenäs Å, Tolf S, Eftimovska E, et al. Digital Health Technologies Enabling Partnerships in Chronic Care Management: Scoping Review. J Med Internet Res. 2022;24(8):e38980.
121. Gandrup J, Ali SM, McBeth J, van der Veer SN, Dixon WG. Remote symptom monitoring integrated into electronic health records: A systematic review. J Am Med Inform Assoc. 2020;27(11):1752-63.
122. Haleem A, Javaid M, Singh RP, Suman R. Telemedicine for healthcare: Capabilities, features, barriers, and applications. Sens Int. 2021;2:100117.
123. Goldzweig CL, Towfigh AA, Paige NM, Orshansky G, Haggstrom DA, Beroes JM, et al. Systematic review. Secure messaging between providers and patients, and patients' access for their own medical record: Evidence on health outcomes, satisfaction, efficiency and attitudes. Whashingthon (DC); 2012; 7. Report No.: VA-ESP Project #05-226.

124. de Jong CC, Ros WJ, Schrijvers G. The Effects on Health Behavior and Health Outcomes of Internet-Based Asynchronous Communication Between Health Providers and Patients With a Chronic Condition: A Systematic Review. J Med Internet Res. 2014;16(1):e19.
125. Nguyen OT, Alishahi Tabriz A, Huo J, Hanna K, Shea CM, Turner K. Impact of Asynchronous Electronic Communication-Based Visits on Clinical Outcomes and Health Care Delivery: Systematic Review. J Med Internet Res. 2021;23(5):e27531.
126. Coquet J, Blayney DW, Brooks JD, Hernandez-Boussard T. Association between patient-initiated emails and overall 2-year survival in cancer patients undergoing chemotherapy: Evidence from the real-world setting. Cancer Med. 2020;9(22):8552-61.
127. Hogan TP, Luger TM, Volkman JE, Rocheleau M, Mueller N, Barker AM, et al. Patient Centeredness in Electronic Communication: Evaluation of Patient-to-Health Care Team Secure Messaging. J Med Internet Res. 2018;20(3):e82.
128. Lanham HJ, Leykum LK, Pugh JA. Examining the Complexity of Patient-Outpatient Care Team Secure Message Communication: Qualitative Analysis. J Med Internet Res. 2018;20(7):e218.
129. Marzban S, Najafi M, Agolli A, Ashrafi E. Impact of Patient Engagement on Healthcare Quality: A Scoping Review. J Patient Exp. 2022;9:23743735221125439.
130. Ruland CM, White T, Stevens M, Fanciullo G, Khilani SM. Effects of a computerized system to support shared decision making in symptom management of cancer patients: preliminary results. J Am Med Inform Assoc. 2003;10(6):573-9.
131. Field J, Holmes MM, Newell D. PROMs data: can it be used to make decisions for individual patients? A narrative review. Patient Relat Outcome Meas. 2019;10:233-41.
132. Heyn L, Finset A, Ruland CM. Talking about feelings and worries in cancer consultations: the effects of an interactive tailored symptom assessment on source, explicitness, and timing of emotional cues and concerns. Cancer Nurs. 2013;36(2):E20-30.
133. Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, et al. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. J Clin Oncol. 2014;32(14):1480-501.
134. Cleeland CS, Wang XS, Shi Q, Mendoza TR, Wright SL, Berry MD, et al. Automated symptom alerts reduce postoperative symptom severity after cancer surgery: a randomized controlled clinical trial. J Clinl Oncol. 2011;29(8):994-1000.
135. Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organisations in an oncologic setting. BMC Health Serv Res. 2013;13:211.
136. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. J Health Inform. 2016;22(2):81-98.
137. Børøsund E, Cvancarova M, Moore SM, Ekstedt M, Ruland CM. Comparing Effects in Regular Practice of E-Communication and Web-Based Self-Management Support Among Breast Cancer Patients: Preliminary Results From a Randomized Controlled Trial. J Med Internet Res. 2014;16(12):e295.
138. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res. 2016;18(5):e97.
139. Varsi C, Ekstedt M, Gammon D, Ruland CM. Using the Consolidated Framework for Implementation Research to Identify Barriers and Facilitators for the Implementation of an Internet-Based Patient-Provider Communication Service in Five Settings: A Qualitative Study. J Med Internet Res. 2015;17(11):e262.
140. Chang F, Paramsothy T, Roche M, Gupta NS. Patient, staff, and clinician perspectives on implementing electronic communications in an interdisciplinary rural family health practice. Prim Health Care Res Dem. 2017;18(2):149-60.
141. Antoun J. Electronic mail communication between physicians and patients: a review of challenges and opportunities. Fam Pract. 2016;33(2):121-6.
142. Jacob C, Sanchez-Vazquez A, Ivory C. Social, Organizational, and Technological Factors Impacting Clinicians' Adoption of Mobile Health Tools: Systematic Literature Review. J Med Internet Res Mhealth Uhealth. 2020;8(2):e15935.

143. Jacob C, Sezgin E, Sanchez-Vazquez A, Ivory C. Sociotechnical Factors Affecting Patients' Adoption of Mobile Health Tools: Systematic Literature Review and Narrative Synthesis. J Med Internet Res Mhealth Uhealth. 2022;10(5):e36284.
144. Elbert NJ, van Os-Medendorp H, van RW, Ekeland AG, Hakkaart-van RL, Raat H, et al. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. J Med Internet Res. 2014;16(4):e110.
145. Corry M, Clarke M, While AE, Lalor J. Developing complex interventions for nursing: a critical review of key guidelines. J Clin Nurs. 2013;22(17-18):2366-86.
147. Laukka E, Huhtakangas M, Heponiemi T, Kujala S, Kaihlanen AM, Gluschkoff K, et al. Health Care Professionals' Experiences of Patient-Professional Communication Over Patient Portals: Systematic Review of Qualitative Studies. J Med Internet Res. 2020;22(12):e21623.
148. Glenwright BG, Simmich J, Cottrell M, O'Leary SP, Sullivan C, Pole JD, et al. Facilitators and barriers to implementing electronic patient-reported outcome and experience measures in a health care setting: a systematic review. J Patient Rep Outcomes. 2023;7(1):13.
149. Bamgboje-Ayodele A, Smith A, Short CE, Fardell JE, Shaw J, Beatty L, et al. Barriers and facilitators to the availability of efficacious self-directed digital health tools for adults living with cancer and their caregivers: A systematic literature review and author survey study. Patient Educ Couns. 2021;104(10):2480-9.
150. Varsi C, Solberg Nes L, Kristjansdottir OB, Kelders SM, Stenberg U, Zangi HA, et al. Implementation Strategies to Enhance the Implementation of eHealth Programs for Patients With Chronic Illnesses: Realist Systematic Review. J Med Internet Res. 2019;21(9):e14255.
151. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci. 2015;10:21.
152. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. Implement Sci. 2015;10:109.
153. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci. 2013;8:139.
154. Robertson T, Simonsen J, editors. Routledge international handbook of participatory design. New York: Routledge; 2013.
155. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ. 2017;358:j3453.
156. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
157. Robertson T, & Wagner, I. Etichs: engagement, representation and politics-in-action. In: Simonsen J, & Robertson, T., editors. Routledge International Handbook of Participartory Design Routledge; 2013. p. 64-85.
158. Keith RE, Crosson JC, O'Malley AS, Cromp D, Taylor EF. Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. Implement Sci. 2017;12(1):15.
159. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implement Sci. 2016;11:72.
160. Polit DF, & Beck, C.T. Nursing Research. Generating and Assessing Evidence for Nursing Practice. 11th ed: Wolters Kluwer Health; 2020.
161. Kvale S, Brinkmann S. Interviews: Learning the craft of qualitative research interviewing: Sage; 2009.
162. Morgan D. Focus group interviewing. In: Gubrium JF HJ, editor. Handbool of interview research: context and method. Thousands Oaks: Sage; 2002. p. 141-59.
163. Bratteig T, Bødker K, Dittrich Y, Mogensen PH, Simonsen J. Methods: Organising principles and general guidelines for Participatory Design projects. In: Jesper Simonsen TR, editor. Routledge International Handbook of Participartory Design. 1 ed. New York. 2013. p. 117-43.

164. Sandvin Olsson AB, Strøm A, Haaland-Øverby M, Fredriksen K, Stenberg U. How can we describe impact of adult patient participation in health-service development? A scoping review. Patient Educ Couns. 2020;103(8):1453-66.
165. Brooke J. SUS - a quick and dirty usability scale. In Jordan P, Thomas B & Weerdmeester B, editors. Usability Evaluation in Industry. p. 189-194. London; Bristol, Pa: Taylor & Francis; 1996 .
166. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983;67(6):361-70.
167. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992;30(6):473-83.
168. Hays RD, Sherbourne CD, Mazel RM. The rand 36-item health survey 1.0. Health Economics. 1993;2(3):217-27.
169. Osborne RH, Batterham RW, Elsworth GR, Hawkins M, Buchbinder R. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). BMC Public Health. 2013;13:658.
170. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101.
171. Kiger ME, Varpio L. Thematic analysis of qualitative data: AMEE Guide No. 131. Med Teach. 2020;42(8):846-54.
172. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA. 2013;310(20):2191-4.
173. Gerwing J, Gulbrandsen P. Contextualizing decisions: Stepping out of the SDM track. Patient Educ Couns. 2019;102(5):815-6.
174. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. Implement Sci. 2022;17(1):75.
175. Timmins F. Exploring the concept of 'information need'. Int J Nurs Pract. 2006;12(6):375-81.
176. Jenkins V, Fallowfield LJ, Saul J. Information needs of patients with cancer: results from a large study in UK cancer centres. Br J Cancer. 2001;84:48 - 51.
177. Lie HC, Juvet LK, Street RL, Jr., Gulbrandsen P, Mellblom AV, Brembo EA, et al. Effects of Physicians' Information Giving on Patient Outcomes: a Systematic Review. JGIM. 2022;37(3):651-63.
178. Wynn R, Gabarron E, Johnsen JK, Traver V. Special Issue on E-Health Services. Int J Environ Res Public Health. 2020;17(8).
179. Wynn R, Traver Salcedo V, Ellingsen G. The Rising Importance of e-Health in Norway. Stud Health Technol Inform. 2022;294:604-8.
180. Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. Int J Med Inform. 2019;124:78-85.
181. Bleijenberg N, de Man-van Ginkel JM, Trappenburg JCA, Ettema RGA, Sino CG, Heim N, et al. Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework. Int J Nurs Stud. 2018;79:86-93.
182. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ open. 2019;9(8):e029954.
183. Schloemer T, Schröder-Bäck P. Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis. Implement Sci. 2018;13(1):88.
184. Schreiweis B, Pobiruchin M, Strotbaum V, Suleder J, Wiesner M, Bergh B. Barriers and Facilitators to the Implementation of eHealth Services: Systematic Literature Analysis. J Med Internet Res. 2019;21(11):e14197.
185. Zhi Q, Carina O, Tim B, Christian K, Harald S. Systematic review on the involvement and engagement of patients as advisers for the organisation of organ transplantation services. BMJ Open. 2023;13(5):e072091.
186. Dineen-Griffin S, Garcia-Cardenas V, Williams K, Benrimoj SI. Helping patients help themselves: A systematic review of self-management support strategies in primary health care practice. PloS One. 2019;14(8):e0220116.

187. Lorig KR, Sobel DS, Stewart AL, Brown BW, Jr., Bandura A, Ritter P, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care. 1999;37(1):5-14.
188. Brady TJ, Murphy L, O'Colmain BJ, Beauchesne D, Daniels B, Greenberg M, et al. A meta-analysis of health status, health behaviors, and health care utilization outcomes of the Chronic Disease Self-Management Program. Prev Chronic Dis. 2013;10:120112.
189. Børøsund E, Cvancarova M, Ekstedt M, Moore SM, Ruland CM. How user characteristics affect use patterns in web-based illness management support for patients with breast and prostate cancer. J Med Internet Res. 2013;15(3):e34.
190. Thurnheer SE, Gravestock I, Pichierri G, Steurer J, Burgstaller JM. Benefits of Mobile Apps in Pain Management: Systematic Review. J Med Internet Res Mhealth Uhealth. 2018;6(10):e11231.
191. Sundararaman LV, Edwards RR, Ross EL, Jamison RN. Integration of Mobile Health Technology in the Treatment of Chronic Pain: A Critical Review. Reg Anesth Pain Med. 2017;42(4):488-98.
192. Madrigal L, Escoffery C. Electronic Health Behaviors Among US Adults With Chronic Disease: Cross-Sectional Survey. J Med Internet Res. 2019;21(3):e11240.
193. Marco-Ruiz L, Wynn R, Oyeyemi SO, Budrionis A, Yigzaw KY, Bellika JG. Impact of Illness on Electronic Health Use (The Seventh Tromsø Study - Part 2): Population-Based Questionnaire Study. J Med Internet Res. 2020;22(3):e13116.
194. Antonio MG, Petrovskaya O, Lau F. Is research on patient portals attuned to health equity? A scoping review. J Am Med Inform Assoc. 2019;26(8-9):871-83.
195. Statistics Norway (SSB- Statistisk sentralbyrå). 2022. Bruk av IKT i husholdningene [Internet]. Available from: https://www.ssb.no/teknologi-og-innovasjon/informasjons-og-kommunikasjonsteknologi-ikt/statistikk/bruk-av-ikt-i-husholdningene
196. Chesser A, Burke A, Reyes J, Rohrberg T. Navigating the digital divide: A systematic review of eHealth literacy in underserved populations in the United States. Inform Health Soc. 2016;41(1):1-19.
197. Wilson J, Heinsch M, Betts D, Booth D, Kay-Lambkin F. Barriers and facilitators to the use of e-health by older adults: a scoping review. BMC Public Health. 2021;21(1):1556.
198. Balki E, Hayes N, Holland C. Effectiveness of Technology Interventions in Addressing Social Isolation, Connectedness, and Loneliness in Older Adults: Systematic Umbrella Review. J Med Internet Res Aging. 2022;5(4):e40125.
199. Ross J, Stevenson F, Dack C, Pal K, May C, Michie S, et al. Developing an implementation strategy for a digital health intervention: an example in routine healthcare. BMC Health Serv Res. 2018;18(1):794.
200. Hallingberg B, Turley R, Segrott J, Wight D, Craig P, Moore L, et al. Exploratory studies to decide whether and how to proceed with full-scale evaluations of public health interventions: a systematic review of guidance. Pilot Feasibility Stud. 2018;4:104.
201. Braun V, Clarke V. Thematic analysis. APA handbook of research methods in psychology. Vol 2: Research designs: Quantitative, qualitative, neuropsychological, and biological. APA handbooks in psychology®. Washington, DC, US: American Psychological Association; 2012. p. 57-71.
202. Helsedirektoratet (2021). Befolkningens helsekompetanse [Internet]. Oslo: Helsedirektoratet [Accessed June 2022]. 2021. Available from: https://www.helsedirektoratet.no/rapporter/befolkningens-helsekompetanseHelsedirektoratet
203. Bruckman A. Analysis of Log File Data to Understand Behavior and Learning in an Online Community. In: Weiss J, Nolan J, Hunsinger J, Trifonas P, editors. The International Handbook of Virtual Learning Environments. Dordrecht: Springer Netherlands; 2006. p. 1449-65.
204. Noble H & Smith J. Issues of validity and reliability in qualitative research. Evid Based Nurs. 2015;18(2):34.
205. Rolfe G. Validity, trustworthiness and rigour: quality and the idea of qualitative research. J Adv Nurs. 2006;53(3):304-10.
206. Porter S. Validity, trustworthiness and rigour: reasserting realism in qualitative research. J Adv Nurs. 2007;60(1):79-86.
207. Lincoln YSG, E. G. . Naturalistic Inquiry Newbury Park, Ca: Sage Publications; 1985.

208. Noble H & Heale R. Triangulation in research, with examples. Evid Based Nurs. 2019;22(3):67.
209. Muscat DM, Shepherd HL, Nutbeam D, Trevena L, McCaffery KJ. Health Literacy and Shared Decision-making: Exploring the Relationship to Enable Meaningful Patient Engagement in Healthcare. J Gen Intern Med. 2021;36(2):521-4.
210. Knapp TR. Why Is the One-Group Pretest–Posttest Design Still Used? Clin Nurs Res. 2016;25(5):467-72.
211. Rangachari P, Mushiana SS, Herbert K. A scoping review of applications of the Consolidated Framework for Implementation Research (CFIR) to telehealth service implementation initiatives. BMC Health Services Research. 2022;22(1):1450.
212. Ardito V, Golubev G, Ciani O, Tarricone R. Evaluating Barriers and Facilitators to the Uptake of mHealth Apps in Cancer Care Using the Consolidated Framework for Implementation Research: Scoping Literature Review. J Med Internet Res Cancer. 2023;9:e42092.
213. Watland S, Solberg Nes L, Hanson E, Ekstedt M, Stenberg U, Børøsund E. The Caregiver Pathway, a Model for the Systematic and Individualized Follow-up of Family Caregivers at Intensive Care Units: Development Study. J Med Internet Res Formative Research. 2023;7:e46299.
214. Qu Z, Oedingen C, Bartling T, Krauth C, Schrem H. Systematic review on the involvement and engagement of patients as advisers for the organisation of organ transplantation services. BMJ Open. 2023 May 10;13(5):e072091.

Paper I

Seljelid et al. BMC Medical Informatics and Decision Making (2020) 20:46
https://doi.org/10.1186/s12911-020-1065-8

BMC Medical Informatics and Decision Making

RESEARCH ARTICLE Open Access

Content and system development of a digital patient-provider communication tool to support shared decision making in chronic health care: InvolveMe

Berit Seljelid[1,2], Cecilie Varsi[1], Lise Solberg Nes[1,2,3], Aud-E Stenehjem[4], Jens Bollerslev[2,5] and Elin Børøsund[1*]

Abstract

Background: Chronic conditions present major health problems, affecting an increasing number of individuals who experience a variety of symptoms that impact their health related quality of life. Digital tools can be of support in chronic conditions, potentially improving patient-provider communication, promoting shared decision making for treatment and care, and possibly even improving patient outcomes. This study aimed to develop a digital tool for patient-provider communication in chronic health care settings and describes the data collection and subsequent content and software development of the *InvolveMe* tool. *InvolveMe* will provide patients with the opportunity to report symptoms and preferences to their health care providers (HCP), and to use secure messaging to interact with the HCPs.

Method: The study employed a combination of interviews with patients with chronic conditions and focus groups with HCPs, examining experiences with chronic conditions and the potential use of a digital tool for support. Participants were recruited from two outpatient clinics at a university hospital. Data collected from interviews and focus groups were analysed using thematic analysis. Content and software development was informed by the data collection and by tool development workshops.

Results: Analyses from interviews with patients ($n = 14$) and focus groups with HCPs ($n = 11$) generated three main themes: 1) *Making symptoms and challenges visible*, 2) *Mastering a new life,* and 3) *Digital opportunities for follow-up*. Each main theme generated separate subthemes. Theme 1 and 2 gave input for content development of the symptom and needs assessment part of the tool, while theme 3 provided ideas for the software development of the *InvolveMe* tool. Tool development workshops with patients ($n = 6$) and HCPs ($n = 6$) supplemented the development.

Conclusions: A digital tool such as *InvolveMe* has the potential to support shared decision making for patients with chronic health conditions. Through integration with an existing patient portal such a tool can provide opportunities for meaningful interactions and communication between patients and HCP's, particularly with regards to symptoms, needs and preferences for care.

Keywords: Shared decision making, eHealth, Digital communication, Patient-provider communication, Digital assessment, Secure messaging, Patient-provider interaction, Patient centered care, Renal transplant recipients, Non-functioning pituitary adenoma

* Correspondence: elin.borosund@rr-research.no
[1]Department of Digital Health Research, Division of Medicine, Oslo University Hospital, Oslo, Norway
Full list of author information is available at the end of the article

Background

A growing number of patients are living with chronic health conditions that affect physical, psychological, social and role functioning, as well as general well-being [1–4]. Patients experience difficulties in recognition of symptoms [5] and that their symptoms often are unknown to health care providers (HCPs) [6, 7]. Comparison between symptoms reported by patients and HCPs has shown that patients detect symptoms sooner [8, 9], and that HCPs often underestimate symptom intensities [8–11]. Experiences of poor communication between patient and HCPs are also common [5, 12]. In addition, patients' comprehension of health information [12], incorrect beliefs and assumptions, are factors that can interfere with symptom management and seeking help [5]. These issues and challenges call for an improvement of chronic health care.

Routine collection of patient reported outcome measures can enhance the quality of visits and has the potential for improved symptom control and patient satisfaction [13]. A better understanding of health related quality of life (HRQoL) aspects could also enable HCPs to deliver more patient-centered care and thereby have a stronger impact on the overall health and symptom burden experienced by patients [14].

The treatment goal for patients in chronic health care settings is related to adequate symptom control and being able to live with the condition in acceptable ways [15]. Patients have an important role in controlling and self-administering treatment, monitoring symptoms and choosing lifestyle [15], which underlines the importance of patients being involved in their own care. Shared Decision Making (SDM) is considered particularly useful in the management of chronic health conditions, as SDM focuses on engaging patients in their own health care, recognizing that behavioral, psychosocial and lifestyle aspects can affect health beyond biomedical interventions [16]. SDM can be explained as a process where patients and HCPs work together to understand and address the patient's situation [17]. In a framework for SDM in chronic health care, there is an emphasis on the patient-provider partnership as well as focus on information exchange, choice deliberation and decision making [15].

Establishing trust and mutual respect is crucial for a patient-provider relationship, and a patient-provider relationship includes emotional as well as cognitive care [18], which again may promote problem-solving, communication and support [15]. Patients sharing personal information about symptoms and needs, including values, preferences and expectations, are essential for the HCP to gain an understanding of the patients' current situation [15].

SDM-tools have been shown to improve patient knowledge, help patients to become more aware of what matters most to them, and help patients to feel more involved in the decision making process [19]. Despite the fact that symptom management is an important and integral part of chronic health care, only few existing SDM-tools include symptom management [19, 20]. Furthermore, a recent systematic review examining SDM tools in chronic health conditions revealed that the included tools were mostly designed to "transfer information" about options and the harms and benefits of these [20]. Suggestions have been made, stating that SDM needs to focus on creating patient-provider interactions promoting communication and care, not just on offering information and choice [17, 21]. This supports the exploration of new ways to promote patient involvement in chronic health care settings, emphasizing patient-provider communication related to symptoms and needs.

Digital systems may carry the potential to aid in SDM in chronic health settings, to address the individuality and variability in symptoms over time among patients, and to improve patient outcomes [14, 22, 23]. Existing research has shown how digital systems can help patients to communicate symptoms [24, 25], to reduce symptom distress and improve overall symptom management [14, 25, 26], as well as to improve HRQoL [14]. Such systems can also help clinicians to provide individually tailored support and increase patient involvement [14, 25–28]. One example of such a digital system is the *Choice*-application, originally developed to support cancer patients with symptom reporting in preparation for consultation [24, 26, 29, 30], subsequently aiding HCPs in individualizing patient care. Other application (app)-based systems designed for self-management in long-term conditions have also been found to improve symptom management, but few existing systems provide features for data sharing ahead of hospital visits [31]. Benefits to patient-provider communication from using secure messaging have also been reported, particularly in terms of assisting patients in self-management of illness and in improving health outcomes [23, 25, 28, 32]. Findings on digital communication systems so far are promising, and such systems can facilitate new ways to promote patient involvement in symptom management of chronic health conditions.

The current study aimed to map patients' (renal transplant recipients (RTX) or patients with a non-functioning pituitary adenoma (NFPA)) symptoms and needs in preparation for the development of a new digital patient-provider communication tool called *InvolveMe,* and then to design and develop the new tool, tailored to suit each patient's situation and preferences with regards to symptom management in out-patient chronic health care settings. The goal was to develop and design the *InvolveMe* tool to provide patients with

the opportunity to: a) self-report symptoms and preferences for care prior to visits, and b) use secure messaging for patient-provider communication between visits.

Methods

Design

The current study is a qualitative study with a participatory design approach, where patients with chronic health conditions, HCPs, researchers and system developers collaborated closely [33]. Participatory design acknowledges the importance of including all stakeholders in the design process and promoting a common understanding of all perspectives during the process [34]. The data collection to map patients' symptoms and needs was guided by existing reseach on symptom management in chronic conditions and advanced through patient interviews, focus groups with HCPs, and finally tool development workshops with patients and HCPs. The development process was informed by the data collection and guided by existing research on digital patient-provider communication and SDM. The final *InvolveMe* tool development was based on the *Choice*-application [24, 26, 29, 30] and integration with an existing patient portal, *MyRec* [35]. See Fig. 1 for an overview of the development process.

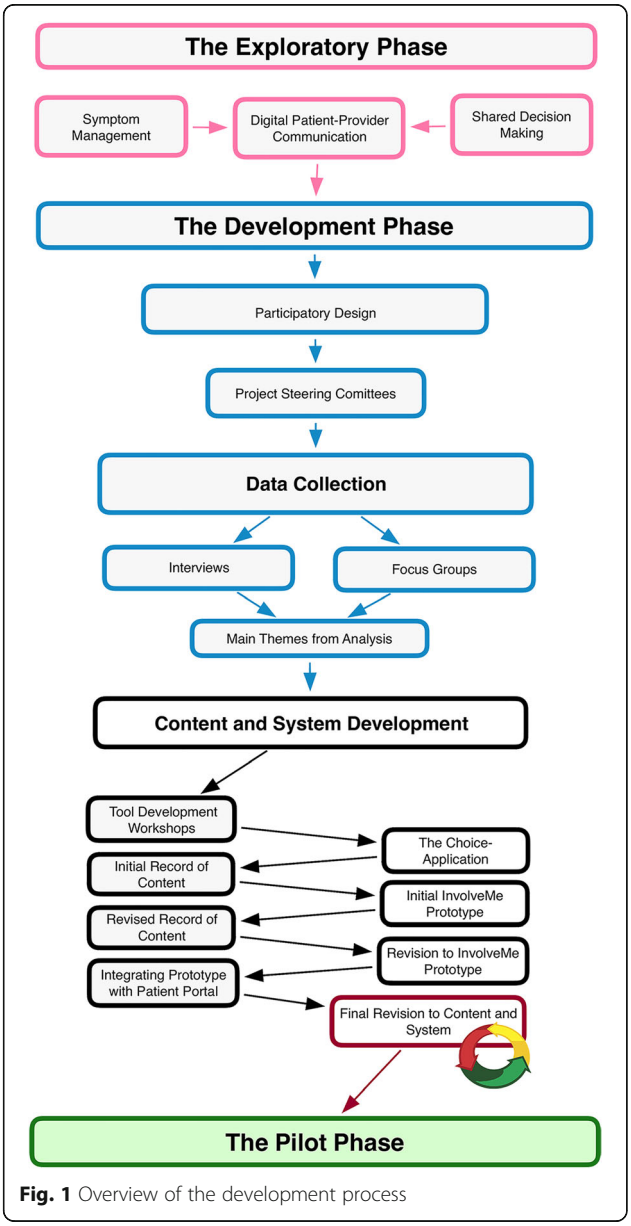


Fig. 1 Overview of the development process

Settings and participants

The participants in the current study were RTX or patients with NFPA, and the HCPs were recruited from either a nephrology- or an endocrine outpatient clinic at a large Tertiary Referral Center at a university hospital in Norway. Patients receiving follow-up at the clinics were invited to participate in the study. They had to be ≥18 years old and able to read and speak Norwegian. Both patient groups frequently experience a long period of slow deterioration of their health status before undergoing surgery, and both groups do experience a variety of symptoms in the aftermath [36–40], which negatively impact HRQoL [41, 42]. Renal replacement therapy through RTX is generally accepted as the preferred treatment for end-stage renal disease [36]. RTX symptoms include, but is not limited to, swelling, itching, thirst and changes in bowel and urinary habits [36]. Patients may also experience symptoms' from medication side-effects and other co-morbid conditions [40]. NFPAs are benign pituitary tumors, and treatment is primarily surgery [37]. Patients face many challenges, included visual limitations, fear of recurrence, persisting distressing thoughts, loneliness and frustration [38, 39]. Both patient groups experience individuality and variability in symptoms, including pain, fatigue, sleeping problems, anxiety and depression [36, 38, 39]. Patients in both groups need and receive long-term follow up in outpatient care after surgery. HCPs in the current study were registered nurses, health support personnel, and physicians responsible for treatment and care for the respective patient groups.

Stakeholder involvement

To strengthen the patient's voice in the research process, the current study used the Guidance for Reporting of Patient and Public Involvement in Research (GRIPP2) prospectively to plan patient involvement [43]. Two patient representatives acted as advisors in the design and development process and contributed with refinement of written research material, interview guides and input for tool content development. The patient representatives were also members of the two Project Steering

Committees established to promote involvement of all stakeholders. In addition, the head (physician) of each participating clinic, a registered nurse, a health support person and the first (BS) and senior (EB) authors participated in the Steering Committees. The Steering Committee's role included decision-making regarding; planning and group facilitation approaches, recruitment and data collection strategies.

Recruitment

Eligible patients were identified and informed about the study by registered nurses at the clinics. After consenting to be informed about the study, the potential participants were contacted by phone by a member of the research team who described the study and study participation in detail. Potential participants received oral as well as written information. HCPs at the participating clinics were also provided with information about the study. Those willing to participate were included in the study and informed consent was obtained from all participants.

Data collection

Interviews with patients and focus groups with HCPs were conducted in order to map important symptoms and needs experienced by the patients groups. This informed the development of a digital patient-provider communication tool with opportunities for patients to self-report symptoms, needs and preferences for care prior to hospital visits, and secure messaging between hospital visits to support patients in the two separate patient groups (RTX and NFPA).

Interviews with patients (n = 14)

Participants completed a baseline demographic questionnaire related to age, sex, diagnosis, time since diagnosis and education. The goal was to collect information about the patients' experience, understanding and perceptions of living with a chronic condition in order to map important symptoms and needs, as well as to gather information about patients' expectations regarding digital communication. Interviews were directed by an interview guide (see Supplementary Material) focusing on these topics and conducted by the first author (BS), either face-to-face ($n = 8$) or by phone ($n = 6$). The interviews lasted between 20 and 75 min, were recorded with a digital voice recorder and transcribed verbatim. Participants received a gift card equivalent of USD 30 for their participation.

Focus groups with health care providers (n = 11)

Participants completed a baseline demographic questionnaire related to age, sex and years of work experience within the specialist health care setting. HCPs were invited to participate in focus groups to explore attitudes and experiences [44]. Two focus groups were conducted face-to-face by the first (BS) and senior (EB) authors. The HCPs from the nephrology- and the endocrine clinic participated in separate groups in order to develop patient group specific content. The interview guide consisted of open-ended themes in order to encourage discussion (see Supplementary Material). The themes focused on HCPs' experiences with the types of questions patients often ask and appear to seek counseling for, as well as issues related to health technology. The focus group sessions lasted approximately 50 min, were recorded with a digital voice recorder and transcribed verbatim.

Analysis

A thematic analysis as described by Braun and Clarke [45, 46] was conducted in order to identify, analyze and report patterns and themes from interviews (i.e., patients) and focus groups (i.e., HCPs). Themes generated from interviews and focus groups were compared to identify concordant and discordant perspectives. The analysis process was led by the first author (BS) in collaboration with the second and last authors (CV and EB). *The first step* in the analysis entailed becoming familiar with the transcripts. Brief notes were made of early impressions. In *step two*, data were organized into initial coding using the analytic software NVivo 11. All data considered relevant were coded. The codes were developed and modified through the continuous coding process. In *step three and four,* respectively, the main themes were generated and refined, and subthemes were identified for all main themes. *In the fifth step,* the wording of each theme and the overall story of the analysis were refined. Finally, in *the sixth step,* compelling quotes were selected and a final analysis based on the research questions conducted. The actual analysis process was more iterative than described, moving back and forth more than proceeding successively.

Content and software development

The process of development was informed by the preceding data collection. The content and software development processes occurred in parallel, mutually influencing each other.

Content development

Content development for the self-reporting of symptoms, needs and preferences part of the *InvolveMe* tool was informed by input from the data collection process. The self-reporting of symptoms, needs and preferences is collectively referred to as assessments. The data collection informed the development of

separate assessments to suit each patient group (RTX and NFPA). Following data collection and analysis, four separate tool development workshops were conducted with patients and HCPs.

Workshops with patients (n = 6) and health care providers(n = 6)

Preliminary findings from interviews and focus groups were presented by the research team in tool development workshops with patients and HCPs in order to involve stakeholders in data evaluation and guide tool content development. To avoid patient-provider relationships influencing the discussions and to fit the content to each diagnostic group, two workshops with three patients each and two workshops with three HCPs each, were conducted. Workshop participants were invited to share their reflections through a card sorting exercise, a method that provides insight into how participants may expect organization of content to be [47]. Each card provided insight from interviews, focus groups and/or existing literature/guidelines [36, 38–42]. Insights from interviews included for example "fatigue" or feeling "depressed", and insights from existing literature included for example "sleeping disturbances" or "sexual dysfunctions". Participants sorted the insights into different themes and were encouraged to remove and/or add items as the workshop progressed. Input was also solicited regarding language and organization of content.

Software development

The *Choice* application contained a predefined list of symptoms that could be marked and graded for degree of bother and priorities for help [24, 26, 29, 30]. Based on options from *Choice*, the *InvolveMe* tool was developed and built to be integrated into an existing hospital patient portal, *MyRec* [35]. *MyRec* already had a secure login and options for secure messaging (email) between patients and HCPs, and the *InvolveMe* tool development therefore evolved around integrating the assessment functionality into *MyRec*.

The *InvolveMe* content and software development underwent several iterations, ensuring easily understandable language, brief and to the point sentences, and options for fitting content to the appropriate devices (e.g., content for small screens). The final selection of tool content was refined to fit a digital format and to facilitate easy and intuitive use. Software iterations were based on feedback (e.g., software features) from stakeholders as well as the constraints of *MyRec*, but were also affected by aspects from the content development (e.g., informational needs).

Results

Participant demographics

In interviews, the participating patients ($n = 14$) were median 54.5 years old (range: 37–67), with six women and eight men. Five patients had NFPA and nine were RTX. See Table 1 for patient demografics and clinical characteristics. In focus groups, six HCPs from a nephrology clinic and five HCPs from an endocrinal clinic participated in diagnostically separate focus groups. The participating HCPs ($n = 11$) were registered nurses ($n = 6$), health support personnel ($n = 1$), and physicians ($n = 4$), median 49 years old (range: 31–61) and had from two to 30 years of clinical experience from specialist health care.

Results from interviews and focus groups

The findings from interviews with patients and focus groups with HCPs generated three main themes: 1) *Making symptoms and challenges visible*, 2) *Mastering a new life*, and 3) *Digital opportunities in follow-up*. See Table 2 for a thematic overview of content, and Table 3 for an overview of software functionalities.

Making symptoms and challenges visible

The participating patients expressed a need for a variety of symptoms to be addressed in the digital tool. Two subthemes were identified under this main theme; *Bodily Symptoms* and *Psychosocial Challenges*.

Bodily symptoms

Patients in both diagnostic groups described their experience with the physical aspects of their conditions, and that the symptoms and their impact

Table 1 Patient demographics and clinical characteristics ($n = 14$)

Characteristics	median	(range)	*n*	%
Age (years)	54.5	(37–67)		
Sex				
Female			6	(43)
Male			8	(57)
Diagnosis				
Non-functioning pituitary adenoma[a]			5	(36)
End stage renal failure (Renal transplant recipient)			9	(64)
Years with diagnosis	8	(0.5–40)		
Years since last surgery	2	(0.5–17)		
Education				
Elementary/high school			2	(14)
University/college ≤4 years			7	(50)
University/college > 4 years			5	(36)

[a]One participant had not received surgery

Table 2 Thematic overview of content; Symptom and needs assessment in the *InvolveMe* tool

Bodily symptoms		
Common for both patient groups	***NFPA***[a]	***RTX***[b]
Pain	Menstruation	Breathlessness
Less interested in sex	irregularities	Swelling
Weakness	Hot flushes/night sweats	Itching
Dizziness	Erection changes	Bowel habit changes
Weight changes	Visual changes	Urinary habit changes
Fatigue	Coordination changes	Thirst
Sleeping problems	Balance changes	Nausea
Psychosocial challenges		
Common for both patient groups	***NFPA***	***RTX***
Anxiety	Stress sensitivity increased	N/A[c]
Depression		
Mood disturbances/fluctuations	Irritability increased	
Memory problems		
Concentration problems Lack of understanding (from family/friends)		
Lack of support (from family/friends)		
Guilt towards children		
Uncomfortable in social situations		
Loneliness		
The need for work related support		
Common for both patient groups	***NFPA***	***RTX***
Work-related understanding	N/A	N/A
Work disability		
The job exacerbates health		
The need for information		
Common for both patient groups	***NFPA***	***RTX***
Healthy diet	N/A	Infection prevention
Physical shape improvement		Skin/mole changes
Alcohol		
Smoking cessation		
Medications side effects		
Treatment options		
Disease progression		
Economic and social rights		
Medication prescriptions and certificates		

[a]*NFPA* Non-functioning pituitary adenomas
[b]*RTX* Renal transplant recipients
[c]*N/A* Not Applicable

often were or felt invisible to their HCPs. One patient stated:

> ***... you have to help patients on their way, particularly related to symptoms ... if you become accustomed to something, you might think it is normal...***

Some symptoms were diagnostic specific, and some were generic. One patient stated:

...I often feel tired. I also have trouble sleeping. I sleep well when I finally fall asleep, but I do not fall asleep when I go to bed. So some days, I sort of- opt out. Simply because I feel so exhausted and tired.

In the focus groups, HCPs described a number of symptoms often raised by the patients. For example, HCPs described weight and sexual changes as issues that were often raised by NFPA patients (these issues were barely mentioned in the interviews with patients). Similarly, HCPs for RTX patients explained that in addition to symptoms from the kidney disease, patients also experienced symptoms from co-morbidities.

Psychosocial challenges

Patients from both patient groups described similar experiences related to change of roles and negative impact on quality of life. One patient stated:

Very often I say no to social activities

Some of the patients described struggling with emotions related to a changed life, while others described emotional concerns related to a failing health status or illness recurrence. One patient said:

...if the blood samples are non-significant, it's easy to forget how the patient actually feels...

A few patients described experiencing difficulties accepting the physical changes caused by their illness, and described feeling alone and unsupported by their surroundings. Some patients described living alone as a source of vulnerability and anxiousness. NFPA patients also expressed vulnerability to stress and irritability. Those with responsibility for young children described worrying about how their illness was affecting their parenting. One patient said:

... and then I'm a little scared for myself as I get really annoyed and angry, even with my own children, so I just have to leave the room, you just can't really handle it there and then.

In focus groups, HCPs for both patient groups described anxiety to be a common symptom for patients early in the disease trajectory, but that the degree of anxiety often decreased after surgery.

Mastering a new life

This theme illustrates challenges that might occur after being diagnosed with a chronic condition. Because of changes along the disease trajectory, patients described constantly having to learn to manage new aspects of their condition. Two subthemes were identified: *The Need for Work Related Support* and *The Need for Information.*

The need for work related support

The participating patients described wanting to live a "normal" life. Those who were able to work wanted to work, even though they described experiencing limitations due to their illness and life situation. One patient stated:

...I only work 50% and that's all I can do.

Several patients described being unable to remain in a physically demanding job. Others described being able to go to work because they had an office job that did not require "too much". Not being able to work full time, or not at all, was described as difficult. The patients also described at times needing practical support from their HCPs, their manager or from colleagues. As one patient stated:

...it is a bit exhausting not to meet any understanding anywhere... I didn't receive any follow-up as a consequence …

The need for work-related support was briefly brought up in the focus groups with HCPs.

The need for information

Many patients mentioned wanting to make lifestyle changes and described needing information about how to do so. Several gave examples about how they had experimented with diet, physical activity and alternative lifestyles. One patient stated:

I have tried everything possible, I'm not on any medication you know...

Patients with RTX described experiencing a new life with many medications which sometimes caused troublesome side-effects. Some stated that information from HCPs was not always useful because of "poor timing" or information not being tailored to their personal needs. Some patients described having experienced that HCPs sometimes hesitated to give them prognostic information. One patient said:

I don't think one should always avoid things that are difficult to bring up or address.

In the focus groups, HCPs stated that most NFPA patients were told by someone, prior to their hospital visits, that they had a tumor in their brain, which increased the patients' level of anxiety. The HCPs described they were

Table 3 Overview of software functionalities in *MyRec* and the *InvolveMe* tool

MyRec's existing functionalities	The integrated InvolveMe functionalities
Secure login and transfer of information	Digital invitation by HCPs to complete assessment prior to consultation
Secure message functionality	A predefined symptom and needs assessment
Available for HCPs on hospital computer	Grading of symptom severity
Patients as well as HCPs can initiate contact	Prioritizing symptoms and needs
Mail and text message notifications (patients/HCPs)	A generated summary based on patient priorities
	Previous assessments available
	Available for patient on smartphone/ tablet/computer
	Designed for patient use in home settings

uncertain as to whether patients could find information on their own.

Digital opportunities in follow-up

This theme illustrates challenges experienced by the patients when navigating the health care system, as well as potential opportunities for digital support and interaction. The main theme contained two subthemes; *Navigating the Health Care System* and *Digital Possibilities for Interaction.*

Navigating the health care system

Some of the patients had broad experience with the health care system through years of managing various condition related challenges, and expressed not always receiving adequate support. One patient stated:

> ***Because I contacted her [HCP], and she promised me that they would call me back, that she would discuss it with a physician, but then I never heard from her again.***

Patients described HCPs to be busy and difficult to contact by phone. A few patients said that if they could not reach their specialist by phone they would go to the hospital and wait until they could have an emergency consultation with their specialist HCP. One patient said:

> ***If I cannot reach them, after all I live less than two miles from the hospital … when I need to, I just go there.***

Patients were uncertain about where to find relevant health information from existing health portals. They described that it was common to forget questions, but said that it was also challenging to know who to ask, or what questions to ask. One patient said:

> ***I think you [HCPs] have to help people to know, that is, it's not always that you know what you are wondering about... and then you don't know what it's okay to ask, or is it appropriate, you know, there's a lot of self-censorship.***

In focus groups, HCPs described their daily work at the clinics as very hectic and that they sometimes forgot to document phone calls because of this. One HCP stated:

> ***Well, there are quite a few phone calls where you think you should have written things down, and then you have like ten calls in a row, so there's information that simply gets lost in a way, cause you somehow just can't catch up.***

A few HCPs described sometimes sharing their private phone number with patients.

Digital possibilities for interaction

Most patients stated that it would be reassuring to use digital communication to contact their HCP. As one patient stated:

> ***Just to have a little more dialogue between all these treatments and visits … for you [HCPs] this is probably just day-to-day business and very common, but for me, it's been the biggest crisis of my life, right? I have after all thought that I was going to die, or never become myself again, or become a vegetable. I've been through all of those, because yes, I know nothing about this stuff.***

Some patients suggested that an option to ask digital questions could prevent medication errors. As one patient said:

> ***I think that it can prevent mistakes, that maybe, that you receive some medicine you don't tolerate, or that you receive the wrong treatment, or that you don't get the follow-up you should have had.***

Patients also stated that digital contact with their health care provider could allow them to share what was important to them. One patient stated:

> ***This week I have had some serious issues with something or other, and then I write it down, and***

she [HCP] knows it. And then she can sit and think about it in advance, before I come for my appointment, and that's really smart.

Several patients stated that having "a digital list with symptoms" would be helpful, including using secure messaging with their HCPs.

Most of the participating HCPs wanted to communicate digitally with their patients, stating that such communication could potentially reduce the patients' anxiety. HCPs also expressed concern that it might be difficult for patients to recall verbal information."A digital list" would be useful for giving insight into patients' needs and expectations prior to hospital visits, but HCPs stated that such a list should not be too extensive. HCPs also expressed the need to use an existing clinical system for digital patient-provider communication, and not an additional system that they would have to log into. As one HCP stated:

We need to have fewer platforms to deal with, more functionality in the platforms we already use.

Content and software development

In line with the participatory design approach, potential future users (i.e., patients and HCPs) provided input on needs and requirements for the digital communication tool. The content and software development of the *InvolveMe* tool are presented below. The first two main themes from the data collection provided input for the development of the symptom assessment part of the *InvolveMe* tool. The third main theme gave input for development of software features for the *InvolveMe* tool, and supported the use of secure messaging between hospital visits to support patients.

The InvolveMe tool content development

The data collection identified patient symptoms, needs and challenges, which were used to make a preliminary content record that was presented in the tool development workshops. Given that living with a chronic condition for many implies challenges related to concentration and fatigue, the research team made a decision that the content language should be brief and easy to read. See Table 2 for a thematic overview of tool content.

Workshops with participants

All patients participating in the tool development workshops were previously interviewed as a part of the initial data collection process. Four of the HCPs participating in the workshops had also participated in the focus groups, while two of the HCPs were "naïve" participants in order to elicit additional input. The workshops provided insight into how participants expected the organization of tool content to be, which provided input into the preliminary content record. At the same time, the workshops ensured that important topics only briefly mentioned in interviews with patients, potentially not yet addressed, were not left out. For example, the workshops with patients verified and elaborated on how psychological challenges and mental health were important factors to address for both patient groups. Similarly, workshops with both patients groups verified sexual dysfunctions as common. In addition, workshops with NFPA patients verified sleeping disturbances as essential to address.

Software development

Based on stakeholder input, the research team (i.e., researchers and system developers) decided that the patient interface should be developed for smartphones or tablets, while the HCPs interface should be developed to fit hospital computers due to data protection legislation. The software development was also influenced by the content development process as the included content affected which features should be built. The assessment part of *InvolveMe* was built to be used by patients in their home settings, and for messages to be sent via the existing secure message functionality in *MyRec*. This would allow HCPs to invite patients to complete assessments prior to hospital visits, using system generated notifications by email or text message. The patients would then log into *MyRec* and open the email invitation to complete the assessment (i.e., a predefined list of symptoms and needs based on the thematic overview of content, see Table 2). The assessment included a functionality for rating how bothersome patients found current symptoms, and a function for prioritizing themes for discussion with their HCPs at the upcoming visit. By completing the assessment, the *InvolveMe* tool generates a summary. When completed and sent, the HCPs would receive a notification, the same notification would also apply for the use of secure messages between hospital visits. An overview of software functionalities is shown in Table 3. Screenshots from the patient interface of the *InvolveMe* tool are presented in Fig. 2.

Discussion

Principal findings

The current study describes the process involved in the exploration, data collection, content and software development of the *InvolveMe* tool; a patient-provider communication tool with two tailored symptoms and needs assessment versions suited to the symptoms and needs

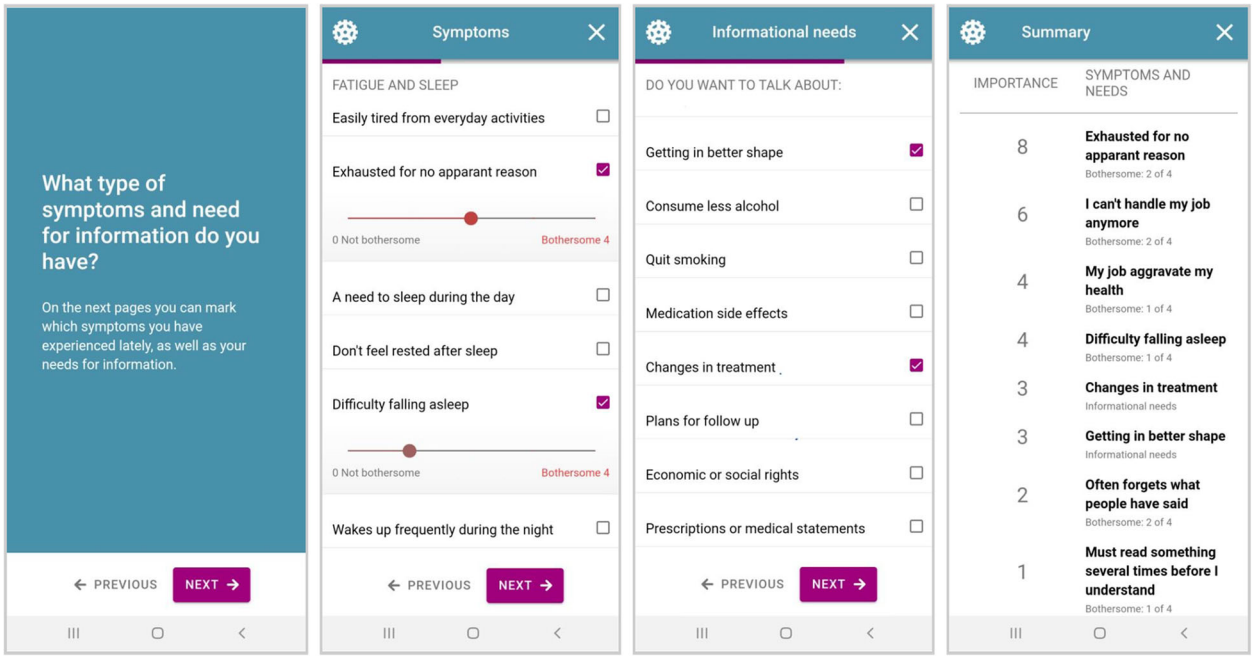


Fig. 2 Screenshots from the patient interface of the *InvolveMe* tool

of patients with NFPA and RTX. Through the use of *InvolveMe*, patients will have the option to report their symptoms and needs, and rate how bothersome their symptoms are. *InvolveMe* will also provide patients with an opportunity to register their priority of themes to address in upcoming visit(s), and generate a summary intended for use in face-to face patient-provider communication during hospital visits. The integration of *InvolveMe* with *MyRec* provides options to complete the assessment at home prior to hospital visits on a variety of portable devices, as well as options to send secure messages between patient and HCPs.

Describing patients' current situation

Data collection from patients and HCPs revealed a wide range of symptoms and needs experienced by the participating patient groups. This is in line with previous research addressing the impact of living with chronic health conditions [1–4, 37–42]. Patients with chronic health conditions are characterized by large individual variations in symptoms, symptom frequency, symptom severity and the degree to which the patients are bothered by the symptoms, which makes it difficult to anticipate the type of care that may be in the patients' best interest. Being able to communicate each patient's current situation to HCPs can provide insight into patients' clinical status and help identify important themes for patient-provider discussions [48], which is of essence for SDM [15]. Digitally reported measures can help patients describe the difficulties they experience [48], an issue described as challenging to convey by patients in the current study. The patients' situation could also change from one hospital visit to another, making repeated assessments prior to each visit crucial for facilitating individually tailored care [13].

Providing emotional support

The interviewed patients described facing many psychological challenges, a topic that was barely raised by the HCPs. Research has shown that if patients express emotional cues at all, these are often missed by the HCPs [49, 50]. Providing emotional support to patients when expressing negative emotions has been found to elicit clinically important information and foster patient-provider relationship [51]. Emotional support can also promote patient involvement, patient adherence to treatment plans, and other actions or behaviors that may lead to better patient outcomes [52]. The psychological symptoms described in the current study were included in the assessment part of the *InvolveMe* tool. Conducting an assessment prior to consultations has been seen to be an effective intervention in which patients can express cues and concerns, and also express such issues at an earlier point in consultations with their HCPs [53]. Facilitating a way for patients to communicate their symptoms to their HCPs has also been linked to reduced symptom distress [25, 26]. The fact that the *InvolveMe* tool includes assessment of psychological symptoms could therefore have the potential to facilitate patient-

provider conversations where emotional symptoms and symptom distress are also included.

Patient preference in symptom management

Including patient preferences can help set priorities for the hospital visit, and may facilitate patient-provider deliberation about symptom management, an essential part of chronic health care. Use of the original *Choice* application, compared with controls not using *Choice*, has been associated with significantly more symptoms being addressed in consultations [30]. Also, HCPs using *Choice* have reported that the tool served as a facilitator for mutual communication engagement between patients and HCPs, and also strengthened the patient voice and promoted shared care planning [27]. This is an important part of addressing the patient situation [17] and in line with SDM [15].

Requesting information based on informational needs

Patients with chronic health conditions have been described as having difficulties interacting with their HCPs and understanding health information [5, 12]. Negative experiences may prevent necessary lifestyle adjustment or change, and may prevent patients from living well. The patient-provider relationship does in fact have a significant effect on healthcare outcomes [54], including influencing patients' subjective symptom burden and HRQoL [55]. Assessing patients' informational preferences can reduce patients' informational needs and improve provision of information [55], which again indicates that information should be provided to patients at a point when they request such information. This mindset was incorporated into the *InvolveMe* tool by providing an opportunity for patients to request information based on present needs. Such features can potentially support patients in making choices about their lifestyle, on their own terms, when they are ready to do so. For example, patients using the *Choice* application reported feeling encouraged to ask more questions, and HCPs provided more information to their patients [30].

Providing digital opportunities for patient-provider interaction

Patients' and HCPs' input on digital opportunities is in line with previous research showing that recall bias and inaccurate information can be reduced by using digital communication [48]. In the chronic health care setting, patient-provider communication through secure messaging can act as a valuable supplement to standard care [23, 28, 32], supporting patient-provider relationships through enabling reassurance and commitment for the patient as well as the HCP. Research also suggests that patient access to use secure messaging with HCP may be linked to reduced depression among patients with serious illness [27]. Access to digital patient-provider communication have been seen to provide patients with a sense that the HCPs are interested in them and more present, an increased sense of connection between patients and HCPs, and also a reduced sense of being alone in dealing with their condition for the patients [48]. Through increasing two-way communication and thereby strengthening the patient-provider relationships, an essential part of SDM [15], secure messaging clearly has the potential to be a powerful tool in the management of chronic health conditions.

Study limitations, strengths and future directions

This study has several limitations. First, two separate patient groups were included in the development process of the *InvolveMe* tool. Differences between the two groups could potentially complicate the development process. However, as shown in Table 2, the two patient groups shared most symptoms and expressed needs. Second, the use of an existing application (i.e., *Choice*) and integration with an existing patient portal (i.e., *MyRec*) may have limited the design and development process, including potentially reducing creativity. However, the development process of *InvolveMe* was based on a digital intervention already proven to have effect [24, 26, 29, 30, 53, 56], and integrated with an existing patient portal already used by HCPs, a combination that likely will support implementation. Finally, the *InvolveMe* tool does not use validated outcome measures to obtain symptoms and needs data, which may raise questions as to whether *InvolveMe* measures as intended. However, the *InvolveMe* tool was not designed to be a validated measure of symptoms, but rather to provide options for patient-provider interaction, and to improve and individualize patient-provider communication in long term follow up of patients with chronic health conditions.

This study also has several strengths. The development process took place in close collaboration with stakeholders, including patients, HCPs, researchers, system developers and patient representatives. Through stakeholder involvement of potential future users, from study initiation through exploration, design and development processes, the study ensured inclusion of content and software functionalities relevant and meaningful for patients as well as HCPs. Such a process has the potential to contribute to increasing the potential effectiveness of the developed intervention. Another strength of the current study is that multiple data collection methods with stakeholders directly informed the selection and refinement of the symptom and needs assessment part of the *InvolveMe* tool.

Future studies should investigate the perspectives of patients as well as HCPs regarding the usefulness and

feasibility of the *InvolveMe* tool in clinical practice. To explore usability and potential effects of the *InvolveMe* tool, a feasibility pilot study is in progress where patients as well as HCPs will test content and software functionalities in a clinical context. In the upcoming pilot study, exploring how use of the *InvolveMe* tool affects the patient-provider interaction and communication will be of essence.

Conclusion

The current study described the participatory design approach, incorporating stakeholder input, evidence and theory, when developing the content and software of *InvolveMe*, a patient-provider communication tool for chronic health care settings. The *InvolveMe* tool has the potential to strengthen patient-provider partnership and improve communication by drawing out what matters to each individual patient. The use of the tool should be regarded as a supplement to standard care. The described design and development approach, aiming to improve and individualize patient-provider communication in long term follow up may provide input for other researchers aiming to develop digital interventions in chronic health care settings. While the usability, feasibility and hypothetical efficacy remains to be tested, a tool such as *InvolveMe* may have the potential to be useful for a variety of patient groups with chronic health conditions.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12911-020-1065-8.

Additional file 1. InvolveMe Interview guide

Abbreviations

GP: General physician; HCP: Healthcare provider; HRQoL: Health Related Quality of Life; NFPA: Non-functioning pituitary adenoma; RTX: Renal transplant recipient; SDM: Shared decision making

Acknowledgements

The authors would like to thank the patients and health care providers who participated in this study. The authors would also like to thank all collaborating project team partners, including the editorial group and software team at Department of Digital Health Research at Oslo University Hospital, particularly editorial team leader Marianne Westeng, editors Marianne Ollivier, Anne Bergland and Elanor Halvorsen Brendmo, design and development team leader Per Tømmer, system designer Yizhak Itzchaki, technical lead Stein Jakob Nordbø and system developers Per Olav Flaten and Daniel Sollie Hansen for their exceptional work throughout the project process. The authors would also like to thank *MyRec's* system manager Sissel Jor, strategic advisor Kaia Spillhaug Thorkildsen and system developer Håkon Vestli. The authors would also like to thank registered nurses Ida Sofie Grorud, Kari Abelsen, Line Cecilie Krabbe and Pernille Fabricius Dybwad for their ongoing engagement, assistance and input in the project. Finally, the authors want to thank the project patient representatives Heidi Larsen and Marianne Øiahals for their encouragement, support and inspiring input in the project.

Authors' contributions

BS and EB conducted the primary data collection. BS, EB and CV performed the data analysis. BS, EB, CV and LSN drafted the manuscript. BS, EB, CV, LSN, AS and JB provided domain expertise. AS and JB have substantively revised the manuscript. All authors read and approved the final manuscript.

Funding

This study was funded by the Norwegian Nurses Organization (Grant # 847382, Principal Investigator EB). The Norwegian Nurses Organization has not participated in conducting the research.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. Access to the patient portal *MyRec* is available at; *https://L2W.no/ytbe*

Ethics approval and consent to participate

The study was approved by the hospital department for data protection and information security (i.e., Institutional Review Board equivalent) at Oslo University Hospital (20178/9223). Written informed consent was obtained from all participants. To guarantee confidentiality, the transcripts were coded with project ID numbers. Only the first author/project administrator (BS) and the senior author/principal investigator (EB) had access to the code connecting the project ID numbers and the actual participant names. Due to the design and development emphasis of the study, the need for study approval was waived by the Regional Committee for Medical and Health Research Ethics for South East Norway, which is in line with the Norwegian legislation (https://L2W.no/Iney).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Department of Digital Health Research, Division of Medicine, Oslo University Hospital, Oslo, Norway. [2]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway. [3]Department of Psychiatry & Psychology, College of Medicine & Science, Mayo Clinic, Rochester, MN, USA. [4]Department of Nephrology, Division of Medicine, Oslo University Hospital, Oslo, Norway. [5]Section of Specialized Endocrinology, Department of Endocrinology, Morbid Obesity and Preventive Medicine, Division of Medicine, Oslo University Hospital, Oslo, Norway.

Received: 8 November 2019 Accepted: 23 February 2020
Published online: 04 March 2020

References

1. Burstrom K, Johannesson M, Diderichsen F. Health-related quality of life by disease and socio-economic group in the general population in Sweden. Health Policy. 2001;55(1):51–69.
2. Saarni SI, Harkanen T, Sintonen H, Suvisaari J, Koskinen S, Aromaa A, et al. The impact of 29 chronic conditions on health-related quality of life: a general population survey in Finland using 15D and EQ-5D. Qual Life Res. 2006;15(8):1403–14.
3. Heyworth IT, Hazell ML, Linehan MF, Frank TL. How do common chronic conditions affect health-related quality of life? Br J Gen Pract. 2009;59(568):e353–8.
4. Wu M, Brazier JE, Kearns B, Relton C, Smith C, Cooper CL. Examining the impact of 11 long-standing health conditions on health-related quality of life using the EQ-5D in a general population sample. Eur J Health Econ. 2015;16(2):141–51.
5. May CR, Cummings A, Myall M, Harvey J, Pope C, Griffiths P, et al. Experiences of long-term life-limiting conditions among patients and carers: what can we learn from a meta-review of systematic reviews of qualitative studies of chronic heart failure, chronic obstructive pulmonary disease and chronic kidney disease? BMJ Open. 2016;6(10):e011694.
6. Aiyegbusi OL, Kyte D, Cockwell P, Marshall T, Gheorghe A, Keeley T, et al. Measurement properties of patient-reported outcome measures (PROMs)

used in adult patients with chronic kidney disease: a systematic review. PLoS One. 2017;12(6):e0179733.
7. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Verdonck-de Leeuw IM. Improving access to supportive cancer care through an eHealth application: a qualitative needs assessment among cancer survivors. J Clin Nurs. 2015;24(9–10):1367–79.
8. Basch E, Iasonos A, McDonough T, Barz A, Culkin A, Kris MG, et al. Patient versus clinician symptom reporting using the National Cancer Institute common terminology criteria for adverse events: results of a questionnaire-based study. Lancet Oncol. 2006;7(11):903–9.
9. Basch E, Jia X, Heller G, Barz A, Sit L, Fruscione M, et al. Adverse symptom event reporting by patients vs clinicians: relationships with clinical outcomes. J Natl Cancer Inst. 2009;101(23):1624–32.
10. Laugsand EA, Sprangers MA, Bjordal K, Skorpen F, Kaasa S, Klepstad P. Health care providers underestimate symptom intensities of cancer patients: a multicenter European study. Health Qual Life Outcomes. 2010;8:104.
11. Vistad I, Cvancarova M, Fossa SD, Kristensen GB. Postradiotherapy morbidity in long-term survivors after locally advanced cervical cancer: how well do physicians' assessments agree with those of their patients? Int J Radiat Oncol Biol Phys. 2008;71(5):1335–42.
12. Friis K, Lasgaard M, Osborne RH, Maindal HT. Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29,473 Danish citizens. BMJ Open. 2016;6(1):e009627.
13. Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, et al. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. J Clin Oncol. 2014;32(14):1480–501.
14. Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organisations in an oncologic setting. BMC Health Serv Res. 2013;13:211.
15. Montori VM, Gafni A, Charles C. A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes. Health Expect. 2006;9(1):25–36.
16. Gionfriddo MR, Leppin AL, Brito JP, Leblanc A, Shah ND, Montori VM. Shared decision-making and comparative effectiveness research for patients with chronic conditions: an urgent synergy for better health. J Comp Eff Res. 2013;2(6):595–603.
17. Hargraves I, LeBlanc A, Shah ND, Montori VM. Shared decision making: the need for patient-clinician conversation, not just information. Health Aff (Millwood). 2016;35(4):627–9.
18. Di Blasi Z, Harkness E, Ernst E, Georgiou A, Kleijnen J. Influence of context effects on health outcomes: a systematic review. Lancet. 2001;357(9258):757–62.
19. Stacey D, Legare F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:Cd001431.
20. Wieringa TH, Rodriguez-Gutierrez R, Spencer-Bonilla G, de Wit M, Ponce OJ, Sanchez-Herrera MF, et al. Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. Syst Rev. 2019;8(1):121.
21. Kunneman M, Montori VM, Castaneda-Guarderas A, Hess EP. What is shared decision making? (and what it is not). Acad Emerg Med. 2016;23(12):1320–4.
22. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. Health Informatics J. 2016;22(2):81–98.
23. Goldzweig CL, Towfigh AA, Paige NM, Orshansky G, Haggstrom DA, Beroes JM, et al. Systematic review. Secure messaging between providers and patients, and patients' access for their own medical record: Evidence on health outcomes, satisfaction, efficiency and attitudes. Whashingthon (DC): Department of Veteran Affairs (US); 2012.
24. Heyn L, Ruland CM, Finset A. Effects of an interactive tailored patient assessment tool on eliciting and responding to cancer patients' cues and concerns in clinical consultations with physicians and nurses. Patient Educ Couns. 2012;86(2):158–65.
25. Johansen MA, Berntsen GK, Schuster T, Henriksen E, Horsch A. Electronic symptom reporting between patient and provider for improved health care service quality: a systematic review of randomized controlled trials. part 2: methodological quality and effects. J Med Internet Res. 2012;14(5):e126.
26. Ruland CM, Holte HH, Roislien J, Heaven C, Hamilton GA, Kristiansen J, et al. Effects of a computer-supported interactive tailored patient assessment tool on patient care, symptom distress, and patients' need for symptom management support: a randomized clinical trial. J Am Med Inform Assoc. 2010;17(4):403–10.
27. Borosund E, Cvancarova M, Moore SM, Ekstedt M, Ruland CM. Comparing effects in regular practice of E-communication and web-based self-management support among breast Cancer patients: preliminary results from a randomized controlled trial. J Med Internet Res. 2014;16(12):e295.
28. Kruse CS, Argueta DA, Lopez L, Nair A. Patient and provider attitudes toward the use of patient portals for the management of chronic disease: a systematic review. J Med Internet Res. 2015;17(2):e40.
29. Ruland CM, White T, Stevens M, Fanciullo G, Khilani SM. Effects of a computerized system to support shared decision making in symptom management of cancer patients: preliminary results. J Am Med Inform Assoc. 2003;10(6):573–9.
30. Heyn L, Finset A, Eide H, Ruland CM. Effects of an interactive tailored patient assessment on patient-clinician communication in cancer care. Psychooncology. 2013;22(1):89–96.
31. Whitehead L, Seaton P. The effectiveness of self-management Mobile phone and tablet apps in long-term condition management: a systematic review. J Med Internet Res. 2016;18(5):e97.
32. de Jong CC, Ros WJ, Schrijvers G. The effects on health behavior and health outcomes of internet-based asynchronous communication between health providers and patients with a chronic condition: a systematic review. J Med Internet Res. 2014;16(1):e19.
33. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. Milbank Q. 2012;90(2):311–46.
34. Robertson T, Wagner I. Ethics: engagement, representation and politics-in-action. In: Simonsen J, Robertson T, editors. Routledge international handbook of Participartory design. New York: Routledge; 2013. p. 64–84.
35. Grisot M, Hanseth O, Thorseng A. Innovation Of, In, On Infrastructures: Articulating the Role of Architecture in Information Infrastructure Evolution. J Ass Inf Systems. 2014;15(Special Issue (4)):197–219.
36. National Institute for Health and Care Exellence. Renal replacement therapy and conservative management. NICE clinical guideline 107. NICE 2018.
37. Joustra SD, Thijs RD, van den Berg R, van Dijk M, Pereira AM, Lammers GJ, et al. Alterations in diurnal rhythmicity in patients treated for nonfunctioning pituitary macroadenoma: a controlled study and literature review. Eur J Endocrinol. 2014;171(2):217–28.
38. Andela CD, Niemeijer ND, Scharloo M, Tiemensma J, Kanagasabapathy S, Pereira AM, et al. Towards a better quality of life (QoL) for patients with pituitary diseases: results from a focus group study exploring QoL. Pituitary. 2015;18(1):86–100.
39. Andela CD, Scharloo M, Ramondt S, Tiemensma J, Husson O, Llahana S, et al. The development and validation of the Leiden bother and needs questionnaire for patients with pituitary disease: the LBNQ-pituitary. Pituitary. 2016;19(3):293–302.
40. Amro A, Waldum-Grevbo B, von der Lippe N, Brekke FB, Miaskowski C, Os I. Symptom clusters from Dialysis to renal transplantation: a five-year longitudinal study. J Pain Symptom Manag. 2016;51(3):512–9.
41. von der Lippe N, Waldum B, Brekke FB, Amro AA, Reisaeter AV, Os I. From dialysis to transplantation: a 5-year longitudinal study on self-reported quality of life. BMC Nephrol. 2014;15:191.
42. Andela CD, Scharloo M, Pereira AM, Kaptein AA, Biermasz NR. Quality of life (QoL) impairments in patients with a pituitary adenoma: a systematic review of QoL studies. Pituitary. 2015;18(5):752–76.
43. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. Res Involv Engagem. 2017;3(1):13.
44. Morgan D. Focus group interviewing. In: Gubrium JF, Holstein JA, editors. Handbook of interview research: context and method. Thousands Oaks: Sage; 2002. p. 141–59.
45. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.
46. Clarke V, Braun V. Thematic analysis. J Posit Psychol. 2017;12(3):297–8.
47. Spencer D. Card sorting: Designing Usable Categories. 1st ed. Brooklyn: Rosenfeld Media; 2009.
48. Qudah B, Luetsch K. The influence of mobile health applications on patient - healthcare provider relationships: a systematic, narrative review. Patient Educ Couns. 2019;102(6):1080–9.

49. Zimmermann C, Del Piccolo L, Finset A. Cues and concerns by patients in medical consultations: a literature review. Psychol Bull. 2007;133(3):438–63.
50. Mjaaland TA, Finset A, Jensen BF, Gulbrandsen P. Physicians' responses to patients' expressions of negative emotions in hospital consultations: a video-based observational study. Patient Educ Couns. 2011;84(3):332–7.
51. Adams K, Cimino JE, Arnold RM, Anderson WG. Why should I talk about emotion? Communication patterns associated with physician discussion of patient expressions of negative emotion in hospital admission encounters. Patient Educ Couns. 2012;89(1):44–50.
52. Rathert C, Wyrwich MD, Boren SA. Patient-centered care and outcomes: a systematic review of the literature. Med Care Res Rev. 2013;70(4):351–79.
53. Heyn L, Finset A, Ruland CM. Talking about feelings and worries in cancer consultations: the effects of an interactive tailored symptom assessment on source, explicitness, and timing of emotional cues and concerns. Cancer Nurs. 2013;36(2):E20–30.
54. Kelley JM, Kraft-Todd G, Schapira L, Kossowsky J, Riess H. The influence of the patient-clinician relationship on healthcare outcomes: a systematic review and meta-analysis of randomized controlled trials. PLoS One. 2014; 9(4):e94207.
55. Riedl D, Schussler G. The influence of doctor-patient communication on health outcomes: a systematic review. Z Psychosom Med Psychother. 2017; 63(2):131–50.
56. Ruland CM, Andersen T, Jeneson A, Moore S, Grimsbo GH, Borosund E, Ellison MC. Effects of an internet support system to assist cancer patients in reducing symptom distress: a randomized controlled trial. Cancer Nurs. 2013;36(1):6–17.

Publisher's Note

Paper II

II

Original Paper

A Digital Patient-Provider Communication Intervention (InvolveMe): Qualitative Study on the Implementation Preparation Based on Identified Facilitators and Barriers

Berit Seljelid[1,2,3], RN, MSc; Cecilie Varsi[1,4], RN, PhD; Lise Solberg Nes[1,2,5], LP, PhD; Kristin Astrid Øystese[6,7], MD, PhD; Elin Børøsund[1], RN, PhD

[1]Department of Digital Health Research, Division of Medicine, Oslo University Hospital, Oslo, Norway

[2]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

[3]Department of Cooperation, Patient Education and Equivalent Health Services, CEO's Staff, Oslo University Hospital, Oslo, Norway

[4]Faculty of Health and Social Sciences, University of South-Eastern Norway, Drammen, Norway

[5]Department of Psychiatry & Psychology, College of Medicine & Science, Mayo Clinic, Rochester, MN, United States

[6]Section of Specialized Endocrinology, Department of Endocrinology, Morbid Obesity and Preventive Medicine, Oslo University Hospital, Oslo, Norway

[7]Department of Medical Biochemistry, Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

Corresponding Author:
Elin Børøsund, RN, PhD
Department of Digital Health Research
Division of Medicine
Oslo University Hospital
Box 4950 Nydalen
Oslo, N-0424
Norway
Phone: 47 22894357
Email: elin.borosund@rr-research.no

Abstract

Background: Chronic health conditions are affecting an increasing number of individuals, who experience various symptoms that decrease their quality of life. Digital communication interventions that enable patients to report their symptoms have been shown to positively impact chronic disease management by improving access to care, patient-provider communication, clinical outcomes, and health-related quality of life. These interventions have the potential to prepare patients and health care providers (HCPs) before visits and improve patient-provider communication. Despite the recent rapid development and increasing number of digital communication interventions that have shown positive research results, barriers to realizing the benefits offered through these types of interventions still exist.

Objective: The aim of this study is to prepare for the implementation of a digital patient-provider communication intervention in the daily workflow at 2 outpatient clinics by identifying potential determinants of implementation using the Consolidated Framework for Implementation Research (CFIR) to tailor the use of digital communication intervention to the intended context and identify key aspects for an implementation plan.

Methods: A combination of focus groups, workshops, and project steering committee meetings was conducted with HCPs (n=14) and patients (n=2) from 2 outpatient clinics at a university hospital. The CFIR was used to guide data collection and analysis. Transcripts, written minutes, and notes were analyzed and coded into 5 CFIR domains using thematic analysis.

Results: Data were examined and analyzed into 18 CFIR constructs relevant to the study purpose. On the basis of the identified determinants, important intervention tailoring includes adjustments to the digital features and adjustments to fit the clinical workflow and a decision to conduct a future pilot study. Furthermore, it was decided to provide the intervention to patients as early as possible in their disease trajectory, with tailored information about its use. Key aspects for the implementation plan encompassed maintaining the identified engagement and positive attitude, involving key stakeholders in the implementation process, and providing the needed support and training.

Conclusions: This study offers insight into the involvement of stakeholders in the tailoring and implementation planning of a digital communication intervention in clinical practice. Stakeholder involvement in the identification of implementation facilitators and barriers can contribute to the tailoring of digital communication interventions and how they are used and can also inform systematic and targeted implementation planning.

(J Med Internet Res 2021;23(4):e22399) doi: 10.2196/22399

KEYWORDS

eHealth; digital communication; secure messages; digital symptom assessment; implementation; tailoring; Consolidated Framework for Implementation Research; CFIR; facilitators; barriers; stakeholders

Introduction

Background

Living with a chronic health condition causes symptoms that negatively affect health-related quality of life (HRQoL) [1-4]. Symptom recognition may be challenging for patients and, by extension, for health care providers (HCPs) [5,6]. This can relate to patients' poor understanding of disease mechanisms and progression, lack of knowledge, and low levels of health literacy [5,7] and to practical barriers to inform HCPs about symptoms [6]. Experiences of difficulties in communication and interaction between patients and HCPs are common, including poor timing of information and challenging symptom recognition, which are factors that may interfere with symptom management and help seeking [5,7]. eHealth communication interventions may offer the potential to alleviate such difficulties.

Studies of eHealth communication interventions have reported benefits in terms of patient-provider communication [8-14], patient-provider relationship [15], patient self-management [16], symptom management [11,17,18], preparation before hospital visits [9,10,18,19], and HRQoL [8,17,20] in chronic health care settings. Despite these benefits, barriers to benefit realization still exist [21], including staff familiarity with technology [22,23], level of patient education [20,23], and issues with user-friendliness [22,24].

Although the positive effects of eHealth interventions on patient-provider communication and patient outcomes are known, HCPs report concerns regarding the integration of eHealth interventions into daily workflow [25,26] and concerns about increased workload [27-29]. In addition, the use of eHealth interventions can challenge HCPs' competence [25,26]. Such challenges may act as barriers to implementation and actual use, which could be another barrier for use. Successful implementation of such eHealth interventions requires attention to the development and evaluation of strategies to implement the interventions [30-32]. An important factor for the acceptance and success of eHealth implementation is the tailoring of the interventions to suit the local context [33]. Stakeholders representing the target group and the actual context can provide important input to reduce system complexity, increase system acceptability, and make systems as user-friendly as possible [33,34]. To increase the likelihood of implementation success, there is also a need to examine intervention characteristics from the end-user perspective in order to inform the tailoring of the intervention to suit contextual needs.

Implementation refers to the systematic uptake of research into HCP practice to improve the quality of health care services [35]. Implementation strategies can be explained as methods or techniques used to enhance the adoption, implementation, and sustainability of HCP clinical practice [36]. However, there is limited guidance regarding the types of implementation strategies that may be effective when implementing eHealth interventions to practice [30]. Nevertheless, it has been suggested that implementation strategies should be selected and tailored to address the unique contextual needs based on an identification of determinants (ie, factors that act as facilitators or barriers) that may influence the implementation process [32]. The identification of determinants can be used to address barriers and leverage facilitators [32,37].

Implementation frameworks can guide the identification of determinants that might influence the implementation, its effectiveness, and the implementation process [32,35]. The Consolidated Framework for Implementation Research (CFIR) is a widely used framework to identify facilitators and barriers [38-40]. The CFIR was developed from a synthesis of 20 existing theories and frameworks and consists of 5 overarching domains, including 39 specific constructs within these 5 domains [38]. The first domain of the CFIR is the *Intervention Characteristics* and includes constructs such as the adaptability of the intervention, the perceived relative advantage, and the complexity and cost of the intervention [38]. The *Outer Setting* domain includes constructs such as the patient's needs and resources related to the intervention, whereas the *Inner Setting* domain includes constructs such as implementation climate and readiness for implementation, the organization's culture, and leadership engagement. The fourth domain is the *Characteristics of Individuals* involved in the intervention or implementation process; it relates to personal attributes, including personal traits such as motivation, values, and competence. The last domain relates to the *Process* and includes planning, execution, and evaluation of the implementation process [38].

Objectives

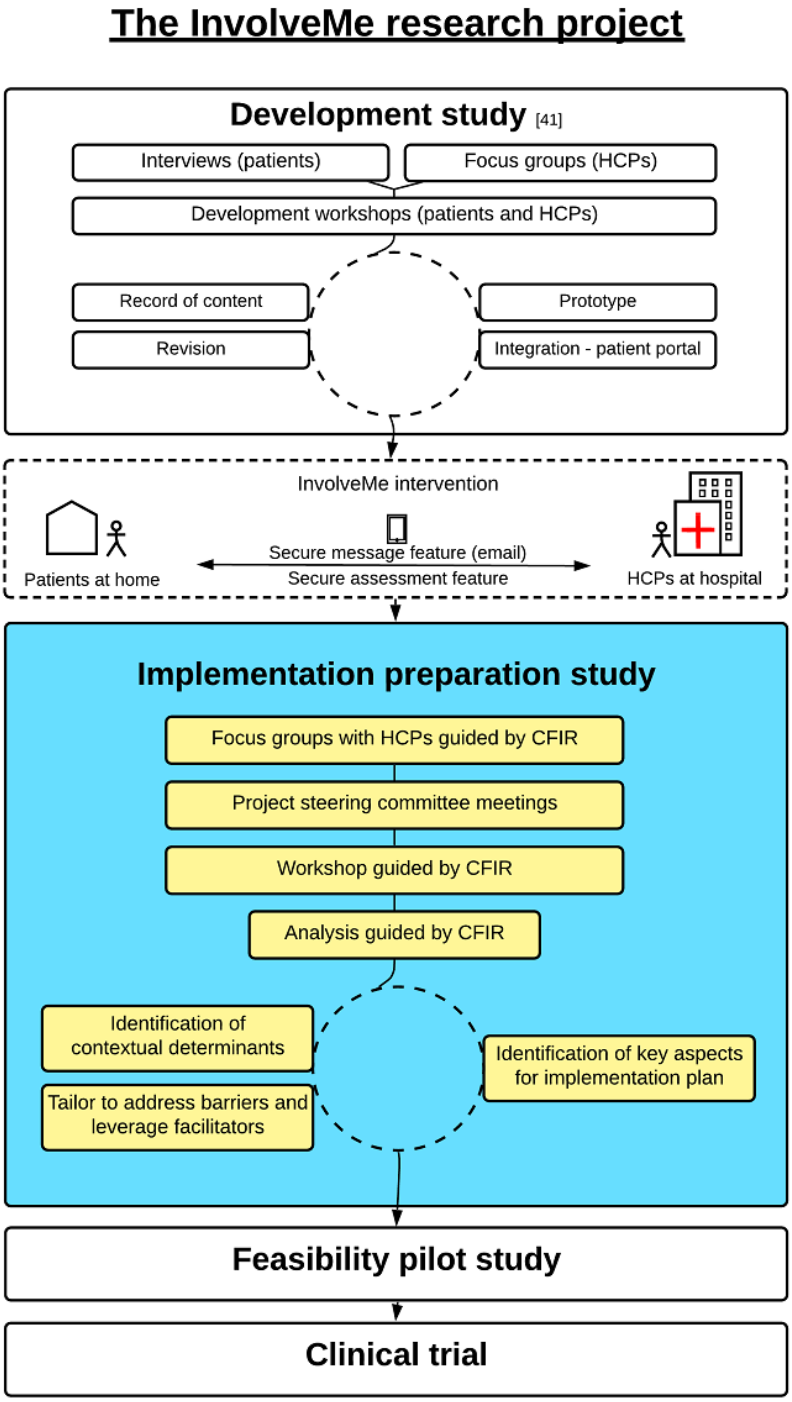
The aim of this study is to prepare the implementation of a digital patient-provider communication intervention, *InvolveMe*, into the daily workflow at 2 outpatient clinics where patients with chronic health conditions are treated by identifying potential facilitators and barriers to implementation using CFIR as the conceptual framework to (1) tailor the *InvolveMe* intervention to the intended context and (2) identify key aspects for an implementation plan.

Methods

Overview

This study is part of the *InvolveMe* research project, which includes the development, implementation, and evaluation of a digital intervention (Figure 1). The *InvolveMe* research project is a collaboration between 2 outpatient clinics and 1 research department at a large university hospital in Norway. The *InvolveMe* intervention will be implemented in 2 outpatient clinics and tested in a future clinical trial (Figure 1).

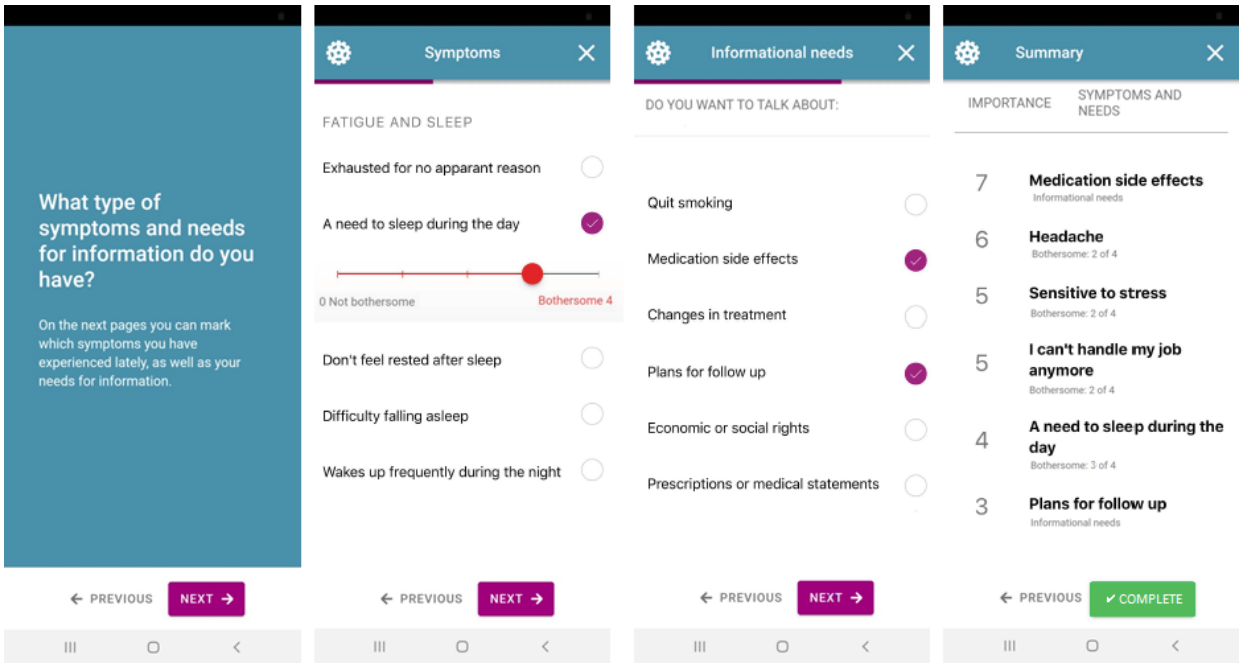
Figure 1. Overview of the InvolveMe research project. CFIR: Consolidated Framework for Implementation Research; HCP: health care providers.



Description of the InvolveMe Intervention

InvolveMe was developed at the initiative of HCPs aiming to improve follow-up for two specific categories of patients: renal transplant recipients and patients with nonfunctioning pituitary adenomas [41]. *InvolveMe* was internally developed at the hospital in close cooperation with registered nurses, physicians, health support personnel, patients, researchers, and system developers (Figure 1). A detailed description of the content and system development of *InvolveMe* is provided elsewhere [41]. The *InvolveMe* intervention contains two features: (1) a secure message feature and (2) a secure assessment feature (ie, predefined list) where patients can prioritize their need for symptom management, information, and preferences for care from home and on a scale from 0 to 10 (Figure 2).

Figure 2. Screenshots of InvolveMe.



Patients and HCPs can use the secure message feature to interact with each other between or after outpatient visits [41]. Completion of the secure assessment feature generates a summary that is sent to the patients' HCPs for use in upcoming consultations. The secure message(s) and the assessment(s) are integrated into an existing patient portal that allows patients to read their electronic patient record (EPR). However, the opposite is not possible (ie, the EPR cannot receive data from the patient portal) owing to information safety regulations.

Design

This study used a participatory and iterative design approach [42] using qualitative methods for data collection. The data collection period was November 2017 to December 2018 and proceeded through focus groups, project steering committee meetings, and a workshop (Figure 1). Data collection from focus groups and workshops was guided by CFIR [38] (Multimedia Appendices 1 and 2). The variety of data collection activities and diverse data collection approaches allowed for mutual stakeholder learning and comprehension of all stakeholder perspectives involved [43]. As part of the main focus of this study is to identify local determinants to tailor the intervention into the intended context (ie, HCPs' practice) and identify key aspects for an implementation plan, most study participants represented the HCP perspective. However, to ensure that the patient perspective was also continuously involved, 2 patients with experience from the *InvolveMe* development study [41] were included in the steering committees to ensure knowledge, inclusion, and prioritization of the patient perspective(s).

The determinants identified from data collection and analysis informed the tailoring of the *InvolveMe* intervention to suit workflow at the 2 participating outpatient clinics and aided in the identification of key aspects to include in an implementation plan. Tailoring, as described in this study, refers to addressing intervention barriers and leveraging facilitators as key aspects of the implementation planning process.

Data Collection Guided by CFIR

CFIR allows researchers to select constructs that they perceive as most relevant and use them to guide the assessment of determinants in the implementation context [38]. The operationalization of CFIR domains in this study was based on discussion and consensus in the research team, where all 5 domains of CFIR were explored for the development of focus group and workshop guides (Multimedia Appendices 1 and 2). Significant themes were to be discussed for determinants important for tailoring the intervention and providing input for the implementation plan (ie, key aspects). By asking about themes to discuss within each domain, rather than questions for each construct, several CFIR constructs would most likely not be covered by the focus group and workshop guides.

Focus Groups

The focus group guide centered around HCPs' experiences from previous successful implementation projects, their perception

of possible advantages and challenges of using a digital patient-provider communication intervention, and how to successfully implement the *InvolveMe* intervention (Multimedia Appendix 1).

Workshop

The workshop guide consisted of the 5 operationalized domains of CFIR (Multimedia Appendix 2): (1) the *InvolveMe* intervention (*Intervention Characteristics*); (2) the patients who will be offered the *InvolveMe* intervention (*Outer Setting*); (3) the 2 outpatient clinics where the patients are being treated (*Inner Setting*); (4) the HCPs (*Characteristics of Individuals*); and (5) the preparation for implementation of the *InvolveMe* intervention (*Process*).

Settings, Participants, and Recruitment

Participants were HCPs and patients. HCPs were purposely selected and recruited from an outpatient nephrology clinic and an outpatient endocrine clinic at a large university hospital in Norway. They were registered nurses, physicians, and health support personnel responsible for the treatment and care of patients with renal transplants or nonfunctioning pituitary adenomas. HCPs were provided with written information about the study and those willing to participate were included. The patients were participants in the development study [41] (Figure 1). They were asked to participate in the project steering committees, representing each of the 2 categories of patients. This was based on detailed knowledge about the *InvolveMe* research project [41], in addition to their own experience of being a patient. The patients were contacted by HCPs at the clinics and asked to participate before being contacted by the first author (BS), who described study participation in detail before the final study participation agreement was received.

HCPs had 2 to 38 years of clinical experience from specialist health care, with a median of 49.5 years (range 28-63 years), and most were female (10/14, 71%). Some HCPs participated in all data collection activities, whereas others participated in 1 or 2 activities (Table 1). The patient participants were female.

Table 1. Overview of participants in the focus groups, project steering committees, and workshop.

Stakeholders[a]	Focus groups (n=11)	Project steering committee (n=6)	Workshop (n=7)
Endocrine outpatient clinic			
Head of clinic (physician)		✓[b]	✓
Registered nurse	✓	✓	✓
Registered nurse	✓		✓
Registered nurse	✓		✓
Physician	✓		
Physician	✓		
Nephrology outpatient clinic			
Head of clinic (physician)		✓	✓
Registered nurse	✓	✓	✓
Registered nurse	✓		
Registered nurse	✓		
Physician	✓		
Physician	✓		
Health support personnel	✓		
Health support personnel			✓
Other stakeholders			
Patient participant		✓	
Patient participant		✓	

[a]All stakeholders participated in the development study [41], except for one head of the clinic and one health support personnel.

[b]Participated in data collection.

Data Collection

Focus Groups

HCPs were invited to participate in focus groups, a method suitable for exploring attitudes and experiences, and to encourage group discussion [44]. The HCPs from the nephrology (n=6) and endocrine (n=5) clinics participated in separate groups to explore context-related determinants and key aspects of an implementation plan (Table 1). The focus groups were facilitated by the first (BS) and last (EB) authors. Both focus group sessions lasted approximately 50 minutes and were recorded with a digital voice recorder and transcribed verbatim.

Project Steering Committee Meetings

A total of 2 project steering committees were established, one for each participating clinic, to promote leadership and stakeholder engagement in the intervention and to ensure input on the process of tailoring the intervention to fit contextual needs. Participants in each of the 2 project steering committees represented either nephrology (n=3) or endocrine (n=3) outpatient clinics (Table 1). The first (BS) and last (EB) authors facilitated the committee meetings. Each group met twice in the preimplementation phase of the study, which lasted for 1 year. All committee meetings lasted approximately 60 minutes and had a set agenda with topics to discuss (eg, workshop preparation and integration of the intervention into practice). Data collection from committee meetings was based on written minutes made by the last author (EB) during meetings. Each participant received and approved the minutes before the analysis.

Workshop

On the basis of the project steering committee meeting discussions and decisions, a joint workshop (n=7) for both participating clinics was considered expedient to share insights and experiences and to identify determinants for tailoring and key aspects for implementation (Table 1). A workshop with HCPs from both clinics was therefore conducted to gain further insight into participants' reflections and expectations about the *InvolveMe* intervention and elaborate on how to implement the intervention in the 2 clinics [45]. Workshop participants were invited to share their reflections through an exercise in which they were presented with the 5 operationalized domains of CFIR to facilitate narration (Multimedia Appendix 2). The presentation of each domain was followed by group discussions on potential facilitators and barriers. Thereafter, Post-it notes were used to present group reflections and encourage discussions between participants from the 2 clinics. The workshop was facilitated by the first (BS) and last (EB) authors and lasted 180 minutes, including a 15-minute break. Data collection from the workshop resulted in a report based on written notes made by the last author (EB) and pictures of the written Post-it notes made and shared by workshop participants.

Analysis

Transcripts, meeting minutes, and notes from the 3 data collection activities were deductively analyzed as one data set, based on thematic analysis by Braun and Clarke [46,47], and into the 5 domains of CFIR (ie, themes). The first author (BS) led the analysis process, which involved 2 coauthors (EB and CV). The first step was to read through and become familiar with the transcripts, meeting minutes, and notes. Early impressions were captured during the writing process. Next, the data were coded (ie, coding by CFIR constructs) using an Excel spreadsheet. Quotes from the focus group transcripts were copied and pasted into the spreadsheet along with text sections from meeting minutes and notes. Colors were used to mark data based on sources. The codes were then resorted and re-evaluated based on the CFIR domains and constructs. Through regular coauthor meetings (BS, EB, and CV), codes were discussed and revised to reach a consensus. Codes that did not appear to fit any of the CFIR constructs were also re-evaluated. The analysis was then refined, and the results were written and reviewed. In the final step, quotes were chosen for representation.

Ethics

The study was performed in accordance with the Helsinki Declaration and approved by the Department for Data Protection and Information Security (equivalent to an institutional review board) at Oslo University Hospital (20178/9223). Written informed consent was obtained from all participants (ie, HCPs and patient representatives). To guarantee confidentiality, the transcripts were coded with project ID numbers and stored on a secure server for sensitive research data, as required by the Department for Data Protection and Information Security at Oslo University Hospital. Only the first author and project administrator (BS) and last author and principal investigator (EB) had access to the code connecting the project ID numbers and the actual participant's name. Owing to the design and implementation emphasis of the study, the need for study approval was waived by the Regional Committee for Medical and Health Research Ethics for South East Norway, which is in line with the Norwegian legislation [48].

Results

Overview

Data were examined and analyzed into 18 CFIR constructs relevant to the study purpose. The constructs are presented by the domains of CFIR, which include description and considerations regarding tailoring of the *InvolveMe* intervention to the intended context (Tables 2-5) and identification of key aspects for the implementation plan (Table 6). A brief description of the relevant CFIR construct is provided to support the interpretation of the results.

Table 2. Intervention Characteristics: determinants, tailoring, and identification of key aspects for implementation planning.

Construct and study results	Considerations regarding determinants	Tailoring and key aspects
Intervention Source: intervention considered as internally developed	Facilitator: the involvement in the development study [41] and this study may promote ownership to the intervention, which may support intervention implementation.	Key aspect: ownership
Relative Advantage: the intervention as an advantage to current practice	Facilitator: HCPs[a] pointed to aspects perceived to be advantages of the intervention. This may be considered as a positive attitude to what is being implemented.	Key aspect: a positive attitude to implement the intervention
Adaptability: use of existing system	Facilitator: participants perceived the previous integration of *InvolveMe* in a patient portal to be beneficial. This may support acceptance and adoption	Key aspect: system acceptance and adoption
Adaptability: a new work task; the secure assessment feature	Barrier: The assessment was a new work task for HCPs, which caused a concern for increased workload and potentially increased time pressure on consultations.	Tailoring: the assessment feature was condensed to a brief list and refinement was made to the summary
Trialability: a need to test before the clinical trial	Barrier: HCPs highlighted that a pilot study would be important to test the intervention and the implementation strategies. A test of the intervention would also inform HCPs that were not formerly involved in the research project and potentially address concerns in advance.	Tailoring: decision, agreed upon by all parties involved, to conduct a pilot study
Complexity: lack of integration between EPR[b] and patient portal	Barrier: it was recognized as important to improve accessibility and avoid paper printouts of the assessment summary.	Tailoring: the summary was created in a format that could be copied and pasted from the patient portal and into the EPR
Complexity: messages sent directly to the physicians	Barrier: it was considered important to tailor the intervention to suit the physician's clinical workflow to succeed with intervention implementation.	Tailoring: a shared email inbox with a dedicated triage moderator was established

[a]HCP: health care provider.

[b]EPR: electronic patient record.

Table 3. Outer Setting: determinants, tailoring, and identification of key aspects for implementation planning.

Construct and study results	Considerations regarding determinants	Tailoring and key aspects
Patient Needs and Resources: *InvolveMe* could potentially contribute to less anxiety	Facilitator: HCPs[a] described patients being worried and anxious early in the disease trajectory. *InvolveMe* could be beneficial to patients in terms of increased information and thereby potentially help patients avoid or experience less anxiety.	Tailoring: to provide the intervention as early as possible to patients
Patient Needs and Resources: patient's motivation to use *InvolveMe*	Facilitator: it can be difficult to reach HCPs on the telephone. *InvolveMe* may have the potential to represent a place where patients can get in contact with HCPs.	Key aspect: motivated patients could contribute to HCPs implementing *InvolveMe*
Patient Needs and Resources: patient acceptance—use of a patient portal	Facilitator: the potential for intervention integration into a patient portal seemed acceptable. This supports findings from the development study [41].	Key aspect: intervention acceptance and adoption
Patient Needs and Resources: patient acceptance—use of a digital health service	Barrier: HCPs described being concerned that *InvolveMe* might be technically demanding for some patients. Therefore, *InvolveMe* was designed to be a voluntary supplement to standard care, not a replacement. The assessment in *InvolveMe* can act as preparation before consultations. To make this clear to all patients, relevant information should be provided.	Tailoring: provide patients with tailored information about the intervention

[a]HCP: health care provider.

Table 4. Inner Setting: determinants, tailoring, and identification of key aspects for implementation planning.

Construct and study results	Considerations regarding determinants	Tailoring and key aspects
Structural Characteristics: 2 outpatient clinics organized differently from each other	Facilitator: knowledge about the different organization and staffing may be of importance for tailoring the intervention to fit each outpatient clinics (ie, the moderator functioning).	Tailoring: one clinic designated a nurse to be the moderator, and the other clinic designated health support personnel
Network and Communication: weekly meetings for activity planning	Facilitator: existing meetings were considered appropriate and feasible to discuss and evaluate the implementation process in the research project.	Key aspect: use of existing weekly meetings to monitor implementation process
Culture: interest in innovations	Facilitator: an interest in innovations may provide opportunities to interact with end users (here HCPs[a]) regarding the intervention. This has the potential to support a collaborative relationship between researchers and HCPs.	Key aspect: a collaborative relationship
Tension for Change: improve patient follow-up	Facilitator: HCPs perceived the current situation as demanding, which could contribute to strengthened motivation to change practice (ie, intervention implementation).	Key aspect: monitoring the number of phone calls and the measurement of HRQoL[b] before and after intervention to visualize change
Leadership Engagement: the heads of the clinics were engaged and active	Facilitator: by their participation in the research project, the heads of the clinics display their commitment and accountability, which may contribute to staff engagement and support a culture for change.	Key aspect: providing anchoring and acceptance for the intervention and a change of practice

[a]HCP: health care provider.

[b]HRQoL: health-related quality of life.

Table 5. Characteristics of Individuals: determinants, tailoring, and identification of key aspects for implementation planning.

Construct and study results	Considerations regarding determinants	Tailoring and key aspects
Knowledge and Beliefs: a positive attitude about using a digital intervention such as *InvolveMe*	Facilitator: a positive attitude may act as a facilitator for the implementation process. Reflection on how to maintain a positive attitude throughout the implementation process should be done to establish a close researcher-clinician relationship. The provision of positive feedback along the implementation process might contribute to maintenance of use and collaboration.	Key aspect: maintaining the positive attitude

Table 6. Process: determinants and identification of key aspects for implementation planning.

Construct and study results	Considerations regarding determinants	Key aspects
Planning: lack of information and assignment of responsibility may reduce the motivation of HCPs[a]	Barrier: providing information and intervention guidance to staff involved in intervention implementation could include providing project information at meetings and brief updates via email or other information channels to all staff members. Meetings and updates could also allow for information exchange on implementation strategies. Easy access to researchers and technical support in case of questions may be of importance.	Providing: • Timely information • Someone to call on a specific number • Technical training and support • Joint project steering committee meetings for mutual exchange of experiences
Engagement: attracting and involving HCPs	Facilitator: some participants initiated writing abstracts to present study details at local and national conferences.	• Maintaining engagement
Opinion Leaders	Facilitator: physicians (and head of clinics) were described by some of the nurses as filling an Opinion Leader role.	• Involving Opinion Leaders in implementation
Implementation Leaders	Facilitator: participants of the project steering committee were suggested as filling the positions as Implementation Leaders.	• Involving members of steering committees in implementation
Champions	Facilitator: registered nurses with a responsibility for the project were seen as potential Champions and drivers of the implementation, inspiring, motivating, and helping other staff members.	• Involving registered nurses in implementation
External Change Agents: provide support to clinics	Facilitator: the clinics wanted a designated external facilitator from the research team to provide support for staff members in implementation.	• First author (BS) designated as External Change Agent in this study

[a]HCP: health care provider.

Intervention Characteristics

Intervention Source is defined as the key stakeholders' perception of whether the intervention is externally or internally developed [38]. Most participants were involved in activities to prepare the content and development of the system underlying *InvolveMe*, as described elsewhere [41]. The *InvolveMe* intervention was collaboratively developed within the hospital, and the participating HCPs expressed a perception of *InvolveMe* ownership.

Relative Advantage refers to the stakeholder's perception of the advantage of implementing the intervention rather than an alternative solution [38]. Although symptom assessments were a part of routine consultations, they were performed based on the preference and prioritization of the HCP and the history of the patients. Most participants perceived that the *InvolveMe* intervention could be an advantage compared with current practice where there is no digital communication between patients and HCPs. The participants reported that such a digital intervention could increase patient safety; raise awareness about the patient's perspective (ie, symptoms and informational needs); and improve patient-provider communication, patient satisfaction, and HRQoL. An intervention that could document contact between patient and provider and reduce the number of phone calls from patients was seen as warranted. One participant stated:

> *An email is much less disruptive than a phone call. An email I open when I have some spare time, while the phone call I have to answer while in the middle of something, while doing something else.* [HCP 10, focus group]

Adaptability refers to the degree to which an intervention can be adapted, tailored, and refined to meet local needs [38]. The participants shared their opinions on how they thought *InvolveMe* could fit into existing workflows in the clinics. The use of an already existing system was perceived as positive. Participants perceived that there were "already too many digital clinical systems" and that it was beneficial for *InvolveMe* to be integrated into an excising system (ie, patient portal) [41]. Some HCPs expressed concern that the intervention would introduce additional work tasks in an already hectic work environment. These concerns were raised surrounding worries that patients might complete extensive assessments, expecting everything to be addressed in the consultation. One participant stated:

> *If it becomes one more thing I have to deal with when meeting a patient for half an hour, we'll have to start considering extending the consultation time.* [HCP 6, focus group]

Trialability relates to the ability to test the intervention on a small scale in the organization and be able to reverse course if warranted [38]. Participants were positive for participating in

a clinical trial to test *InvolveMe*. However, HCPs raised concerns about carrying out the planned trial without them being able to test the intervention in advance.

Complexity is defined as the perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, intricacy, and the number of steps required for implementation [38]. The participants stated that the digital communication tool must be intuitive and easy for them to use. As expressed by one participant:

> *It has to be something that is intuitive and easy to answer and...something you don't spend a lot of extra time on.* [HCP 9, focus group]

Although *InvolveMe* could be integrated into a patient portal, the participants expressed concern that the intervention, because of data protection and privacy regulations, likely would not be allowed to communicate directly with the hospital EPR. If current regulations would require that paper printouts from *InvolveMe* had to be manually scanned into the EPR, rather than received directly from the patient portal, participants were concerned that this would add to their workload. The participating physicians also raised concerns about receiving secure messages directly to an individual mailbox, without some form of triage. There were also some concerns that the message functionality might become more like a chat, with messages going back and forth between patients and HCPs, potentially increasing the time HCPs spend communicating with each other for management of the patients' many questions.

Outer Setting

The construct of *Patient Needs and Resources* concerns the extent to which patients' needs and facilitators and barriers to meeting these needs are accurately known and prioritized by the organization [38]. The participating HCPs explained that they, based on their own experience, perceived patients as the most worried and anxious early in the disease trajectory. They described a structured follow-up for the 2 categories of patients, with room for improvement. As expressed by one participant:

> *That's also what we, me too, have been thinking about for many years when it comes to our patients, that they come to the 3-month check-up and they have questions that we could have answered for them [before the time of check-up], but they've had no place to pose their questions before consultation.* [HCP 2, focus group]

HCPs described that they thought most patients would be motivated to use *InvolveMe* and that the intervention could improve patient-provider communication related to symptoms, needs, and preferences, but also serve as a secure digital channel where patients knew that they could get in touch with their HCPs between consultations. This aspect was also discussed in the workshop. One participant described the following:

> *Satisfied patients, they will feel more seen and heard.* [Post-it note, workshop]

The use of the existing system was considered positive for patient use. However, the HCPs were concerned about various aspects of patient acceptance. They expressed thoughts that some patients might be afraid of losing in-person contact with their HCPs and that digital communication might not suit all patients. This issue was particularly raised as a digital intervention could potentially require a level of digital competence that some patients might not have. One participant stated:

> *Some patients might be afraid to use technology.* [Post-it note, workshop]

Adding to the HCP input, the patient participants in this study supplemented patient input from the development study [41] and strengthened the patient's voice by providing direct input on the *InvolveMe* intervention. They were very positive toward the use of *InvolveMe* and expressed their view that digital patient-provider communication would strengthen patient follow-up.

Inner Setting

The construct of *Structural Characteristics* is explained as the social architecture, age, maturity, and size of an organization [38]. The 2 included outpatient clinics were organized differently from each other, although both clinics described staff stability. One clinic was larger than the other and included 2 registered nurses and several physicians. This clinic also had several health support personnel who organized much of the patient-administrative work for registered nurses and physicians. The other clinic included registered nurses and physicians in a relatively small HCP group, which was perceived as an advantage by the HCPs in question in terms of implementation. One participant stated:

> *It is probably an advantage that we are a small group, and not thousands of people.* [HCP 5, focus group]

The construct of *Network and Communication* involves the nature and quality of social networks and the nature and quality of formal and informal communication in an organization [38]. Both clinics had weekly meetings for activity planning, where research projects, including this study, were discussed.

Culture, as a construct, includes the norms, values, and basic assumptions of a given organization [38]. The HCPs reported that they were generally interested in innovations. This interest was also displayed in attendance and discussions at presentations and meetings about *InvolveMe.* Most of the participating HCPs also pointed to the potential for improved symptom management through interventions such as *InvolveMe*. One participant stated:

> *It's the issue of identifying the patient's problem...that we sometimes struggle to capture.* [HCP 4, focus group]

Tension for Change is the degree to which HCPs perceive the current situation as intolerable or needing change [38]. With regard to digital patient-provider communication, there was a general tension for change among all groups of HCPs in this study. All participants described receiving many phone calls from patients, and that they needed and wanted an easier method for patient follow-up than what current practice allowed, suggesting that digital communication could be one way to improve this issue. One participant stated:

> *There will be less "noise" if we have one of those electronic communication channels...then we would have the opportunity to convey something, and at the same time reduce the patient's level of anxiety.* [HCP 4, focus group]

Leadership Engagement refers to the commitment, involvement, and accountability of leaders regarding implementation [38]. The heads of the participating clinics were positive and engaged members of the project steering committee. They were also supportive and involved in the research project, facilitating and participating in research activities and allocating clinic personnel to participate in research project activities and meetings.

Characteristics of Individuals

The construct of *Knowledge and Beliefs* about the intervention involves individuals' attitudes and the value placed on the intervention and familiarity with facts, truths, and principles related to the intervention [38]. The participants expressed, for the most part, a positive attitude toward using *InvolveMe* and stated that they believed the use of such an intervention could improve clinical practice through highlighting the importance of good patient-provider communication related to symptom management. One participant stated:

> *Being able to clarify some expectations makes it easier to...the patient is better prepared for consultation, they understand what they are struggling with and why they come in for consultation...it will potentially make it easier to talk to them when some things are clarified in advance...* [HCP 4, focus group]

Participating HCPs expressed that digital interventions, such as *InvolveMe*, should be a part of modern practice. The positive attitude toward an intervention such as *InvolveMe* was also expressed in other ways, for example, written on a Post-it note:

> *Will provide structure to the workday.* [Post-it note, workshop]

HCPs also stated that they believed that such an intervention could make patients feel safe and cared for. One participant said:

> *Possibly an increased level of security [for the patient] provided by a communication channel that is not filtered through a switchboard...* [HCP 5, focus group]

Process

The construct of *Planning* is explained as the degree to which a scheme or method of behavior, and tasks for implementing an intervention in advance, corresponds with the consideration of the quality of those schemes or methods [38]. The participants in this study stated that a lack of information and assignment of responsibility could potentially reduce HCP motivation. The importance of providing information and guidance for use to everyone involved at the clinics was highlighted:

> *When switching to new systems, it is always important to have an easily accessible support person who can help solve issues right away.* [HCP 5, focus group]

The heads of the participating clinics suggested joint project steering committee meetings to exchange information on implementation strategies in the implementation process. In addition, availability from someone from the research team, including the possibility to call if the HCPs had any questions, was suggested. The need for technical support and training was also suggested:

> *Some training in the use of the software maybe...*
>
> *Yes, but I often think we get too much of that...*
>
> *Agreed, but not too long in advance then, as it is so easy to forget. But you could get help with specific things that you wonder about, and then you learn and acquire knowledge, while if you're sitting in a classroom, learning about a lot of things that you can't really easily relate to...* [Discussion between HCP 6 and 9, focus group]

The construct of *Engagement* involves attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, or similar activities [38]. There was definite engagement in the planned intervention in this study. For example, some participants initiated writing abstracts to present study details at local and national conferences. This initiation was discussed in project steering committees, and the research team allocated responsibility for the writing process. Abstracts written for the part of the process also received two Best Poster Awards and a Meritorious Abstract Award [49] and contributed to maintaining engagement.

Opinion Leaders are individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues regarding the implementation of the intervention [38]. Physicians (and head of clinics) were described by some of the nurses as filling an *Opinion Leader* role. Participants of the project steering committee were suggested to fill the positions as *Implementation Leaders*. Registered nurses who were responsible for the project were seen as potential *Champions* and drivers of the implementation.

External Change Agents are individuals who are affiliated with an outside entity and who formally influence and facilitate interventions in a desirable direction [38]. By facilitating the project steering committee meetings, the first (BS) and last (EB) authors potentially influenced and facilitated the intervention as *External Change Agents*. In addition, the participants suggested a facilitator from the research team to be available to the clinic staff members for support during the implementation process.

Discussion

Principal Findings

This study identifies the determinants using the CFIR framework [38] to inform tailoring of the *InvolveMe* intervention and to identify key aspects for implementation planning based on context.

The identification of determinants in this study supports findings from existing literature [23,33,50]. However, the influence of

context on implementation outcomes must be considered to understand the need to tailor interventions [51]. To the best of the authors' knowledge, descriptions of how identified determinants can be used to tailor interventions to context are largely lacking. The HCPs participating in this study were mostly positive toward implementing the digital communication intervention *InvolveMe* and perceived the intervention as having the potential to improve patient-provider communication. This is in line with existing research showing that improvements in communication can act as facilitators in eHealth implementation [24,50].

In the development study [41] preceding this study, the participants voiced a concern about lack of integration with existing systems, which corresponds with findings from other studies where lack of accessibility and fit into organizational structures have been identified as barriers to implementation of eHealth interventions [23,33,50]. Therefore, the *InvolveMe* intervention was integrated into a patient portal already in use by patients and HCPs. What was initially perceived as a barrier in the development study [41] was hence turned into something, perceived by participants, beneficial in this study. This confirmed the decision made in the development study [41], acting as a potential facilitator for intervention implementation and potentially improving acceptance and adoption [33].

The HCPs in this study voiced some concerns regarding the assessment feature in terms of being a new work task that could potentially increase the workload. The assessment feature was therefore condensed to a brief list and refinements were made to the assessment summary by conducting several user tests in close collaboration with HCPs, patient participants, and the research team. This strategy is supported by the literature, showing user-friendliness and integration into care as known facilitators for the implementation of eHealth interventions [22,50,52]. In addition, this strategy can prevent the need for intervention redesign, which is likely to delay use and increase costs, which are known barriers to eHealth interventions [33].

The involvement of relevant stakeholders is a known facilitator of implementation [50,53]. Although stakeholders were involved in the development [41] of the *InvolveMe* intervention, the participants in this study provided valuable additional information for the tailoring of the intervention, including the need to test the intervention before any upcoming clinical trial. Participants in this study raised concerns about potential implications for clinical workflow and workload when using a digital communication intervention. Concerns about increased workload are a well-known barrier to the implementation of eHealth interventions [28,50]. A growing point of importance is also to tailor eHealth interventions to existing clinical workflows, minimizing potential burdens [30]. A moderator function for triaging secure messages should therefore be organized in a flexible way, depending on the clinic organization and available HCPs. Such tailoring to the local context may facilitate intervention integration into clinical workflow, a known facilitator for implementation of eHealth interventions in practice [22,50].

In this study, HCPs also expressed concerns about patient acceptance of a digital communication intervention, described as a lack of digital competence among some patients. This concern is supported by patient education literature [20,24,54]. However, there are some indications that it is feasible to deliver eHealth interventions to improve eHealth and health literacy skills among patients with chronic health conditions [22,54]. To be able to offer interventions, such as *InvolveMe* to patients, regardless of digital competence, studies have suggested employing blended care models, involving a mixture of in-person, technology, or telephone contact as a way to help facilitate use [23,55,56]. Furthermore, alternating health care delivery between digital communication and in-person meetings has been described as a way to avoid losing in-person contact with patients [23].

To ensure successful implementation of an eHealth intervention in a certain context, the need to develop and follow an implementation plan is widely recognized [36] and the lack of such a plan is considered a barrier to implementation [33]. In this study, results from the CFIR *Planning* construct provided insight into the participants' thoughts on how to involve key stakeholders, secure leadership support, and how to provide information training and coaching. These factors have previously been described as important for incorporation into an implementation plan [32,37]. In addition, several facilitators (eg, ownership, positive attitude, and system acceptance) identified in the other CFIR domains were considered important to build on (ie, leverage facilitators) when planning for implementation. HCPs struggling with the use of technology are a known barrier in the implementation of eHealth interventions [23]. Training of HCPs is therefore a preferred and widely used implementation strategy [53], and a combination of software training and training in how to incorporate the intervention into daily clinical workflow may be required [30,31]. In this study, it was hence considered an important aspect to include training and follow-up of HCPs in the implementation plan. Training of designated clinicians who would subsequently train others to use *InvolveMe* was planned [32]. External support (ie, provided by a member of the research team) was also identified as a key aspect of the implementation plan.

The heads of both clinics participating in this study were involved in the development study [41] and in the tailoring and implementation planning. Several studies have shown that implementation strategies that encourage leadership support and engagement are crucial to implementation success [30]. Leaders are often seen as providers of new knowledge and as key influencers related to implementation initiatives, including facilitating effective teamwork and cultivating a culture of learning [57]. In addition, leaders can assign dedicated staff to perform the required change, which may ease workload and the concern for increased work [57]. Therefore, strategies targeting leaders, such as continuing the project steering committee meetings, should be considered key aspects to include in the implementation plan of interventions, such as *InvolveMe*, into outpatient clinics. In addition, carrying out implementation preparation workshops (Multimedia Appendix 2), as in this study, might also capture local knowledge of what works and not, knowledge that can be shared between implementation sites [32].

In this study, the project steering committee meetings were also intended to build a coalition between patient participants, HCPs, and the research team to cultivate a good relationship in the implementation effort, another described implementation strategy [32,37,53], and thus a key aspect to include in an implementation plan. Collaborative relationships are crucial for implementing plans and, through a social exchange communicating the potential impact of innovations, for the implementation of interventions, such as *InvolveMe*, into clinical practice may be facilitated [57].

Strengths and Limitations

This study has some limitations that need to be addressed. *First*, the study was conducted at a single university hospital. This might limit transferability to other settings. However, the inclusion of 2 outpatient clinics, following up 2 different patient categories, might increase transferability to other settings. *Second*, the study had a relatively small sample size, a factor potentially limiting transferability. A small sample size may limit the ability of data to describe the entire local context at the clinics involved. However, the study was performed in outpatient clinics where the implementation of the intervention is planned to take place, thus enabling identification of local determinants and key aspects that may be crucial for an implementation plan. *Third*, there was an imbalance in the number of HCPs compared with patients in this study. Traditionally, implementation involves the improvement of HCP practices [35]. CFIR does not differ from this tradition, as CFIR places patients under the *Outer Setting* domain, where only one single construct is intended to capture patients' needs and resources [38]. As such, patients are considered to have a peripheral role in their implementation. However, this study examined all perspectives and interplay of all stakeholders involved, including patient participants, which helped to illuminate stakeholder aspects and may help increase the likelihood of successful implementation to practice [33]. In addition, even with a limited number of patient participants, patient participants' experience from the development study [41] and subsequent direct input on various topics in this study may have ensured relevance and reliability from the patient perspective. *Fourth*, the perceived facilitators and barriers of participants in this study might not necessarily correspond to facilitators and barriers experienced in clinical practice in general. However, recent evidence indicates that the limited use of tailoring to context could explain the limited implementation success [30]. Knowledge generated during preparation for implementation can contribute to intervention tailoring and context-specific individualization, which implies that stakeholders' needs are more likely met, and hence intervention design and implementation preparation are improved [58].

This study has some strengths. Applying a structured and comprehensive framework such as CFIR within the field of implementation is considered to be a strength guiding data collection and analysis [59]. Identifying and describing determinants that affect implementation, as well as identifying key aspects for implementation planning, are also strengths [59]. Furthermore, the use of CFIR in this study provided a common language through the use of constructs and definitions for the analysis of data and thus may provide comparable results that may make it easier to assess why and how certain elements work. However, it should be noted that the strength of CFIR as a comprehensive framework may also be a weakness. CFIR does not distinguish between the relative importance of all of its constructs, which may imply that the details necessary for implementation success could be lost if trying to capture as many constructs as possible. In this study, a number of CFIR constructs were not covered by the data collection, as only discrete but significant themes and questions were targeted (Multimedia Appendices 1 and 2). Another challenge using CFIR is that some constructs are broad and difficult to capture and some may overlap with other constructs. Further descriptions and explanations related to constructs could enhance the CFIR and thus make the framework more intuitive to use when planning for implementation.

Future Directions

The ongoing COVID-19 pandemic has triggered a significant need for a wide range of digital communication services between patients and HCPs and has led to increased demand for digital intervention from within the health care services themselves. As such, and with the tremendous challenges posed by this significant health challenge, the pandemic might turn out to be a powerful facilitator for the implementation of digital interventions in health care services.

This study revealed some specific aspects that need to be investigated in future research. In particular, the results show that a pilot study may contribute to identify gaps and inform further necessary tailoring of the intervention and an implementation plan (ie, strategies) before clinical trials. This emphasizes that, regardless of stakeholder involvement in intervention development, a pilot test should always be considered.

Future studies should also aim to better understand how the CFIR framework can inform an implementation planning process in terms of tailoring interventions before implementation and the selection of implementation strategies based on identified determinants. In addition, refinements of the CFIR to strengthen the patient-related constructs and make the framework easier to apply would be beneficial for researchers and for HCPs conducting implementation in clinical practice.

Conclusions

This study contributes to the field of implementation science by using identified determinants to inform the tailoring of a digital communication intervention (ie, *InvolveMe*) and to identify key aspects of an implementation plan to context. Important intervention tailoring aspects identified were adjustments to the digital features and adjustments to fit the clinical workflow as well as recommendations to conduct a future pilot study before testing in larger clinical trials. Future research into the implementation of digital communication interventions should focus on the early identification of determinants and attention to tailoring to address barriers and leverage facilitators. In addition, key aspects of implementation planning should be identified, raising the probability of implementation success.

Acknowledgments

This study was funded by the Norwegian Nurses Organization grant 847382 (principal investigator: EB). The authors would like to thank the patient participants and HCPs who participated in this study. The authors would also like to thank all collaborating project team partners, including the editorial group and software team in the Department of Digital Health Research at Oslo University Hospital.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group guide with Consolidated Framework for Implementation Research domains.
[PDF File (Adobe PDF File), 98 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Workshop theme guide with Consolidated Framework for Implementation Research domains.
[PDF File (Adobe PDF File), 144 KB-Multimedia Appendix 2]

References

1. Burström K, Johannesson M, Diderichsen F. Health-related quality of life by disease and socio-economic group in the general population in Sweden. Health Policy 2001 Jan;55(1):51-69. [doi: 10.1016/s0168-8510(00)00111-1] [Medline: 11137188]
2. Saarni SI, Härkänen T, Sintonen H, Suvisaari J, Koskinen S, Aromaa A, et al. The impact of 29 chronic conditions on health-related quality of life: a general population survey in Finland using 15D and EQ-5D. Qual Life Res 2006 Oct;15(8):1403-1414. [doi: 10.1007/s11136-006-0020-1] [Medline: 16960751]
3. Heyworth ITM, Hazell ML, Linehan MF, Frank TL. How do common chronic conditions affect health-related quality of life? Br J Gen Pract 2009 Nov;59(568):353-358 [FREE Full text] [doi: 10.3399/bjgp09X453990] [Medline: 19656444]
4. Wu M, Brazier JE, Kearns B, Relton C, Smith C, Cooper CL. Examining the impact of 11 long-standing health conditions on health-related quality of life using the EQ-5D in a general population sample. Eur J Health Econ 2015 Mar;16(2):141-151 [FREE Full text] [doi: 10.1007/s10198-013-0559-z] [Medline: 24408476]
5. May CR, Cummings A, Myall M, Harvey J, Pope C, Griffiths P, et al. Experiences of long-term life-limiting conditions among patients and carers: what can we learn from a meta-review of systematic reviews of qualitative studies of chronic heart failure, chronic obstructive pulmonary disease and chronic kidney disease? BMJ Open 2016 Oct 05;6(10) [FREE Full text] [doi: 10.1136/bmjopen-2016-011694] [Medline: 27707824]
6. Lubberding S, van Uden-Kraan CF, Te Velde EA, Cuijpers P, Leemans CR, Leeuw IMV. Improving access to supportive cancer care through an eHealth application: a qualitative needs assessment among cancer survivors. J Clin Nurs 2015 May;24(9-10):1367-1379. [doi: 10.1111/jocn.12753] [Medline: 25677218]
7. Friis K, Lasgaard M, Osborne RH, Maindal HT. Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29,473 Danish citizens. BMJ Open 2016 Jan 14;6(1) [FREE Full text] [doi: 10.1136/bmjopen-2015-009627] [Medline: 26769783]
8. Goldzweig CL, Towfigh AA, Paige NM, Orshansky G, Haggstrom DA, Beroes JM, et al. Systematic review: secure messaging between providers and patients, and patients' access to their own medical record: evidence on health outcomes, satisfaction, efficiency and attitudes. VA Evidence-based Synthesis Program Reports 2012. [Medline: 22973584]
9. Heyn L, Ruland CM, Finset A. Effects of an interactive tailored patient assessment tool on eliciting and responding to cancer patients' cues and concerns in clinical consultations with physicians and nurses. Patient Educ Couns 2012 Feb;86(2):158-165. [doi: 10.1016/j.pec.2011.04.024] [Medline: 21592719]
10. Heyn L, Finset A, Eide H, Ruland CM. Effects of an interactive tailored patient assessment on patient-clinician communication in cancer care. Psychooncology 2013 Jan;22(1):89-96. [doi: 10.1002/pon.2064] [Medline: 21919122]
11. Johansen MA, Berntsen GKR, Schuster T, Henriksen E, Horsch A. Electronic symptom reporting between patient and provider for improved health care service quality: a systematic review of randomized controlled trials. part 2: methodological quality and effects. J Med Internet Res 2012 Oct 03;14(5):e126 [FREE Full text] [doi: 10.2196/jmir.2216] [Medline: 23032363]
12. Whitehead L, Seaton P. The effectiveness of self-management mobile phone and tablet apps in long-term condition management: a systematic review. J Med Internet Res 2016 May 16;18(5):e97 [FREE Full text] [doi: 10.2196/jmir.4883] [Medline: 27185295]

13. de Jong CC, Ros WJ, Schrijvers G. The effects on health behavior and health outcomes of Internet-based asynchronous communication between health providers and patients with a chronic condition: a systematic review. J Med Internet Res 2014 Jan 16;16(1):e19 [FREE Full text] [doi: 10.2196/jmir.3000] [Medline: 24434570]
14. Børøsund E, Cvancarova M, Moore SM, Ekstedt M, Ruland CM. Comparing effects in regular practice of e-communication and web-based self-management support among breast cancer patients: preliminary results from a randomized controlled trial. J Med Internet Res 2014 Dec 18;16(12):e295 [FREE Full text] [doi: 10.2196/jmir.3348] [Medline: 25525672]
15. Qudah B, Luetsch K. The influence of mobile health applications on patient - healthcare provider relationships: a systematic, narrative review. Patient Educ Couns 2019 Jun;102(6):1080-1089. [doi: 10.1016/j.pec.2019.01.021] [Medline: 30745178]
16. Lee JA, Choi M, Lee SA, Jiang N. Effective behavioral intervention strategies using mobile health applications for chronic disease management: a systematic review. BMC Med Inform Decis Mak 2018 Feb 20;18(1):12 [FREE Full text] [doi: 10.1186/s12911-018-0591-0] [Medline: 29458358]
17. Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organisations in an oncologic setting. BMC Health Serv Res 2013 Jun 11;13:211 [FREE Full text] [doi: 10.1186/1472-6963-13-211] [Medline: 23758898]
18. Ruland CM, Holte HH, Røislien J, Heaven C, Hamilton GA, Kristiansen J, et al. Effects of a computer-supported interactive tailored patient assessment tool on patient care, symptom distress, and patients' need for symptom management support: a randomized clinical trial. J Am Med Inform Assoc 2010;17(4):403-410 [FREE Full text] [doi: 10.1136/jamia.2010.005660] [Medline: 20595307]
19. Ruland CM, White T, Stevens M, Fanciullo G, Khilani SM. Effects of a computerized system to support shared decision making in symptom management of cancer patients: preliminary results. J Am Med Inform Assoc 2003;10(6):573-579 [FREE Full text] [doi: 10.1197/jamia.M1365] [Medline: 12925545]
20. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. Health Informatics J 2016 Jun;22(2):81-98 [FREE Full text] [doi: 10.1177/1460458214534092] [Medline: 24916567]
21. eHealth Action Plan 2012-2020: innovative healthcare for the 21st century. 2012. URL: https://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century [accessed 2021-03-22]
22. Keyworth C, Hart J, Armitage CJ, Tully MP. What maximizes the effectiveness and implementation of technology-based interventions to support healthcare professional practice? A systematic literature review. BMC Med Inform Decis Mak 2018 Nov 07;18(1):93 [FREE Full text] [doi: 10.1186/s12911-018-0661-3] [Medline: 30404638]
23. Kruse CS, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: a systematic review. J Telemed Telecare 2018 Jan;24(1):4-12 [FREE Full text] [doi: 10.1177/1357633X16674087] [Medline: 29320966]
24. Kruse CS, Argueta DA, Lopez L, Nair A. Patient and provider attitudes toward the use of patient portals for the management of chronic disease: a systematic review. J Med Internet Res 2015 Feb 20;17(2):e40 [FREE Full text] [doi: 10.2196/jmir.3703] [Medline: 25707035]
25. Varsi C, Ekstedt M, Gammon D, Ruland CM. Using the consolidated framework for implementation research to identify barriers and facilitators for the implementation of an internet-based patient-provider communication service in five settings: a qualitative study. J Med Internet Res 2015 Nov 18;17(11):e262 [FREE Full text] [doi: 10.2196/jmir.5091] [Medline: 26582138]
26. Børøsund E, Ruland CM, Moore S, Ekstedt M. Nurses' experiences of using an interactive tailored patient assessment tool one year past implementation. Int J Med Inform 2014 Jul;83(7):23-34. [doi: 10.1016/j.ijmedinf.2013.10.010] [Medline: 24268722]
27. Chang F, Paramsothy T, Roche M, Gupta NS. Patient, staff, and clinician perspectives on implementing electronic communications in an interdisciplinary rural family health practice. Prim Health Care Res Dev 2017 Mar;18(2):149-160. [doi: 10.1017/S1463423616000414] [Medline: 27995826]
28. Antoun J. Electronic mail communication between physicians and patients: a review of challenges and opportunities. Fam Pract 2016 Apr;33(2):121-126. [doi: 10.1093/fampra/cmv101] [Medline: 26711957]
29. Kummervold PE, Johnsen JK. Physician response time when communicating with patients over the internet. J Med Internet Res 2011 Nov 01;13(4):e79 [FREE Full text] [doi: 10.2196/jmir.1583] [Medline: 22044909]
30. Varsi C, Nes LS, Kristjansdottir OB, Kelders SM, Stenberg U, Zangi HA, et al. Implementation strategies to enhance the implementation of ehealth programs for patients with chronic illnesses: realist systematic review. J Med Internet Res 2019 Sep 27;21(9) [FREE Full text] [doi: 10.2196/14255] [Medline: 31573934]
31. Elbert NJ, van Os-Medendorp H, van Renselaar W, Ekeland AG, Hakkaart-van Roijen L, Raat H, et al. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. J Med Internet Res 2014 Apr 16;16(4):e110 [FREE Full text] [doi: 10.2196/jmir.2790] [Medline: 24739471]
32. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci 2015 Feb 12;10:21 [FREE Full text] [doi: 10.1186/s13012-015-0209-1] [Medline: 25889199]

33. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci 2016 Oct 26;11(1):146 [FREE Full text] [doi: 10.1186/s13012-016-0510-7] [Medline: 27782832]
34. Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med 2006 May 16;144(10):742-752 [FREE Full text] [doi: 10.7326/0003-4819-144-10-200605160-00125] [Medline: 16702590]
35. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015 Apr 21;10:53 [FREE Full text] [doi: 10.1186/s13012-015-0242-0] [Medline: 25895742]
36. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci 2013 Dec 01;8:139 [FREE Full text] [doi: 10.1186/1748-5908-8-139] [Medline: 24289295]
37. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. Implement Sci 2015 Aug 07;10:109 [FREE Full text] [doi: 10.1186/s13012-015-0295-0] [Medline: 26249843]
38. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009 Aug 07;4:50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
39. Keith RE, Crosson JC, O'Malley AS, Cromp D, Taylor EF. Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. Implement Sci 2017 Feb 10;12(1):15 [FREE Full text] [doi: 10.1186/s13012-017-0550-7] [Medline: 28187747]
40. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implement Sci 2016 May 17;11:72 [FREE Full text] [doi: 10.1186/s13012-016-0437-z] [Medline: 27189233]
41. Seljelid B, Varsi C, Solberg Nes L, Stenehjem A, Bollerslev J, Børøsund E. Content and system development of a digital patient-provider communication tool to support shared decision making in chronic health care: InvolveMe. BMC Med Inform Decis Mak 2020 Mar 04;20(1):46 [FREE Full text] [doi: 10.1186/s12911-020-1065-8] [Medline: 32131808]
42. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. Milbank Q 2012 Jun;90(2):311-346 [FREE Full text] [doi: 10.1111/j.1468-0009.2012.00665.x] [Medline: 22709390]
43. Robertson T, Wagner I. Ethics: engagement, representation and politics-in-action. In: Simonsen J, Robertson T, editors. Routledge International Handbook of Participartory Design - 1st Edition. London: Routledge; 2013.
44. Morgan DL. Focus group interviewing. In: Gubrium JF, Holstein JA, editors. Handbook of Interview Research. Thousand Oaks, CA: SAGE Publications Ltd; 2001:141-159.
45. Stickdorn M, Schneider J. This is service design thinking: basics, tools, cases. Hoboken, New Jersey, United States: Wiley; 2012:1-384.
46. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psycho 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
47. Clarke V, Braun V. Thematic analysis. J Posit Psychol 2016 Dec 09;12(3):297-298. [doi: 10.1080/17439760.2016.1262613]
48. Acts of legislation. Regional Committees for Medical and Health Research Ethics. 2020. URL: https://helseforskning.etikkom.no/reglerogrutiner/loverogregler?p_dim=34770&_ikbLanguageCode=us [accessed 2021-03-22]
49. Seljelid B, Varsi C, Stenehjem AE, Bollerslev J, Solberg Nes L, Børøsund E. Content development of an electronic shared decision making tool for patients with chronic illness; mapping symptoms and needs. Society of Behavioral Medicine 2019 Annual Meeting Abstracts. Annals of Behavioral Medicine 2019 Mar;53(1):S1-S842 [FREE Full text] [doi: https://doi.org/10.1093/abm/kaz007]
50. Schreiweis B, Pobiruchin M, Strotbaum V, Suleder J, Wiesner M, Bergh B. Barriers and facilitators to the implementation of ehealth services: systematic literature analysis. J Med Internet Res 2019 Nov 22;21(11) [FREE Full text] [doi: 10.2196/14197] [Medline: 31755869]
51. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res 2019 Mar 25;19(1):189 [FREE Full text] [doi: 10.1186/s12913-019-4015-3] [Medline: 30909897]
52. Kruse CS, Bolton K, Freriks G. The effect of patient portals on quality outcomes and its implications to meaningful use: a systematic review. J Med Internet Res 2015 Feb 10;17(2):e44 [FREE Full text] [doi: 10.2196/jmir.3171] [Medline: 25669240]
53. Albers B, Metz A, Burke K, Bührmann L, Bartley L, Driessen P, et al. Implementation support skills: findings from a systematic integrative review. Research on Social Work Practice 2020 Oct 27;31(2):147-170 [FREE Full text] [doi: 10.1177/1049731520967419]
54. Chapman E, Haby MM, Toma TS, de Bortoli MC, Illanes E, Oliveros MJ, et al. Knowledge translation strategies for dissemination with a focus on healthcare recipients: an overview of systematic reviews. Implement Sci 2020 Mar 04;15(1):14 [FREE Full text] [doi: 10.1186/s13012-020-0974-3] [Medline: 32131861]

55. Solem IKL, Varsi C, Eide H, Kristjansdottir OB, Børøsund E, Schreurs KMG, et al. A user-centered approach to an evidence-based electronic health pain management intervention for people with chronic pain: design and development of EPIO. J Med Internet Res 2020 Jan 21;22(1) [FREE Full text] [doi: 10.2196/15889] [Medline: 31961331]
56. Børøsund E, Mirkovic J, Clark MM, Ehlers SL, Andrykowski MA, Bergland A, et al. A stress management app intervention for cancer survivors: design, development, and usability testing. JMIR Form Res 2018 Sep 06;2(2):e19 [FREE Full text] [doi: 10.2196/formative.9954] [Medline: 30684438]
57. Li S, Jeffs L, Barwick M, Stevens B. Organizational contextual features that influence the implementation of evidence-based practices across healthcare settings: a systematic integrative review. Syst Rev 2018 May 05;7(1):72 [FREE Full text] [doi: 10.1186/s13643-018-0734-5] [Medline: 29729669]
58. Cranley LA, Cummings GG, Profetto-McGrath J, Toth F, Estabrooks CA. Facilitation roles and characteristics associated with research use by healthcare professionals: a scoping review. BMJ Open 2017 Aug 11;7(8) [FREE Full text] [doi: 10.1136/bmjopen-2016-014384] [Medline: 28801388]
59. Moullin JC, Sabater-Hernández D, Fernandez-Llimos F, Benrimoj SI. A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework. Health Res Policy Syst 2015 Mar 14;13:16 [FREE Full text] [doi: 10.1186/s12961-015-0005-z] [Medline: 25885055]

Abbreviations

CFIR: Consolidated Framework for Implementation Research
EPR: electronic patient record
HCP: health care provider
HRQoL: health-related quality of life

Edited by G Eysenbach, R Kukafka; submitted 13.07.20; peer-reviewed by C Pithara, C Jacob, G Cohen; comments to author 04.08.20; revised version received 09.10.20; accepted 18.03.21; published 08.04.21

Please cite as:
Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E
A Digital Patient-Provider Communication Intervention (InvolveMe): Qualitative Study on the Implementation Preparation Based on Identified Facilitators and Barriers
J Med Internet Res 2021;23(4):e22399
URL: https://www.jmir.org/2021/4/e22399
doi: 10.2196/22399
PMID: 33830063

Paper III

Original Paper

Feasibility of a Digital Patient–Provider Communication Intervention to Support Shared Decision-Making in Chronic Health Care, InvolveMe: Pilot Study

Berit Seljelid[1,2,3], MSc; Cecilie Varsi[1,4], PhD; Lise Solberg Nes[1,2,5], PhD; Kristin Astrid Øystese[6,7], MD, PhD; Elin Børøsund[1], PhD

[1]Department of Digital Health Research, Division of Medicine, Oslo University Hospital, Oslo, Norway

[2]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

[3]Department of Cooperation, Patient Education and Equivalent Health Services, Oslo University Hospital, Oslo, Norway

[4]Faculty of Health and Social Sciences, University of South-Eastern Norway, Drammen, Norway

[5]Department of Psychiatry & Psychology, College of Medicine & Science, Mayo Clinic, Rochester, MN, United States

[6]Section of Specialized Endocrinology, Department of Endocrinology, Morbid Obesity and Preventive Medicine, Division of Medicine, Oslo University Hospital, Oslo, Norway

[7]Department of Medical Biochemistry, Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

Corresponding Author:
Elin Børøsund, PhD
Department of Digital Health Research
Division of Medicine
Oslo University Hospital
PB. 4950 Nydalen
Oslo, 0424
Norway
Phone: 47 92667161
Email: elin.borosund@rr-research.no

Abstract

Background: Enhanced communication with health care providers (HCPs) can improve symptom management and health-related quality of life (HRQoL) for patients with chronic health conditions. Access to appropriate communication venues is needed to improve communication, however. As such, digital communication interventions mediated by patient portals carry the potential to support patient-provider communication and interaction and through this, also facilitate shared decision-making (SDM). The *InvolveMe* intervention was designed to provide patients with the opportunity to communicate symptoms and informational needs prior to consultation via digital assessment, including prioritizing what is most important to discuss with their HCPs, as well as to interact with HCPs through secure messages between outpatient visits.

Objective: The aim of this study was to assess the feasibility of the *InvolveMe* intervention by investigating acceptability, demand (ie, system use), and limited efficacy.

Methods: The study was designed as a single-arm, pre-post feasibility study combining quantitative and qualitative methods for data collection. Patients from an endocrine outpatient clinic were invited to use the *InvolveMe* intervention for 3 months, and HCPs administering *InvolveMe* were invited to participate in a focus group. Guided by descriptions of how to design feasibility studies by Bowen et al, feasibility was tested by exploring (1) acceptability, using data collected during recruitment from patient participants and nonparticipants (ie, declined to participate or did not meet study requirements), HCP experiences with recruitment, and the System Usability Scale (SUS); (2) demand via exploration of system use through extraction of system log data and HCP experiences with system use; and (3) limited efficacy testing, via exploration of potential effects from the Short-Form Health Survey (RAND 36), Hospital Anxiety and Depression Scale, and Health Literacy Questionnaire.

Results: Patient participants (N=23) were a median 54 (range 26-78) years old and primarily male (14/23, 61%). Nonparticipants (N=16) were a median 73 (range 55-80) years old and primarily male (12/16, 75%). The average SUS score was 72.2, indicating good system usability. Assessments were completed by 8 participants from home prior to outpatient visits. The assessments entailed various bodily symptoms and needs for information. Participants sent 17 secure messages related to patient administrative

matters, symptoms, and challenges. Focus group participants (N=4) were all female and registered nurses. Data were analyzed in 2 predefined themes: Acceptability and Demand. Acceptability included the subthemes intervention attractiveness and intervention suitability. Demand included the subthemes elements of SDM and intervention challenges and opportunities. All patient participants completed outcome measures at baseline, and 19 (19/23, 83%) completed outcome measures at 3 months. These preliminary efficacy findings were mixed and inconclusive.

Conclusions: The study design provided findings from both patient and HCP perspectives and supported feasibility of the *InvolveMe* intervention. The investigation of acceptability and demand supported the potential for remote SDM mediated by patient portals using assessments and secure messages.

Trial Registration: ClinicalTrials.gov NCT NCT04218721; https://www.clinicaltrials.gov/ct2/show/NCT04218721

(JMIR Form Res 2022;6(4):e34738) doi: 10.2196/34738

KEYWORDS

digital assessment; secure messages; patient portal; remote shared decision-making; chronic health conditions; assessment; portal; decision-making; chronic condition; chronic; communication; intervention; feasibility; pilot; acceptability; usage; demand; patient-reported outcome measures; PROM; outcome

Introduction

Living with a chronic health condition is demanding, as chronic health conditions often cause a variety of symptoms (eg, anxiety, depression, fatigue, loneliness, and sleeping problems) that may negatively affect health-related quality of life (HRQoL) [1-4]. In order to manage the various symptoms they experience, patients need to be able to communicate and interact with health care providers (HCPs) [5,6]. However, experiences with poor communication and interaction between patients and HCPs are common, which may interfere with symptom management and help-seeking [7,8]. Shared decision-making (SDM) may, with its focus on the patient and HCP working together to understand and address the patient's situation, carry the potential to improve patient-provider communication and interaction [9-11]. Traditionally, SDM has taken place in physical patient-provider encounters. However, information and communication technology (ie, eHealth) has provided new opportunities for SDM to be explored by improving access to care, enabling information exchange, supporting patient-provider communication, and building relationships [12].

Remote SDM may provide benefits by helping HCPs to understand which aspect of the patient's problem requires action and, together with the patient, identify the action required to solve the problem [13]. Patient portals present one way to engage patients and providers in remote SDM [14]. A patient portal provides patients with secure online access to their own health information, such as HCP's journal notes, medication lists, and opportunities for communication with their HCPs via secure messaging [15]. A review of patient portals [14] found that use of portals supported information sharing, improved preparation before visits, and supported patient-provider communication. Furthermore, portal use was found to encourage engagement in self-management of chronic disease [14,16] and empower patients in SDM [14]. However, the review rated the evidence related to portal use for improved communication, information sharing, and patient-provider relationships as low [14]. Secure messaging was identified as the most commonly reported portal feature, with patient-generated data by remote patient-reported symptoms (ie, assessments tools) less frequently reported [14].

Secure messages can also be an integral part of SDM, providing patients and HCPs with opportunities for contact, and benefits to patient-provider communication from using secure messages have been implied [17-19]. A review identified patients' main triggers for sending secure messages as accessibility to HCPs, self-management, and unmet needs [20]. Furthermore, the review highlighted that consequences of patient-provider secure messaging included patient empowerment, health promotion, and acquisition of uncertain answers [20]. Another review, focusing on use of secure messages, reported improved or comparable patient health outcomes for patients with chronic conditions when using secure messages compared with in-person care, describing quality of care as equivalent or improved for chronic conditions [21]. Use of secure messages among cancer patients has also been associated with improved survival and reduced treatment-related admissions, as well as reduced emergency visits [22]. In addition, the use of secure messages has been associated with improved glycemic level among patients with diabetes [23].

Remote assessment in preparation for health care visits can support symptom management [24], which is an important and integral part of chronic health care. Collecting patient-reported symptom data remotely can provide an opportunity to address the individuality and variability in symptoms over time among patients. Remote collection of patient-reported symptoms can also make the clinical workflow more efficient by not requiring patients to complete assessments in the waiting room or report symptoms within the limited time for consultation with HCPs [24]. A recent review found that there were few published studies examining integrated systems (ie, more than one system act together as one) for remote patient-reported symptoms, primarily feasibility and pilot studies, and subsequently limited evidence exists related to care and outcomes from using such integrated systems [24]. However, results from standalone systems (ie, a system that functions independently of other systems) for remote patient-reported symptoms are promising. The use of such systems has been reported to reduce symptom burden [25-27] and decrease emergency visits and in-hospital admissions [28]. Also, a review found improved symptom control, HRQoL, patient satisfaction, and patient-provider communication when patient-reported symptoms were used in

feedback to patients [29]. A review on the effectiveness of digital assessment tools to improve SDM [12] also found that communication, especially information sharing related to the patient's HRQoL and social aspects, as well as provider management of the patient's condition, improved through use. The review highlighted that digital assessment tools can be especially important for people with chronic health conditions [12].

Even though benefits of patient-provider communication and patient outcomes from the use of secure messages and remote patient-reported symptoms have been reported, research examining digital interventions combining secure messages and remote patient-reported symptoms through patients' portals to facilitate SDM is scarce. There are also patient barriers to the use of patient portals, such as lack of user-friendliness, technical support, education, and access to the internet [16,30]. Patient age may also play a role [30], and tailoring digital patient-provider communication interventions through the involvement of stakeholders representing end users (eg, patients or HCPs) appears crucial [31,32]. Stakeholders can provide insight to help tailor interventions to suit the local context (eg, hospital setting) and thus make interventions more acceptable, user-friendly, and less complex [31,32]. There are several factors that may impact intervention implementation, both relating to population and individuals [33]. For example, adaptation and tailoring to context are acknowledged as important implementation strategies [34], and creating an understanding of the context in which the intervention will be used can hence help avoid development of interventions that may fail during evaluation [33].

Seeking to address some of the issues raised by existing research, the current research team designed and developed a digital patient-provider communication intervention, called *InvolveMe*, aiming to support patients living with chronic health conditions, such as patients with nonfunctioning pituitary adenomas (NFPA) [35]. This single-arm pilot study aimed to assess the feasibility of the *InvolveMe* intervention by exploring acceptability, demand (ie, system use), and limited efficacy using a combination of qualitative and quantitative methods.

Methods

The *InvolveMe* Intervention

The *InvolveMe* intervention was developed to support SDM in the follow-up of patients with chronic health conditions, by being tailored to suit the patient group [35]. The intervention was further tailored to suit the intended context (ie, endocrine outpatient clinic) [36], in this study, patients with NFPA. *InvolveMe* provides patients with the opportunity to remotely report symptoms, needs, and preferences for care by completing an assessment (ie, predefined symptom list) in the hospital's patient portal. In addition, patients can use the secure messaging feature in the patient portal to interact with HCPs about symptoms and needs between hospital visits [35]. To allow for integration in patient portals, the *InvolveMe* assessment feature was developed as a Single Page Application (ie, web-technology) in line with the HL7 FHIR standard (ie, a specification for health care interoperability) [37]. The assessment part of *InvolveMe* is organized in 4 categories: (1) *bodily symptoms* (eg, pain, fatigue), (2) *psychosocial challenges* (eg, anxiety, loneliness), (3) *the need for work-related support* (eg, work-related understanding, whether the job exacerbates health), and (4) *the need for information* (eg, medication side effects, treatment change). The system allows for all symptoms and needs to be marked. In the first 3 categories, patients can rate how bothersome they find the symptom, while in *The need for information* category of the assessment, patients can request information from a predefined list. All symptoms and needs can be prioritized according to patients' preferences for care, on a scale from 0 to 10. The completion of the assessment generates a summary that is sent to the patients' HCPs (ie, as an attachment via the secure message feature).

In this study, the assessment was used as preparation prior to upcoming in-person outpatient consultations, as well as for feedback during the consultations. Secure messages were sent from, and received in, a shared message inbox managed by a dedicated moderator (ie, registered nurses). Routines for the moderator were established in dialog with the registered nurses to suit daily clinical workflow. The moderator would send a secure message through the patient portal approximately one week prior to the planned visit with an invitation for patients to complete an assessment (See Figure 1). *InvolveMe* was accessed by patient participants through the hospital patient portal and could be used on smartphones, tablets, or PCs. The shared message inbox had an automated message response, providing patients with contact information in case of medical emergency, response time, and contact information for the endocrine outpatient clinic. See Figure 2 for selected screenshots of the *InvolveMe* assessment feature from the patient interface. HCPs accessed the shared message inbox through hospital computers. See Figure 3 for screenshots showing the HCP interface of a completed, received assessment. The *InvolveMe* intervention was provided as an addition to standard care.

Figure 1. Invitation to complete the *InvolveMe* assessment from the patient interface.

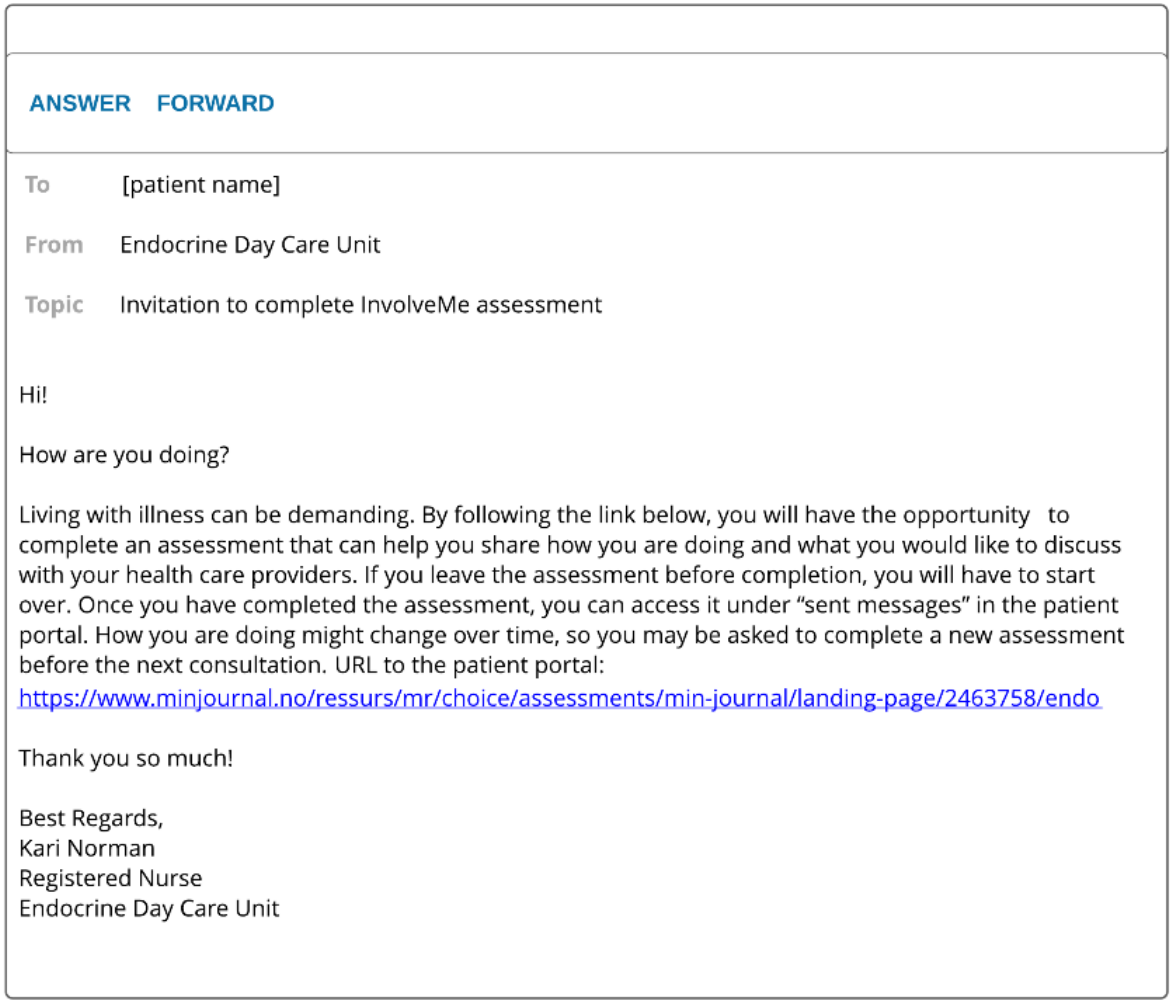


Figure 2. Screenshots of the *InvolveMe* assessment feature from the patient interface.

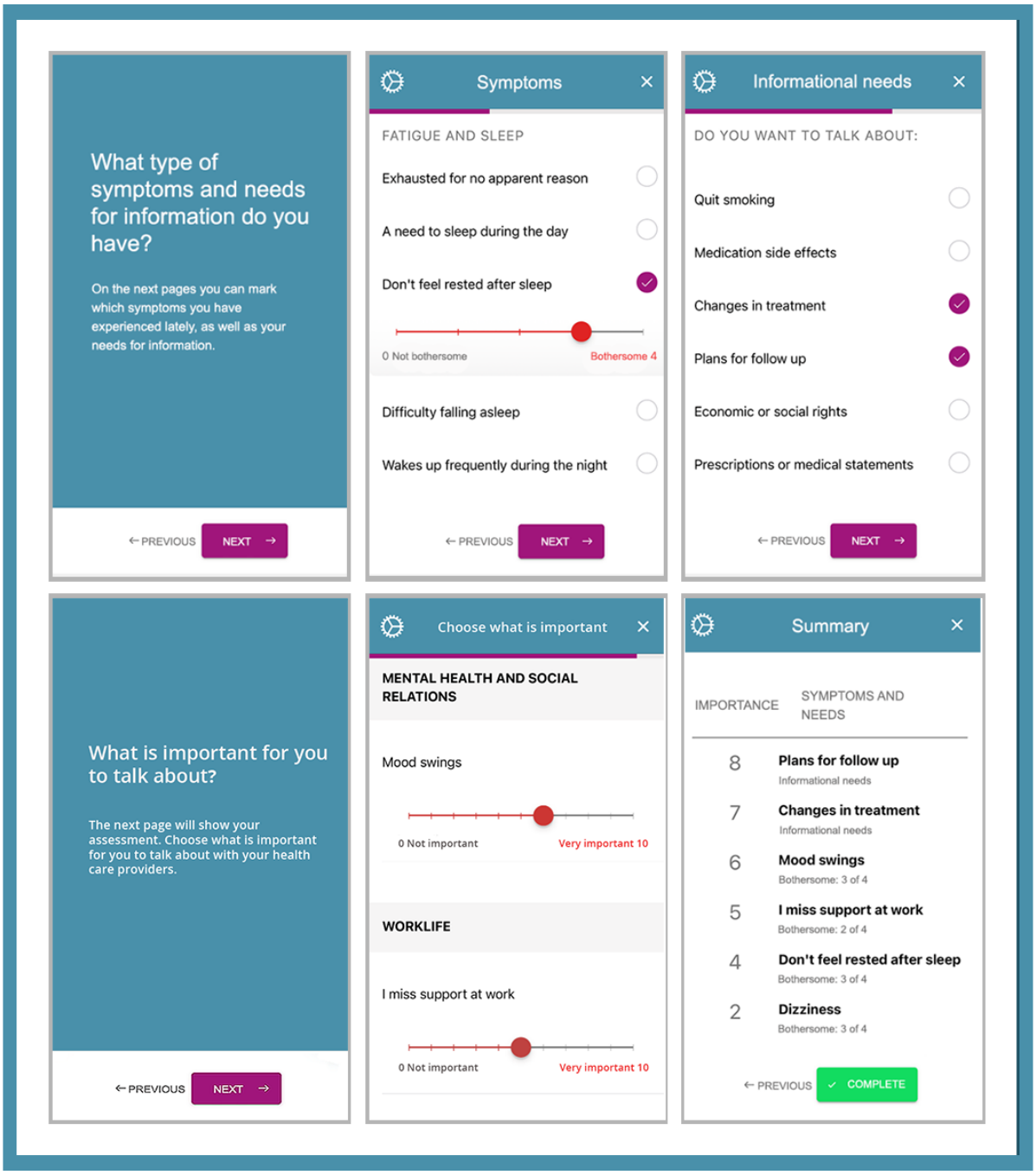
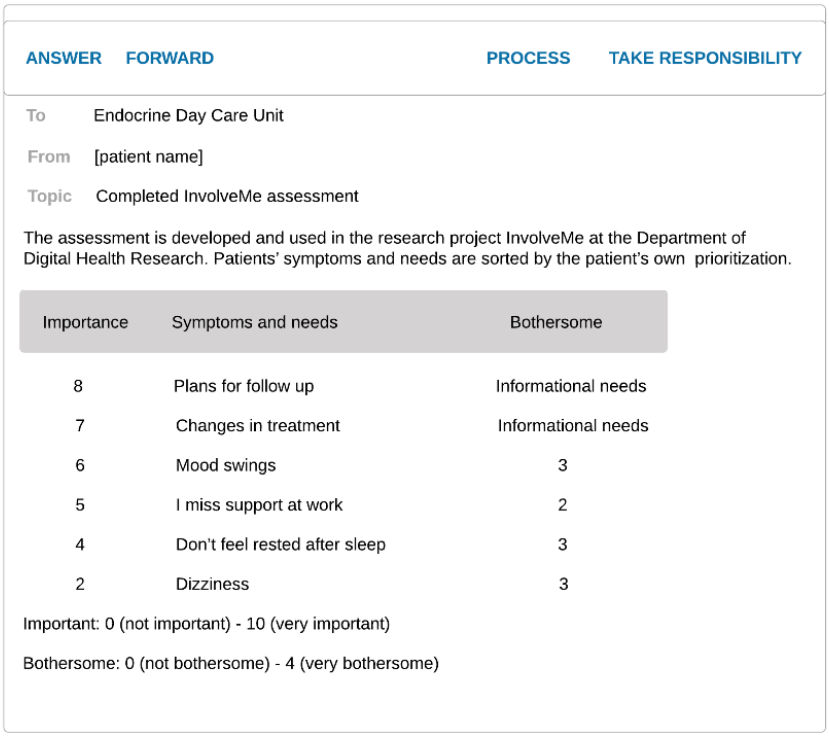


Figure 3. Completed assessment received from the health care professional (HCP) interface.



Study Design

In order to evaluate the effectiveness of complex interventions, initial testing and refinement of the intervention to ensure its feasibility are recommended [38]. Feasibility studies are important for producing findings that can be used to tailor interventions and examine recruitment settings [39]. This study was therefore designed as a pre-post feasibility study, with all patient participants receiving the *InvolveMe* intervention. In addition to the perspective of patients, the perspective of nonparticipants (ie, patients who declined to participate or did not meet study requirements) was included in this study to elaborate on potential barriers for use of eHealth interventions, which are of special interest for universal health care delivery, as provided in Norway. In addition, the perspective of HCPs was included to gain an understanding of intervention delivery and use in clinical practice. Feasibility conceptualization was guided by Bowen et al [39], exploring (1) acceptability (To what extent is *InvolveMe* judged as suitable, satisfying, or attractive?), (2) demand (Exploration of the actual use of the *InvolveMe* intervention and experiences with use from the HCP perspective), and (3) limited efficacy testing (Does the tool show promise of being successful with the intended population?) [39]. For the study purpose, this study combines quantitative and qualitative methods for data collection.

Setting, Participants, and Recruitment

The participants in this study were patients with NFPA and HCPs recruited from an endocrine outpatient clinic at a university hospital in Norway. NFPA are benign pituitary tumors, with which patients frequently experience a long period of slow deterioration of their health status before undergoing surgery, and they usually experience a variety of symptoms in the aftermath [40-42], which negatively impacts HRQoL [41,42]. Patients experience individuality and variability in symptoms, including pain, fatigue, sleeping problems, anxiety, and depression, and they may also face challenges related to visual limitations, fear of recurrence, distressing thoughts, loneliness, and frustration [41,43]. Patients with NFPA need and receive long-term follow-up in outpatient care after surgery. The initiative to include this patient group came from the endocrine outpatient clinic participating in this study, which recognized a need to improve patient follow-up after surgery.

Eligibility criteria for inclusion of patients in the study were (1) a diagnosis of NFPA (anywhere in the disease trajectory); (2) receiving treatment and follow-up from the study endocrine outpatient clinic; (3) ≥18 years of age; (4) able to understand oral and written Norwegian; (5) access to a smartphone, tablet, or personal computer; (6) access to the internet with a secure access key (BankID).

Participating HCPs were registered nurses responsible for care and follow-up of NFPA patients at the endocrine outpatient clinic. Some of them had previously participated in studies related to the development and intervention tailoring of *InvolveMe* [35,36].

Ethical Considerations

The study was approved by the Regional Committee for Medical and Health Research Ethics (2018/2201) and the Oslo University Hospital Institutional Review Board equivalent function (2017/9223). Informed consent was obtained from all participants.

Study Procedure

Registered nurses and physicians at the endocrine outpatient clinic identified eligible patient participants based on study inclusion criteria, and the registered nurses asked if these

patients were interested in receiving information about the study. Some of the patients were contacted and asked prior to upcoming consultations; others were asked during consultations. Those interested in receiving more information were contacted by the first author (BS) by phone and provided with information about the study purpose and procedures. Those interested in study participation signed a digital information and consent form. Patient-reported outcome measures were collected online through a secure server at Services for Sensitive Data (TSD; University of Oslo). After completing baseline outcome measurements, patient participants were contacted by the first author and informed how to register and log into the patient portal to access the *InvolveMe* features. After the first log on, HCPs sent a welcome message with information about the project to the patient participant. Patient and HCP participants could contact the first author by phone during the day on weekdays in case of questions. All contacts with participants were logged. The patient participants were informed to direct emergency issues or non-study-related questions to their primary care team or the nearest hospital or urgent care treatment unit.

HCPs at the endocrine outpatient clinic were provided with information about the study, and those willing to participate were included.

Data Collection and Outcome Measures

Timeframe

Data collection from patient participants was carried out from April 2020 until October 2020, when an unexpected incident led to the closure of the hospital patient portal and subsequently closure of the study before the planned study period completion. Outcome measures were collected from patient participants prior to them receiving access to *InvolveMe* and after 3 months of access. Numbers of assessments and secure messages, as well as the content in the secure messages, were also collected. Data from HCP participants were collected through a digital focus group in December 2021.

Sociodemographics and Disease-Related Measures

Information about patient participants' age, sex, level of education, work, income, and year of diagnosis and whether participants had received surgery were collected at baseline. HCP participants were all female registered nurses working in the endocrine outpatient clinic.

Acceptability—Patient Perspective

To explore to what extent the intervention was judged as satisfying or attractive, the first author's experiences from introducing patient participants to the *InvolveMe* intervention, including registration and login procedures in the patient portal, were written down. In addition, patient participants completed the System Usability Scale (SUS), a 10-item survey that provides a comprehensive assessment of subjective usability [44], at the 3-month follow-up. The SUS is a widely used subjective rating tool with acceptable reliability and validity [45-47]. Data from patients who declined to participate in the study (ie, nonparticipants), including age, sex, and reason for not participating in the study, if given unsolicited, were collected.

Demand (System Use)—Patient Perspective

Details of actual system use of the *InvolveMe* intervention were extracted from the patient portal. These data included the number and content of secure messages sent by patient participants, number of assessment invitations sent from HCPs, and number of and content in the assessments completed by patient participants. In addition, reasons for noncompletion of assessments were collected by the first author by phone (ie, written down).

Acceptability and Demand—HCP Perspective

The HCP participants were invited to share their experiences in a focus group that was conducted digitally due to national in-person meeting restrictions during the COVID-19 pandemic. The focus group interview guide consisted of open-ended questions based on operationalization of acceptability and demand [39] after dicussions and consensus of the research team. To explore to what extent the intervention was judged as attractive, suitable, and satisfying (ie, acceptability), participants were asked questions about experiences with recruitment and system usability. To explore experiences with system use (ie, demand), participants were asked questions about the use of secure messages and assessments. The focus group was facilitated by the first (BS) and last (EB) authors, lasted 45 minutes, was recorded with a digital voice recorder, and was transcribed verbatim by the first author.

Limited Efficacy Testing

To explore the feasibility of outcome measures and whether *InvolveMe* could show promise of being successful with the intended population, as well as explore preliminary indications of the potential impact of using *InvolveMe*, participants completed the following outcome measures: anxiety and depression, HRQoL, and health literacy.

Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HADS), a 14-item measure of anxiety and depression [48]. Items were rated on a 4-point scale (0-3), with a total score ranging from 0 to 42. The HADS is divided into 2 subscales: anxiety (HADS-A; 7 items) and depression (HADS-D; 7 items).

HRQoL was measured with the noncommercial RAND 36 survey, a 36-item HRQoL measure of physical, emotional, cognitive, role and social functioning, physical health, and general and global health [49,50]. Scores can range between 0 and 100 for all subscales, with lower scores indicating higher disability (0=maximum disability, 100=no disability).

Health literacy was measured with the Health Literacy Questionnaire (HLQ) [51]. The 44-item questionnaire includes 9 independent scales, with each scale including 4 to 6 items. The first 5 scales (Part 1 of the HLQ) are scored using response options indicating the level of agreement to items (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree), while the 4 remaining scales (Part 2 of the HLQ) report on the capacities to undertake different tasks (1=cannot do or always difficult, 2=usually difficult, 3=sometimes difficult, 4=usually easy, 5=always easy) [51].

Statistical Analysis

Statistical analyses were completed using SPSS version 25 (IBM Corp, Armonk, NY). Data on baseline characteristics and perceived usefulness are presented as medians and ranges for continuous variables and as proportions with percentages for categorical variables. Dependent paired *t* tests were used to analyze pre-post intervention changes. All tests were 2-sided, and *P* values <.05 were considered statistically significant.

Qualitative Analyses

Data from secure messages sent by patient participants and data from the focus group with HCP participants were analyzed using thematic analysis inspired by Braun and Clarke [52]. The analysis process was led by the first author (BS) in close collaboration with the last author (EB). Data from 17 secure messages (ie, written text) were read by the first and last authors and coded inductively by the first author [52]. Quotes (ie, written text) to illustrate the content of the secure messages were then chosen by the first and last authors and discussed within the research team.

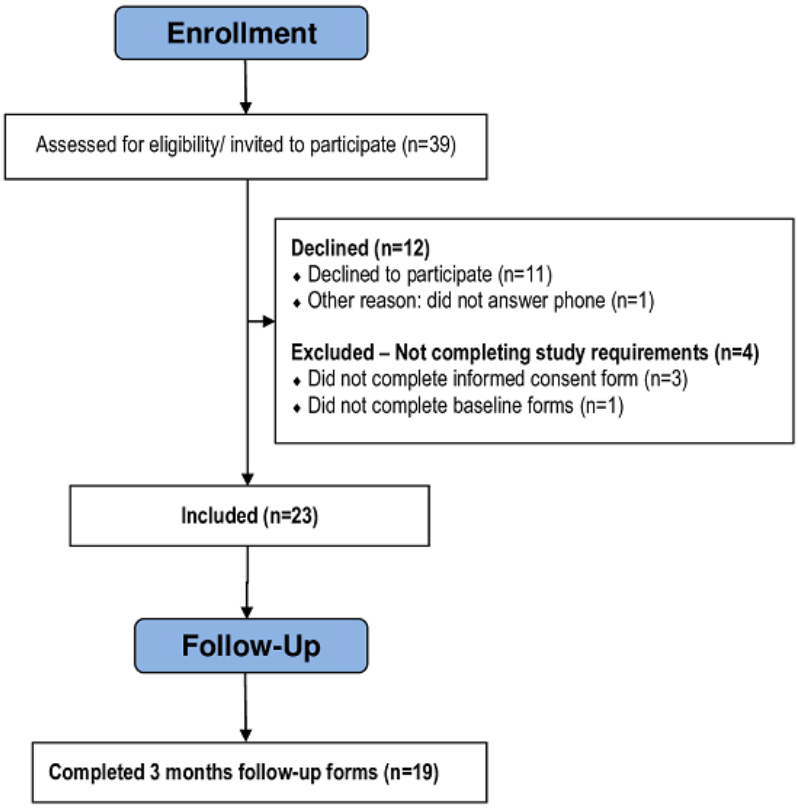
The first and last authors read the transcript from the HCP focus group to become familiarized with the data [52]. Then, the 2 authors used the interview guide to code the transcript deductively into 2 predefined codes: (1) acceptability and (2) demand. Next, subthemes within each main theme were identified. Themes and subthemes were then re-examined, and quotes to illustrate each subtheme were finally chosen and discussed within the research team [52].

Results

Recruitment, Participant Flow, Sample Description

Of 39 patients with NFPA who were assessed for eligibility, 23 (59%) agreed to participate (ie, patient participants), and 16 (41%) declined or did not meet study requirements (ie, nonparticipants). The 23 participants who were included in the study completed baseline measures and received the *InvolveMe* intervention. Of these, 19 participants completed the 3-month follow-up outcome measures. Due to technical issues with the hospital patient portal, the study closed after 6 months, which meant that 4 of the final included participants had limited time (ie, 1 to 4 weeks) to use *InvolveMe*. These 4 were hence not invited to complete the 3-month follow-up outcome measures. One of these participants completed and returned a secure assessment, but none of them used the secure message option in *InvolveMe*. Figure 4 provides details of the study recruitment and participant flow.

Figure 4. Recruitment flowchart.



Patient participants (N=23) were a median 54 (range 26-78) years old at inclusion. Of these, 17 (74%) had completed surgery. Participants were mostly male (14/23, 61%), and almost one-half (10/23, 44%) noted elementary school as their highest level of education (see Table 1 for details). The nonparticipants (N=16) were a median 73 (range 55-80) years old and mostly male (12/16, 75%). HCP participants (N=4) were all female and registered nurses working at the endocrine outpatient clinic.

Table 1. Patient participants' baseline demographics and illness characteristics (N=23).

Characteristics	Results
Age (years), median (range)	54 (26-78)
Sex, n (%)	
Female	9 (39)
Male	14 (61)
Marital status, n (%)	
Married/cohabitating	15 (65)
Single/divorced	8 (35)
Education, n (%)	
Elementary/high school	10 (44)
University/college ≤4 years	7 (30)
University/college >4 years	6 (26)
Employment status, n (%)	
Full-time/part-time work	7 (30)
Sick leave/disability benefits	10 (44)
Retired/other	6 (26)
Income (NOK[a]), n (%)	
200,000-399,999	6 (26)
400,000-599,999	7 (30)
600,000-799,999	0 (0)
800,000-1,000,000	2 (9)
>1,000,000	8 (35)
Surgery, n (%)	17 (74)
Months since surgery[b], median (range)	11 (1-39)

[a]NOK: Norwegian krones; a currency exchange rate of NOK 1=US $0.90 is applicable.

[b]n=17.

Acceptability—Patient Perspective

Among the 23 patients receiving the *InvolveMe* intervention, 7 (30%) needed additional technical support and assistance beyond the 2 planned contacts during study inclusion to be able to complete study requirements (ie, to complete the digital consent form, complete the digital baseline forms, or register in the patient portal). There were no questions from participants related to completing outcome measures after the initial guidance on how to complete the digital forms. At the 3-month follow-up, the 19 participants also completed the SUS. Mean system usability (ie, SUS) score was 72.2 (SD 14.6), which equals good system usability [44]. Of the 16 nonparticipants, 4 (25%) were positive toward participating but did not complete study requirements such as informed consent or baseline outcome measures. Reasons for declining were mainly described as not having a smartphone (7/16, 44%), feeling overwhelmed (2/16, 13%), or that they thought the intervention would be difficult to use (2/16, 13%). Some stated that it could be challenging to participate in a digital intervention, and some were not familiar with certain terms such as “smartphone.”

Demand (System Use)—Patient Perspective

During the 3-month study period, 43% (10/23) used the *InvolveMe* intervention (ie, used the secure message, completed the assessment, or both) before study closure.

Secure Messages

Of the included patient participants, 4 (4/23, 17%) sent a total of 17 secure messages (ie, assessments not included) during the study. HCPs responded to all, mainly by messages, some by phone or in-person in the upcoming consultation. The content of the messages from participants were sorted into 2 codes: (1) Patient Administrative Matters and (2) Symptoms and Challenges.

For the “Patient Administrative Matters” code, the 9 secure messages mainly concerned a change in the scheduled time of a hospital appointment, prescriptions for medications, or other practical matters. One participant wrote:

> *I have called the pharmacy for a while, but they have not received my medicine. Think the medicine is called something like [medication name]. I was advised by*

> *the doctor to take it during my appointment in May. Have called you too, but no answer.* [Participant 11]

For the "Symptoms and Challenges" code, the 8 secure messages concerned various symptoms and challenges experienced by the participants. The messages centered on a need for guidance (ie, including information and advice) regarding how to manage various symptoms and how to live with the chronic health condition. One participant wrote:

> *What should I feel or look for when I work with challenging things over time, or to see the degree to which I can work-out. Previously I have been told to double the dose of [medication] when needed, but when is that? What are the risks associated with the procedures that have been performed?* [Participant 5]

Another participant wrote:

> *I am still on sick leave, as I feel VERY and UNUSUALLY tired. I get easily tired after doing something. Have also had strict restrictions about making sure I take it easy, not bending forward, sleeping in at least a 30 degrees upwards position, not just showering hot, not eating hot/spicey food etc. (...) Have today raised hemoglobin to [X], as I have lost a lot of blood which may have affected the situation? (...) I'm not quite sure what to do to feel better?* [Participant 16]

Assessments

HCPs sent invitations to complete intervention assessments to all patients with upcoming consultations. Of the 13 invitations sent, 8 (62%) participants completed the assessments prior to the scheduled consultation. In a phone conversation, 1 patient said about the assessment:

> *So incredibly beneficial to be enabled to meet prepared.* [Statement, Participant 17]

Patient participants marked their symptoms and needs in all 4 assessment categories. The categories *Bodily symptoms* and the *Need for information* were marked in all assessments. The most prevalent need for information was about the disease trajectory, marked by 7 (7/8, 88%) participants. The number of marked symptoms and needs varied from 3 to 17 (median 6.5). See Table 2 for an overview of content in the completed assessments.

Table 2. Overview of the content in completed assessments (n=8).

Assessment main categories	Completed individual assessments							
	1	2	3	4	5	6	7	8
Bodily symptoms	Y[a]	Y	Y	Y	Y	Y	Y	Y
Psychosocial challenges	N[b]	Y	Y	Y	Y	N	Y	Y
The need for work related support	N	N	Y	N	N	N	Y	N
The need for information	Y	Y	Y	Y	Y	Y	Y	Y

[a]Y: yes.

[b]N: no.

Reasons for not completing the assessment varied: The upcoming consultation was rescheduled; the assessment was not received by the user due to technological difficulties; and one participant "felt fine" and felt no need to complete an assessment. Two participants did not receive an assessment notification in the patient portal and were therefore not aware of the assessment invitation. Patients had to register their contact information in the hospital patient portal in order to receive notifications there, and a failure to do so could potentially explain why these participants did not receive a notification.

Acceptability and Demand—HCP Perspective

Findings from the focus group with HCP participants were analyzed into the 2 predefined themes of Acceptability and Demand.

Acceptability

Participating HCPs provided a variety of feedback on the intervention, constituting 2 subthemes: (1) Intervention Attractiveness and (2) Intervention Suitability.

In the Intervention Attractiveness subtheme, HCP participants described their experience with the intervention in favorable words and phrases. They described the availability that the intervention provided for the patients as favorable, being able to contact HCPs when they needed to. They also stated that the intervention provided a unique option, especially for patients with complex health issues or heavy symptom burden. They stated that they would have liked to use the intervention for a longer period than the actual study period and said they would like to be a part of and use the intervention in a potential future clinical trial. Regarding recruitment of patient participants, the HCPs described most patients as interested and easy to recruit for this study. As one HCP stated: "...it was not difficult to recruit patients at all, they were, many were positive..."

In the Intervention Suitability subtheme, participating HCPs described the need for a secure and safe place for patients and HCPs to be able to communicate digitally and stated that the intervention was suited for this purpose. They highlighted that their, as well as the patient participants', previous involvement in the process of intervention development and tailoring was an important factor to make the intervention suited to purpose. However, based on experiences of recruiting participants for the pilot study, the HCPs were not entirely convinced that the

intervention was suitable for older patients. One HCP stated that older patients sometimes lacked the necessary equipment (eg, a smartphone) to participate, and reflecting on this, other HCPs contemplated whether a pre-educational group could be useful for eligible patient participants that needed guidance on how to use the intervention. The participating HCPs described themselves and the participating patients as satisfied with the *InvolveMe* intervention and described how patients had provided positive feedback to them about the intervention. One HCP stated that "...the participating patients gave the impression of being very satisfied, they thought it was exciting, and nice, that they could send questions."

Demand

The participating HCPs described the actual use of the *InvolveMe* intervention, and findings constituted 2 subthemes: (1) Elements of SDM and (2) Intervention Challenges and Opportunities.

In the Elements of SDM subtheme, HCPs described how the assessment helped patient participants sort their thoughts before the hospital visits and stated that it acted as a way of providing information about common symptoms and needs. One HCP described the assessments completed prior to consultation as making it easier to address sensitive topics in in-person conversations with patients. This was supported by the other participating HCPs. Some of them described how patients' identification and prioritization of topics important to them contributed to a focus in the consultation conversation, centering around what was most important to discuss for the patients. The HCPs described how the assessments had contributed to change their perspective on what was important to discuss with patients and said that, through this information exchange focusing on patients' current situations, a more individualized follow-up was facilitated based on the patient's needs. As described by one of the HCPs:

> *...the most important thing is that it is user centered, that patients dare to raise issues that are important to them, so that we can focus on what is important, for them to benefit the most from the health care service, this is very important and very rewarding.*

Also, one HCP described how the intervention provided support and contact for patients who felt unprepared for the aftermath of surgery. This was also supported by the other participating HCPs.

In the Intervention Challenges and Opportunities subtheme, participating HCPs described the intervention as time-consuming initially, as they had to learn a new system (ie, hospital patient portal) and develop new routines to be adapted into the daily clinical workflow. However, they stated that, after having learned to use the system, it was no longer time-consuming but rather something that could be executed in between other daily tasks. As stated by one HCP:

> *...we had to learn a new system, which we spent some time on, but I think it was quite easy to learn the system, and it quickly became the routine.*

One participating HCP also stated that they spent some time between themselves discussing potential responses to patients before replying to the secure messages from patients. They reported considering this as something positive, providing quality-assured responses to patients and also contributed to the development of care though contributing to professional discussions. One participant stated that the assessment could potentially even provide support for new HCPs with little prior knowledge about the patient group. They also highlighted, based on feedback from patients, that access to the intervention was valued, even by the patients not using the intervention (ie, participating nonusers), stating that interventions were often used the most by those with complex health issues or heavy symptom burden.

Limited Efficacy Testing: Pre-Post Intervention Results

Pre-post intervention findings at the 3-month follow-up revealed statistically significant increases in symptoms of anxiety (mean difference [MD] 3.9, 95% CI 2.3-5.5) and depression (MD 2.7, 95% CI 0.9-3.8) for the participating patients. Time since surgery had no impact on these results. HRQoL findings indicated a statistically significant improvement for the "Role Physical" subscale (MD 25.0, 95% CI 3.0-47.0) but not for the 7 other subscales. There was a high degree of heterogeneity in the data, with large variance and subsequently broad CIs for the HRQoL subscales (eg, the "Role Emotional" subscale improved by 17.5, but due to the large variance, the findings were not statistically significant). Scores related to health literacy remained stable, with no statistically significant changes from baseline to follow-up. See Multimedia Appendix 1 for details.

Discussion

Principal Findings

Findings from this feasibility pilot study gave insights related to the acceptability and demand of the *InvolveMe* intervention. Exploration of intervention acceptability identified good system usability, and the findings also provided insights regarding patients' reasons for not participating, as well as demographic factors impacting intervention participation (eg, older age among nonparticipants). Furthermore, some participants appeared to struggle with understanding terms used to describe study participation. The examination of demand (ie, system use) suggests that completed assessments and use of secure messages may respectively act as preparation for upcoming visits and provide patients with the opportunity to request guidance on symptom management. The limited efficacy testing showed mixed findings in terms of HRQoL, anxiety, and depression but indicated a study population with high health literacy.

This study provided insight into opportunities for remote SDM through use of secure messages and digital assessments mediated by a patient portal. During the study period, only 17% of participants used the secure message feature. However, simply having the access and opportunity to communicate with HCPs may be of benefit to patients, even without using this option [53]. This was as expected and also suggested in focus group with HCPs. About half of the secure messages sent in the study contained questions related to symptom and treatment complication guidance, which may indicate that the secure messages were used by those who experienced a heavy symptom

burden at the time. This was also pointed out by the HCPs during the focus group.

Existing research has found patients to be interested in using secure messages with their HCPs and that patients prefer the convenient and asynchronous aspects provided by secure messaging through portals [14]. The modest use of secure messages in the current study could have been due to the brief study timeframe, and providing patient access over a longer period of time could have provided increased knowledge and experience related to the use of secure messages. Some patients may also lack interest in communicating through portals as they are satisfied with the existing in-person communication [14]. Health literacy is another factor that may play a role in patient portal use, as research has pointed to patients with lower literacy skills as being less likely to use patient portals [14]. However, the participants in this study did not have low literacy skills, quite the contrary.

The assessments collected prior to consultation in this study revealed a wide range of symptoms and needs experienced by the patient participants, which may help identify important topics and priorities for patient-provider discussions and SDM, as also pointed out in the focus group with HCPs. Such assessments may address the individuality and variability in symptoms, aiding patients with communicating their symptoms, needs, and preferences for care to their HCPs [54,55]. In all completed assessments, the study participants used the opportunity provided to request information. This could help improve the provision of tailored information to suit the patients' situations and thus support patients in making choices about their lifestyle, when ready to do so. It has been suggested that, when patient preferences are asserted, HCPs may manage patient concerns and health conditions more effectively [12]. In line with SDM, the *InvolveMe* assessment feature, providing insight into patients' current situations, may facilitate collaboration between the patient and provider to mutually understand and address the patient's situation [9-11].

In this study, 41% of the eligible patients declined to participate or did not complete study requirements (ie, nonparticipants), which is a low percentage of people declining compared with similar studies examining eHealth interventions (ie, 60%-68%) [56,57]. However, evidence on how patients accept eHealth interventions is limited [58], and increasing knowledge related to reasons for nonparticipation (eg, user friendliness, complexity) is necessary in order to improve intervention acceptance.

Nonparticipants in this study were older (median 73 years) than the participants (median 54 years), corresponding with findings from existing research [56,59]. Increased age has been described as contributing to lower levels of digital skills [60,61], a known barrier for adopting new technology [30,62]. Along these lines, a review pointed to substantial health equity disparities in patient portal use, where older persons, persons with low socioeconomic status, persons with low health literacy, and persons with chronic health conditions appear to use portals less often [62].

In this study, some of the eligible patient participants struggled to understand some of the terms used to describe the study participation in detail. Use of technology may inadvertently create health equity concerns by not paying sufficient attention to the social determinants of health during the implementation process [62]. Instead of focusing on barriers for portal use, which may place responsibility on patients already experiencing health disparities, one should focus on developing interventions that are easy to use in order to reduce disparities [62,63]. Findings from this study, as well as existing research on strategies to minimize potential disparities in use [14,63,64], point to the need to develop strategies to increase the number of participants in future studies.

System usability was rated as good but not excellent in this study, which indicates room for intervention improvement. However, using the SUS [44] to measure usability may not have been ultimate in this study, as participants most likely rated the overall system usability, including all the features of the hospital patient portal, not the specific features of the *InvolveMe* intervention alone. When aiming to measure usability and evaluate features integrated into an existing system, the SUS may not be specific enough, and other or additional usability measures should be considered.

The psychosocial outcome measures in this study were primarily included to test feasibility of the measures (eg, are they easy to answer digitally, do they capture changes). Even though some participants initially struggled with completing the outcome measures, all 19 participants receiving the 3-month follow-up measures completed these. There were no questions from the participants related to outcome measures after the initial guidance on how to complete these, indicating satisfactory study routines for this aspect. The noted statistically significant increases in anxiety and depression during the 3-month study period were unexpected. These findings could however be related to the ongoing pandemic during this study, and a recent study revealed that the general population was almost 3 times more likely to suffer from symptoms of anxiety and depression due to the pandemic [65]. The current study period coincided with a national decrease in COVID-19 cases around baseline (ie, May 2020 to June 2020) and a national increase in cases around the 3-month follow-up (ie, August 2020 to September 2020), which might explain the pre-post increase in symptoms of anxiety and depression. However, given the feasibility nature as well as the limited number of participants in the study, efficacy conclusions cannot be made.

Compared with indicators of health literacy (ie, *Active engagement with HCPs* and *Read and understand health information*) from a population-based survey (ie, including people with chronic health conditions) [8] as well as general population participants [66], health literacy scores from this study indicate a study population with high health literacy. Reasons for these findings are not evident, although participants in this study were younger compared with nonparticipants, and higher age has been associated with lower health literacy [60,67].

Even though the closure of the hospital patient portal during this study caused premature study closure, the software development of the *InvolveMe* assessment feature is in accordance with a standard enabling the completed assessment to be sent as an attachment via the secure message feature in

the national patient portal [68] as well. Use of standards for provision of eHealth systems has been recognized as a key factor for successful implementation [31,32], and the importance of developing new software features and systems according to established standards are clearly emphasized through this feasibility pilot study.

The COVID-19 pandemic brought an urgent need for remote care through secure, technical systems and as such, boosted the use of the national patient portal [68] in various ways. For example, as of March 2020, all COVID-19 test results were accessible to Norwegian citizens through the national patient portal, and a number of HPCs, including general practitioners, began using the national portal for most nonurgent care and follow-up. This increase in use of eHealth systems as a consequence of the pandemic has also been identified through a recent review, highlighting how the transformation of care from in-person to virtual or remote accelerated during this time [69]. The *InvolveMe* intervention, incorporated into the national patient portal, may provide features currently not used in the national portal, further promoting patient-provider communication and interaction and serving the need for remote care systems.

Study Limitation and Strengths

This study has several limitations. First, the study was designed to assess the feasibility of a digital patient-provider communication intervention to support patients with NFPA. All patient participants received access to the intervention, without randomization, and statements regarding the effectiveness of the intervention cannot be made. Efficacy testing was however not a major part of this feasibility pilot study. Second, the participants were recruited through a collaborating partner (ie, endocrine outpatient clinic), and it may therefore be assumed that the participating sample were highly motivated and the study cannot conclude whether patients with NFPA in general would be interested in, or benefit from, such an intervention. Indications on feasibility are however promising. Third, the urgent closure of the hospital patient portal led to an unpredictably shortened study period, which might have affected study outcome. Fourth, the focus group with HCPs was conducted 1 year after the pilot study was finished, and all HCP participants were registered nurses. This might have affected recall of experiences, and other additional professionals could have elaborated even more on questions asked in focus group.

This study also has several strengths. First, both patient and HCP perspectives are included in the study, underlining the importance of stakeholder involvement when aiming for real world implementation [30-32]. Second, all eligible patients were invited for participation. This provided insight into who would be interested in the opportunity to assess symptoms and information needs prior to consultations and use secure messages to communicate digitally with HCPs between consultations, as well as reasons for nonparticipation. Such information could be used to tailor educational material and study routines for participant follow-up during the study. Third, the data collection related to acceptability and demand provided essential information for tailoring of the *InvolveMe* intervention as well as study routines in preparation for a future clinical trial.

Future Directions

Through exploration of acceptability, demand (ie, system use), and limited efficacy testing, this study established feasibility of the digital patient-provider communication intervention *InvolveMe*. Findings provided ideas and suggestions for further tailoring in order to prepare for a future clinical trial, such as the development of study-specific questions (ie, in addition to SUS) [44]; use of simple, plain language in the recruitment processes and patient education material; as well as having a dedicated support person involved in the study. In the study, some participants struggled with completing study requirements. Future research should aim to incorporate ways to help adults not familiar with technology to become familiar with and adopt digital interventions.

The increasing number of persons living with chronic health conditions entails, in addition to individual personal challenges, increases costs and demands for resources, representing a major challenge for health care services. Therefore, future research should continue to explore how assessments and secure messages mediated through patient portals can promote and support remote SDM in a variety of chronic health conditions.

Finally, in order to examine actual effects of digital patient-provider communication interventions such as *InvolveMe*, larger-scale clinical trials are needed.

Conclusions

This feasibility pilot study explored how a digital patient-provider communication intervention, *InvolveMe*, could be of use for patients living with chronic health conditions, such as patients with NFPA. Feasibility was established, and the importance of developing software according to given standards was highlighted. Given the findings showing that patient participants used the secure assessment and messages to communicate about bodily symptoms, needs for information, and challenges they experienced, the use of patient-provider interventions such as *InvolveMe* has the potential to facilitate SDM by enhancing accessibility and information exchange and to strengthen the patient-provider relationship for patients living with chronic health conditions.

Acknowledgments

This study was funded by the Norwegian Nurses Organization (Grant #847382; principal investigator EB). The authors would like to thank the patients who participated in the study. The authors would also like to thank the heads of the participating departments, Aud E. Stenehjem and Jens Bollerslev, as well as the health care providers at the Endocrine Day Care Unit, Rikshospitalet, Oslo University Hospital, for their support and encouragement in the research process. Also, the authors would like to thank the patient representatives participating throughout. Finally, the authors would like to thank the research team

members, especially Marianne Ollivier and Elise Flakk Nordang from the content development group and the design and software team by Per Tømmer, at the Department of Digital Health Research at Oslo University Hospital, for their contribution throughout the project process.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Pre-post intervention changes.
[DOCX File , 16 KB-Multimedia Appendix 1]

References

1. Saarni SI, Härkänen T, Sintonen H, Suvisaari J, Koskinen S, Aromaa A, et al. The impact of 29 chronic conditions on health-related quality of life: a general population survey in Finland using 15D and EQ-5D. Qual Life Res 2006 Oct;15(8):1403-1414. [doi: 10.1007/s11136-006-0020-1] [Medline: 16960751]
2. Burström K, Johannesson M, Diderichsen F. Health-related quality of life by disease and socio-economic group in the general population in Sweden. Health Policy 2001 Jan;55(1):51-69. [doi: 10.1016/s0168-8510(00)00111-1] [Medline: 11137188]
3. Heyworth ITM, Hazell ML, Linehan MF, Frank TL. How do common chronic conditions affect health-related quality of life? Br J Gen Pract 2009 Nov;59(568):e353-e358 [FREE Full text] [doi: 10.3399/bjgp09X453990] [Medline: 19656444]
4. Wu M, Brazier JE, Kearns B, Relton C, Smith C, Cooper CL. Examining the impact of 11 long-standing health conditions on health-related quality of life using the EQ-5D in a general population sample. Eur J Health Econ 2015 Mar;16(2):141-151 [FREE Full text] [doi: 10.1007/s10198-013-0559-z] [Medline: 24408476]
5. Rasmussen GS, Kragballe K, Maindal HT, Lomborg K. Experience of being young with psoriasis: self-management support needs. Qual Health Res 2018 Jan;28(1):73-86. [doi: 10.1177/1049732317737311] [Medline: 29192872]
6. Wahl AK, Langeland E, Larsen MH, Robinson HS, Osborne RH, Krogstad A. Positive changes in self-management and disease severity following climate therapy in people with psoriasis. Acta Derm Venereol 2015 Mar;95(3):317-321 [FREE Full text] [doi: 10.2340/00015555-1939] [Medline: 25110924]
7. May CR, Cummings A, Myall M, Harvey J, Pope C, Griffiths P, et al. Experiences of long-term life-limiting conditions among patients and carers: what can we learn from a meta-review of systematic reviews of qualitative studies of chronic heart failure, chronic obstructive pulmonary disease and chronic kidney disease? BMJ Open 2016 Oct 05;6(10):e011694 [FREE Full text] [doi: 10.1136/bmjopen-2016-011694] [Medline: 27707824]
8. Friis K, Lasgaard M, Osborne RH, Maindal HT. Gaps in understanding health and engagement with healthcare providers across common long-term conditions: a population survey of health literacy in 29,473 Danish citizens. BMJ Open 2016 Jan 14;6(1):e009627 [FREE Full text] [doi: 10.1136/bmjopen-2015-009627] [Medline: 26769783]
9. Hargraves I, LeBlanc A, Shah ND, Montori VM. Shared decision making: the need for patient-clinician conversation, not just information. Health Aff (Millwood) 2016 Apr;35(4):627-629. [doi: 10.1377/hlthaff.2015.1354] [Medline: 27044962]
10. Montori VM, Gafni A, Charles C. A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes. Health Expect 2006 Mar;9(1):25-36 [FREE Full text] [doi: 10.1111/j.1369-7625.2006.00359.x] [Medline: 16436159]
11. Ruland CM, White T, Stevens M, Fanciullo G, Khilani SM. Effects of a computerized system to support shared decision making in symptom management of cancer patients: preliminary results. J Am Med Inform Assoc 2003;10(6):573-579 [FREE Full text] [doi: 10.1197/jamia.M1365] [Medline: 12925545]
12. Wickramasekera N, Taylor SK, Lumley E, Gray T, Wilson E, Radley S. Can electronic assessment tools improve the process of shared decision-making? A systematic review. Health Inf Manag 2020 Oct 05:1833358320954385 [FREE Full text] [doi: 10.1177/1833358320954385] [Medline: 33016126]
13. Hartasanchez SA, Heen AF, Kunneman M, García-Bautista A, Hargraves IG, Prokop LJ, et al. Remote shared decision making through telemedicine: A systematic review of the literature. Patient Educ Couns 2022 Feb;105(2):356-365. [doi: 10.1016/j.pec.2021.06.012] [Medline: 34147314]
14. Antonio MG, Petrovskaya O, Lau F. The state of evidence in patient portals: umbrella review. J Med Internet Res 2020 Nov 11;22(11):e23851 [FREE Full text] [doi: 10.2196/23851] [Medline: 33174851]
15. What is a patient portal? HealthIT. 2017 Sep 29. URL: https://www.healthit.gov/faq/what-patient-portal [accessed 2022-03-21]
16. Kruse CS, Argueta DA, Lopez L, Nair A. Patient and provider attitudes toward the use of patient portals for the management of chronic disease: a systematic review. J Med Internet Res 2015 Feb 20;17(2):e40 [FREE Full text] [doi: 10.2196/jmir.3703] [Medline: 25707035]
17. Kruse CS, Bolton K, Freriks G. The effect of patient portals on quality outcomes and its implications to meaningful use: a systematic review. J Med Internet Res 2015 Feb 10;17(2):e44 [FREE Full text] [doi: 10.2196/jmir.3171] [Medline: 25669240]

18. Goldzweig CL, Towfigh AA, Paige NM, Orshansky G, Haggstrom DA, Beroes JM, et al. Systematic Review: Secure Messaging Between Providers and Patients, and Patients' Access to Their Own Medical Record: Evidence on Health Outcomes, Satisfaction, Efficiency and Attitudes. Washington, DC: Department of Veterans Affairs; 2012.
19. de Jong CC, Ros WJ, Schrijvers G. The effects on health behavior and health outcomes of Internet-based asynchronous communication between health providers and patients with a chronic condition: a systematic review. J Med Internet Res 2014 Jan 16;16(1):e19 [FREE Full text] [doi: 10.2196/jmir.3000] [Medline: 24434570]
20. Shang L, Zuo M, Ma D, Yu Q. The antecedents and consequences of health care professional-patient online interactions: systematic review. J Med Internet Res 2019 Sep 25;21(9):e13940 [FREE Full text] [doi: 10.2196/13940] [Medline: 31573908]
21. Nguyen OT, Alishahi Tabriz A, Huo J, Hanna K, Shea CM, Turner K. Impact of asynchronous electronic communication-based visits on clinical outcomes and health care delivery: systematic review. J Med Internet Res 2021 May 05;23(5):e27531 [FREE Full text] [doi: 10.2196/27531] [Medline: 33843592]
22. Coquet J, Blayney DW, Brooks JD, Hernandez-Boussard T. Association between patient-initiated emails and overall 2-year survival in cancer patients undergoing chemotherapy: Evidence from the real-world setting. Cancer Med 2020 Nov;9(22):8552-8561 [FREE Full text] [doi: 10.1002/cam4.3483] [Medline: 32986931]
23. Heisey-Grove DM, McClelland LE, Rathert C, Tartaglia A, Jackson K, DeShazo JP. Associations between patient health outcomes and secure message content exchanged between patients and clinicians: retrospective cohort study. J Med Internet Res 2020 Oct 29;22(10):e19477 [FREE Full text] [doi: 10.2196/19477] [Medline: 33118938]
24. Gandrup J, Ali SM, McBeth J, van der Veer SN, Dixon WG. Remote symptom monitoring integrated into electronic health records: A systematic review. J Am Med Inform Assoc 2020 Nov 01;27(11):1752-1763 [FREE Full text] [doi: 10.1093/jamia/ocaa177] [Medline: 32968785]
25. Maguire R, McCann L, Kotronoulas G, Kearney N, Ream E, Armes J, et al. Real time remote symptom monitoring during chemotherapy for cancer: European multicentre randomised controlled trial (eSMART). BMJ 2021 Jul 21;374:n1647 [FREE Full text] [doi: 10.1136/bmj.n1647] [Medline: 34289996]
26. Cleeland CS, Wang XS, Shi Q, Mendoza TR, Wright SL, Berry MD, et al. Automated symptom alerts reduce postoperative symptom severity after cancer surgery: a randomized controlled clinical trial. J Clin Oncol 2011 Mar 10;29(8):994-1000 [FREE Full text] [doi: 10.1200/JCO.2010.29.8315] [Medline: 21282546]
27. Mooney KH, Beck SL, Wong B, Dunson W, Wujcik D, Whisenant M, et al. Automated home monitoring and management of patient-reported symptoms during chemotherapy: results of the symptom care at home RCT. Cancer Med 2017 Mar;6(3):537-546 [FREE Full text] [doi: 10.1002/cam4.1002] [Medline: 28135050]
28. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. J Clin Oncol 2016 Feb 20;34(6):557-565 [FREE Full text] [doi: 10.1200/JCO.2015.63.0830] [Medline: 26644527]
29. Graupner C, Kimman ML, Mul S, Slok AHM, Claessens D, Kleijnen J, et al. Patient outcomes, patient experiences and process indicators associated with the routine use of patient-reported outcome measures (PROMs) in cancer care: a systematic review. Support Care Cancer 2021 Feb;29(2):573-593 [FREE Full text] [doi: 10.1007/s00520-020-05695-4] [Medline: 32875373]
30. Kruse CS, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: A systematic review. J Telemed Telecare 2018 Jan;24(1):4-12 [FREE Full text] [doi: 10.1177/1357633X16674087] [Medline: 29320966]
31. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci 2016 Oct 26;11(1):146 [FREE Full text] [doi: 10.1186/s13012-016-0510-7] [Medline: 27782832]
32. Schreiweis B, Pobiruchin M, Strotbaum V, Suleder J, Wiesner M, Bergh B. Barriers and facilitators to the implementation of eHealth services: systematic literature analysis. J Med Internet Res 2019 Nov 22;21(11):e14197 [FREE Full text] [doi: 10.2196/14197] [Medline: 31755869]
33. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open 2019 Aug 15;9(8):e029954 [FREE Full text] [doi: 10.1136/bmjopen-2019-029954] [Medline: 31420394]
34. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci 2015 Feb 12;10:21 [FREE Full text] [doi: 10.1186/s13012-015-0209-1] [Medline: 25889199]
35. Seljelid B, Varsi C, Solberg Nes L, Stenehjem A, Bollerslev J, Børøsund E. Content and system development of a digital patient-provider communication tool to support shared decision making in chronic health care: InvolveMe. BMC Med Inform Decis Mak 2020 Mar 04;20(1):46 [FREE Full text] [doi: 10.1186/s12911-020-1065-8] [Medline: 32131808]
36. Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E. A digital patient-provider communication intervention (InvolveMe): qualitative study on the implementation preparation based on identified facilitators and barriers. J Med Internet Res 2021 Apr 08;23(4):e22399 [FREE Full text] [doi: 10.2196/22399] [Medline: 33830063]
37. HL7 FHIR Foundation. URL: https://fhir.org/ [accessed 2022-03-21]

38. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008 Sep 29;337:a1655 [FREE Full text] [doi: 10.1136/bmj.a1655] [Medline: 18824488]
39. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med 2009 May;36(5):452-457 [FREE Full text] [doi: 10.1016/j.amepre.2009.02.002] [Medline: 19362699]
40. Joustra SD, Thijs RD, van den Berg R, van Dijk M, Pereira AM, Lammers GJ, et al. Alterations in diurnal rhythmicity in patients treated for nonfunctioning pituitary macroadenoma: a controlled study and literature review. Eur J Endocrinol 2014 Aug;171(2):217-228. [doi: 10.1530/EJE-14-0172] [Medline: 24826835]
41. Andela CD, Niemeijer ND, Scharloo M, Tiemensma J, Kanagasabapathy S, Pereira AM, et al. Towards a better quality of life (QoL) for patients with pituitary diseases: results from a focus group study exploring QoL. Pituitary 2015 Feb;18(1):86-100. [doi: 10.1007/s11102-014-0561-1] [Medline: 24682940]
42. Andela CD, Scharloo M, Pereira AM, Kaptein AA, Biermasz NR. Quality of life (QoL) impairments in patients with a pituitary adenoma: a systematic review of QoL studies. Pituitary 2015 Oct;18(5):752-776. [doi: 10.1007/s11102-015-0636-7] [Medline: 25605584]
43. Andela CD, Scharloo M, Ramondt S, Tiemensma J, Husson O, Llahana S, et al. The development and validation of the Leiden Bother and Needs Questionnaire for patients with pituitary disease: the LBNQ-Pituitary. Pituitary 2016 Jun;19(3):293-302 [FREE Full text] [doi: 10.1007/s11102-016-0707-4] [Medline: 26809957]
44. Brooke J. SUS: A 'Quick and Dirty' Usability Scale. In: Usability Evaluation in Industry. Bristol, PA: Taylor & Francis; 1996.
45. Bangor A, Kortum P, Miller JT. Determining what individual SUS scores mean: Adding an adjective rating scale. Journal of Usability Studies 2009;4(3):114-123 [FREE Full text]
46. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. International Journal of Human-Computer Interaction 2008 Jul 30;24(6):574-594. [doi: 10.1080/10447310802205776]
47. Lewis JR, Sauro J. The Factor Structure of the System Usability Scale. In: Kurosu M, editor. Human Centered Design. HCD 2009. Lecture Notes in Computer Science, vol 5619. Berlin, Heidelberg: Springer; 2009:94-103.
48. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983 Jun;67(6):361-370. [doi: 10.1111/j.1600-0447.1983.tb09716.x] [Medline: 6880820]
49. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. Health Econ 1993 Oct;2(3):217-227. [doi: 10.1002/hec.4730020305] [Medline: 8275167]
50. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992 Jun;30(6):473-483. [Medline: 1593914]
51. Osborne RH, Batterham RW, Elsworth GR, Hawkins M, Buchbinder R. The grounded psychometric development and initial validation of the Health Literacy Questionnaire (HLQ). BMC Public Health 2013 Jul 16;13:658 [FREE Full text] [doi: 10.1186/1471-2458-13-658] [Medline: 23855504]
52. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
53. Varsi C, Gammon D, Wibe T, Ruland CM. Patients' reported reasons for non-use of an internet-based patient-provider communication service: qualitative interview study. J Med Internet Res 2013 Nov 11;15(11):e246 [FREE Full text] [doi: 10.2196/jmir.2683] [Medline: 24220233]
54. Heyn L, Ruland CM, Finset A. Effects of an interactive tailored patient assessment tool on eliciting and responding to cancer patients' cues and concerns in clinical consultations with physicians and nurses. Patient Educ Couns 2012 Feb;86(2):158-165. [doi: 10.1016/j.pec.2011.04.024] [Medline: 21592719]
55. Johansen MA, Berntsen GKR, Schuster T, Henriksen E, Horsch A. Electronic symptom reporting between patient and provider for improved health care service quality: a systematic review of randomized controlled trials. part 2: methodological quality and effects. J Med Internet Res 2012 Oct 03;14(5):e126 [FREE Full text] [doi: 10.2196/jmir.2216] [Medline: 23032363]
56. Jonker LT, Lahr MMH, Festen S, Oonk MHM, de Bock GH, van Leeuwen BL. Perioperative telemonitoring of older adults with cancer: Can we connect them all? J Geriatr Oncol 2020 Nov;11(8):1244-1249 [FREE Full text] [doi: 10.1016/j.jgo.2020.08.008] [Medline: 32893182]
57. Benson GA, Sidebottom A, Sillah A, Boucher JL, Miedema MD, Knickelbine T, et al. Reach and effectiveness of the HeartBeat Connections telemedicine pilot program. J Telemed Telecare 2018 Apr;24(3):216-223. [doi: 10.1177/1357633X17692723] [Medline: 29278986]
58. Flodgren G, Rachas A, Farmer AJ, Inzitari M, Shepperd S. Interactive telemedicine: effects on professional practice and health care outcomes. Cochrane Database Syst Rev 2015 Sep 07(9):CD002098 [FREE Full text] [doi: 10.1002/14651858.CD002098.pub2] [Medline: 26343551]
59. Lang C, Voigt K, Neumann R, Bergmann A, Holthoff-Detto V. Adherence and acceptance of a home-based telemonitoring application used by multi-morbid patients aged 65 years and older. J Telemed Telecare 2022 Jan;28(1):37-51 [FREE Full text] [doi: 10.1177/1357633X20901400] [Medline: 32009577]

60. Chesser A, Burke A, Reyes J, Rohrberg T. Navigating the digital divide: A systematic review of eHealth literacy in underserved populations in the United States. Inform Health Soc Care 2016;41(1):1-19. [doi: 10.3109/17538157.2014.948171] [Medline: 25710808]
61. Review No 02/2021: EU actions to address low digital skills. European Court of Auditors. 2021 Feb 23. URL: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=58096 [accessed 2022-03-21]
62. Antonio MG, Petrovskaya O, Lau F. Is research on patient portals attuned to health equity? A scoping review. J Am Med Inform Assoc 2019 Aug 01;26(8-9):871-883 [FREE Full text] [doi: 10.1093/jamia/ocz054] [Medline: 31066893]
63. Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. J Am Med Inform Assoc 2019 Aug 01;26(8-9):855-870 [FREE Full text] [doi: 10.1093/jamia/ocz023] [Medline: 30958532]
64. Cheng C, Beauchamp A, Elsworth GR, Osborne RH. Applying the electronic health literacy lens: systematic review of electronic health interventions targeted at socially disadvantaged groups. J Med Internet Res 2020 Aug 13;22(8):e18476 [FREE Full text] [doi: 10.2196/18476] [Medline: 32788144]
65. Ebrahimi OV, Hoffart A, Johnson SU. Physical distancing and mental health during the COVID-19 pandemic: factors associated with psychological symptoms and adherence to pandemic mitigation strategies. Clinical Psychological Science 2021 Mar 12;9(3):489-506. [doi: 10.1177/2167702621994545]
66. Bo A, Friis K, Osborne RH, Maindal HT. National indicators of health literacy: ability to understand health information and to engage actively with healthcare providers - a population-based survey among Danish adults. BMC Public Health 2014 Oct 22;14:1095 [FREE Full text] [doi: 10.1186/1471-2458-14-1095] [Medline: 25339154]
67. Berens E, Vogt D, Messer M, Hurrelmann K, Schaeffer D. Health literacy among different age groups in Germany: results of a cross-sectional survey. BMC Public Health 2016 Nov 09;16(1):1151 [FREE Full text] [doi: 10.1186/s12889-016-3810-6] [Medline: 27829401]
68. Helse Norge. URL: https://www.helsenorge.no/ [accessed 2022-03-21]
69. Shanbehzadeh M, Kazemi-Arpanahi H, Kalkhajeh SG, Basati G. Systematic review on telemedicine platforms in lockdown periods: Lessons learned from the COVID-19 pandemic. J Educ Health Promot 2021;10:211 [FREE Full text] [doi: 10.4103/jehp.jehp_1419_20] [Medline: 34395648]

Abbreviations

HADS: Hospital Anxiety and Depression Scale
HCP: health care provider
HLQ: Health Literacy Questionnaire
HRQoL: health-related quality of life
MD: mean difference
NFPA: nonfunctioning pituitary adenomas
SDM: shared decision-making
SUS: System Usability Scale

Edited by A Mavragani; submitted 05.11.21; peer-reviewed by T Irizarry; comments to author 28.11.21; revised version received 21.01.22; accepted 14.03.22; published 07.04.22

Please cite as:
Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E
Feasibility of a Digital Patient–Provider Communication Intervention to Support Shared Decision-Making in Chronic Health Care, InvolveMe: Pilot Study
JMIR Form Res 2022;6(4):e34738
URL: https://formative.jmir.org/2022/4/e34738
doi: 10.2196/34738
PMID: 35389356

Appendices

1) Interview guide patients Study I (translated into English)
2) Interview guide HCPs Study I (translated into English)
3) Interview guide HCPs Study II (translated into English)
4) Interview guide HCPs Study III (in Norwegian)
5) Workshop theme guide HCPS Study II (translated into English)
6) Ethical approval by the Department of Data Protection and Information Security (20178/9223) (in Norwegian)
7) Risk assessment approval by the Department of Data Protection and Information Security (in Norwegian)
8) Waived approval (Framleggingsvurdering) by the Regional Committee for Medical and Health Research Ethics Study I and II 2017/1132A (in Norwegian)
9) Ethical approval by the Regional Committee for Medical and Health Research Ethics Study III (2018/2201) (in Norwegian)
10) Change notification approval by the Regional Committee for Medical and Health Research Ethics Study III (2018/2201) 22.01.2020 (in Norwegian)
11) Change notification approval by the Regional Committee for Medical and Health Research Ethics Study III (2018/2201) 25.09.2020 (in Norwegian)
12) Change notification approval by the Regional Committee for Medical and Health Research Ethics Study III (2018/2201) 26.11.2020 (in Norwegian)
13) Information and consent form NFPA patients (in Norwegian) Study I and II
14) Information and consent form RTX patients (in Norwegian) Study I and II
15) Information and consent form NFPA patients (in Norwegian) Study III
16) Information and consent form HCPs - NFPA (in Norwegian) Study I and II
17) Information and consent form HCPs - RTX (in Norwegian) Study I and II
18) Information and consent form HCPs - NFPA (in Norwegian) Study III

InvolveMe
Interview guide
Patients

Theme: Development of a digital communication tool
We aim to develop a digital patient- provider communication tool. The tool should be used prior to hospital visits as a preparation for consultations for both patient and health care providers. Also, it should provide the opportunity for follow-up between consultations.

1. Can you talk about the course of the disease and your current health situation?

2. Can you talk about how consultations with health care providers usually take place today?

3. Can you talk about what you wish was different in the follow-up from health care providers?

4. Can you talk about how you keep track of symptoms and illness today?

5. How do you use technology in everyday life, and do you use it to monitor your own illness/symptoms ?

6. Can you tell us what requirements and expectations you have for the content and use of a digital communication tool?

In conclusion:

7. Is there anything that is particularly important that we should keep in mind when we start tool development?

InvolveMe
Focus group Interview guide
Health care providers

Theme: Development of a digital communication tool
We aim to develop a digital patient- provider communication tool. The tool should be used prior to hospital visits as a preparation for consultations for both patient and health care providers. Also, it should provide the opportunity for follow-up between consultations.

1. Can you describe the patient group?

2. Can you talk about how consultations are carried out today?

3. Can you talk about what impression you have on how patients themselves monitor disease progression and symptoms today?

4. Is there anything that you wish could be different regarding the follow-up of the patient group?

5. Can talk about how technology is used in patient follow-up today?

6. Can you talk about what kind of requirements and expectations you have for content and usability of a digital communication tool?

In conclusion:

7. Is there anything that would be particularly important for us to keep in mind when starting tool development?

InvolveMe
Focus Group Guide
Health care providers

Theme: Implementation of a digital patient- provider communication intervention

Introduction by first-author (BS): In this project we have developed a digital intervention to be used by you and your patients. The intervention provides a secure symptom and needs assessment to be used prior to hospital visits as a preparation for consultations for patients and health care providers and the opportunity for follow-up before, after and in between hospital consultations - with an option for secure message (email) between patients and health care providers. We need your thoughts and suggestions on this aim in order to make the intervention suit your daily workflow.

What do you think would be potential advantages that the digital intervention may have for:

- The patient group [Intervention Characteristics, Outer Setting]
- Health care providers and managers [Intervention Characteristics, Inner Setting]
- The way you work (The work process) [Intervention Characteristics, Inner Setting]
- The outpatient clinic [Intervention Characteristics, Inner Setting]

Think back on the recent implementation of the new version of the electronic patient record (EPR)* at the outpatient clinic

- What challenges did the implementation of the EPR face? [Inner Setting]
- What challenges can implementation of the digital tool face? [Inner Setting]
- Do you have suggestions for how challenges can be meet? [Process]

Was there anything that worked well in relation to the implementation of the EPR?

- If so, what was it? [Inner Setting, Process]
- What contributed to its success? [Process]

What does it take to succeed with implementation of the digital tool?

- What can you do to make it work? [Process]

In conclusion: Is there anything that would be particularly important for us to keep in mind?

*We had made an inquiry an knew beforehand that this was a resent implementation conducted at the outpatient clinics.

Oslo universitetssykehus

Intervjuguide helsepersonell

Erfaringer fra pilotstudie

Fokusgruppen med helsepersonell har som hensikt å undersøke erfaringer med bruk av eHelseløsningen "InvolverMeg" og forbedringspotensiale før en observasjonsstudie.

Følgende temaer vil belyses:

- Hvordan har det vært å bruke løsningen (motta kartlegging og besvare meldinger)?
- Opplevde fordeler og ulemper med løsningen?
- Samsvar med eksisterende rutiner – Bør noe endres?
- Påvirkning på innhold/kommunikasjon i pasientsamtalen?
- I hvilken grad har dere fått ny innsikt om pasienters situasjon, både den enkelte pasient og pasientgruppen som helhet?
- Er det noe annet dere vil legge til som det er viktig at vi får med oss videre?

InvolveMe
Workshop Theme Guide
Health care providers

Theme: Implementation of a digital patient- provider communication intervention

Introduction by first-author (BS): The aim of this workshop is to gain knowledge about potential facilitators and barriers to the use of a digital patient -provider communication intervention, and to use this knowledge to tailor the intervention and prepare for implementation.

Theme: Desired use of the *InvolveMe* intervention (facilitators & barriers)**.**
Keywords to help start the group discussion:

- Who should be responsible for what? [Intervention Characteristics]
- What obstacles can arise? [Intervention Characteristics]
- Potential advantages and disadvantages? [Intervention Characteristics]
- Any risks? [Inner Setting]

Theme: The patients who will be offered the *InvolveMe* intervention
(facilitators & barriers for patients use).
Keywords to help start the group discussion:

- What is important for patients who will be offered the intervention? [Outer Setting]
- Patients' needs [Outer Setting]
- Patients motivation for use? [Outer Setting]
- Is the tool suitable for every patient? [Outer Setting]
- Potential advantages and disadvantages? [Intervention Characteristics, Outer Setting]

Theme: **The outpatient clinics where the patients are treated** (facilitators & barriers)
Keywords to help start the group discussion:

- Workflow [Inner Setting]
- Disruption of the of the workflow [Inner Setting]
- Collective responsibility? [Inner Setting]
- Interdisciplinary collaboration? [Inner Setting]
- Potential advantages and disadvantages? [Inner Setting]
- Any risks? [Inner Setting]

Theme: Health care providers at the outpatient clinic (facilitators & barriers).
Keywords to help start the group discussion:

Related to *InvolveMe*:

- Enthusiasm in the outpatient clinic [Characteristics of individuals]
- What about expectations? [Characteristics of individuals]
- What do other staff members at the outpatient clinic say? [Characteristics of individuals]
- Why do you want to do this? [Characteristics of individuals]
- What do you want to achieve? [Characteristics of individuals]
- What is important to HCPs? [Characteristics of individuals]

Theme: Preparations for the implementation of the *InvolveMe* intervention.
Keywords to help start the group discussion:

- The need for training? [Process]
- The need for support? [Process]
- Implementation monitoring? [Process]
- Evaluation of implementation process. [Process]
- Organization of management related to the implementation? [Process]

Oslo universitetssykehus HF

Postadresse:
Postboks 4950 Nydalen
0424 Oslo

Sentralbord:
02770

Org.nr:
NO 993 467 049 MVA

www.oslo-universitetssykehus.no

PERSONVERNOMBUDETS TILRÅDING

Til:	Elin Børøsund, prosjektleder Senter for pasientmedvirkning og samhandlingsforskning (SPS) Medisinsk Klinikk
Kopi:	Berit Seljelid
Fra:	Personvernombudet ved Oslo universitetssykehus
Saksbehandler:	Tor Åsmund Martinsen
Dato:	23.06.17
Offentlighet:	Ikke unntatt offentlighet
Sak:	Personvernombudets tilråding til innsamling og databehandling av personopplysninger
Saksnummer/ ePhortenummer:	20178/9223

Personvernombudets tilråding til innsamling og behandling av personopplysninger for prosjektet:

«InvolveMe»

Formål:
Hensikten med prosjektet er å tilpasse og studere bruk av en eHelseløsning hvor brukerne kan registrere symptomer og hva de ønsker å snakke med helsepersonell om før konsultasjon på sykehus, samt bruk av sikker epost for veiledning og oppfølgning fra helsepersonell.

Prosjektet har tre delmål:
1) Designe og tilpasse eHelseløsningen.
2) Forberede implementering av eHelseløsningen, herunder kartlegge barrierer/fasilitatorer, samt utvikle kontektspesifikke rutiner for implementering.
3) Undersøke bruk av eHelseløsningen, mulige effekter hos brukerne relatert til blant annet symptomer og livskvalitet, samt implementeringsaspektet (egen søknad sendes til REK for delmål 3)

Vi viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Det følgende er personvernombudets tilråding av prosjektet.

Med hjemmel i personopplysningsforskriften § 7-12, jf. helseregisterloven § 5, har Datatilsynet ved oppnevning av personvernombud ved Oslo Universitetssykehus (OUS), fritatt sykehuset fra meldeplikten til Datatilsynet. Behandling og utlevering av person-/helseopplysninger meldes derfor til sykehusets personvernombud.

Databehandlingen tilfredsstiller forutsetningene for melding gitt i personopplysningsforskriften § 7-27 og er derfor unntatt konsesjon.

Personvernombudet tilrår at prosjektet gjennomføres under forutsetning av følgende:

1. Databehandlingsansvarlig er Oslo universitetssykehus HF ved adm. dir.
2. Avdelingsleder eller klinikkleder ved OUS har godkjent studien.
3. Behandling av personopplysningene / helseopplysninger i prosjektet skjer i samsvar med og innenfor det formål som er oppgitt i meldingen.
4. Data lagres som oppgitt i meldingen. Annen lagringsform forutsetter gjennomføring av en risikovurdering som må godkjennes av Personvernombudet.
5. Oppslag i journal med formål å identifisere potensielle deltagere til studien gjøres av ansatte ved sykehuset, eller innleide som er under sykehusets instruksjonsmyndighet, og som har selvstendig lovlig grunnlag for oppslaget. Oppslag i journal uten pasientens forhåndssamtykke kan ikke være begrunnet med studien som formål, men må ha annet lovlig grunnlag. Det vises til sykehusets eHåndbok og dokumentet «Grunnlag for oppslag i journal», dokumentID 12640. Se http://ehandboken.ous-hf.no/.
6. Studien er frivillig og samtykkebasert. Innmeldte samtykke benyttes.
7. Eventuelle fremtidige endringer som berører formålet, utvalget inkluderte eller databehandlingen må forevises personvernombudet før de tas i bruk.
8. Kryssliste som kobler avidentifiserte data med personopplysninger lagres som angitt i meldingen og oppbevares separat på prosjektleders avlåste kontor.
9. Publisering i tidsskrift forutsettes å skje uten at deltagerne kan gjenkjennes direkte eller indirekte.
10. Kontaktperson for prosjektet skal hvert tredje år sende personvernombudet ny melding som bekrefter at databehandlingen skjer i overensstemmelse med opprinnelig formål og helseregisterlovens regler.
11. Data slettes eller anonymiseres ved prosjektslutt 01.03.2027 ved at krysslisten slettes og eventuelle andre identifikasjonsmuligheter i databasen fjernes. Når formålet med registeret er oppfylt sendes melding om bekreftet sletting til personvernombudet.

Prosjektet er registrert i sykehusets offentlig tilgjengelig database over forsknings- og kvalitetsstudier.

Med hilsen

Tor Åsmund Martinsen
Personvernrådgiver

Oslo universitetssykehus HF
Stab fag, pasientsikkerhet og samhandling
Avdeling for personvern og informasjonssikkerhet

Fra: Ole Johan Rasch [mailto:olrasc@ous-hf.no]
Sendt: 27. mars 2019 13:01
Til: Elin Børøsund <Elin.Borosund@rr-research.no>
Kopi: Marianne Westeng <Marianne.Westeng@rr-research.no>; Per Tømmer <Per.Tommer@rr-research.no>; OUSHF PB Personvern <personvern@oslo-universitetssykehus.no>
Emne: SV: Risikovurdering av et elektronisk kartleggingsverktøy - Choice3, i prosjektet InvolverMeg/InvolveMe 2017-9223

Hei,

Viser til vedlagt risikovurdering av «Choice versjon 3 – InvolveMe».

Risikovurderingen er godkjent, forutsatt at all aktivitet som er beskrevet gjennomføres, og helseforetaket vurderer dermed at risikonivå for informasjonssikkerhet er akseptabel, herunder at restrisiko er akseptabel.

Ole Johan Rasch
Informasjonssikkerhetsrådgiver
Avdeling for informasjonssikkerhet og personvern
Oslo universitetssykehus HF
www.oslo-universitetssykehus.no/personvern

Fra: Elin Børøsund
Sendt: 27. mars 2019 09:48
Til: Ole Johan Rasch
Kopi: Marianne Westeng; Per Tømmer
Emne: RE: Risikovurdering av et elektronisk kartleggingsverktøy - Choice3, i prosjektet InvolverMeg/InvolveMe 2017-9223

Hei Ole Johan,

Her kommer versjon 1.0 av risikovurderingen hvor gulmarkering og kommentarer er fjernet. Jeg har også tatt bort tidligere kapittel 5 i sin helhet da vi ikke beskriver «Anbefalte risikoreduserende tiltak». Si ifra om noe er uklart.

Med vennlig hilsen
Elin Børøsund
Prosjektleder
Seniorforsker, PhD, RN
Senter for Pasientmedvirkning og samhandlingsforskning
Medisinsk klinikk | Oslo universitetssykehus HF
Mob: +47 92 66 71 61
epost: elin.borosund@rr-research.no

Besøksadresse: Aker sykehus, Trondheimsveien 235, 0586 Oslo, Bygg 6, 8 etg.
www.spsresearch.no

Oslo universitetssykehus

From: post@helseforskning.etikkom.no [mailto:post@helseforskning.etikkom.no]
Sent: 14. juni 2017 12:41
To: Elin Børøsund
Subject: Sv: REK sør-øst 2017/1132 InvolverMeg: Implementering av eHelseløsninger i klinisk praksis for å styrke oppfølging, kommunikasjon og involvering

Vår ref.nr.: 2017/1132 A

Vi viser til skjema for framleggingsvurdering mottatt 02.06.2017 angående prosjektet «InvolverMeg: Implementering av eHelseløsninger i klinisk praksis for å styrke oppfølging, kommunikasjon og involvering». Framleggingsvurderingen er vurdert av komiteens leder.

Formålet med dette prosjektet, slik det fremgår av framleggingsvurderingen, er å utvikle og teste et eHelse-verktøy for mennesker med kronisk sykdom, basert på deres behov og eksisterende forskning. Forskerne skal gjennom intervjuer, fokusgrupper, workshops og brukertesting utvikle og tilpasse en eHelseløsning for kartlegging av symptomer og kommunikasjon med helsepersonell. Prosjektet er delt inn i tre faser, og det er bare fase I og II som omfatter design, utvikling og forberedning av implementering som er vurdert her.

Etter REKs vurdering faller prosjektet, slik det er beskrevet, utenfor virkeområdet til helseforskningsloven. Helseforskningsloven gjelder for medisinsk og helsefaglig forskning, i loven definert som forskning på mennesker, humant biologisk materiale og helseopplysninger, som har som formål å frambringe ny kunnskap om helse og sykdom, jf. helseforskningsloven §§ 2 og 4a. Formålet er avgjørende, ikke om forskningen utføres av helsepersonell eller på pasienter/sårbare grupper eller benytter helseopplysninger.

Prosjekter som faller utenfor helseforskningslovens virkeområde kan gjennomføres uten godkjenning av REK. Det er institusjonens ansvar å sørge for at prosjektet gjennomføres på en forsvarlig måte med hensyn til for eksempel regler for taushetsplikt og personvern. Vi anbefaler å ta kontakt med lokalt personvernombud.

Vi gjør oppmerksom på at vurderingen og konklusjonen er å anse som veiledende jf. forvaltningsloven § 11. Dersom dere likevel ønsker å søke REK vil søknaden bli behandlet i komitémøte, og det vil bli fattet et enkeltvedtak etter forvaltningsloven.

Med vennlig hilsen
Tove Irene Klokk
Rådgiver
post@helseforskning.etikkom.no
T: 22845522

Regional komité for medisinsk og helsefaglig forskningsetikk REK sør-øst-Norge (REK sør-øst)
http://helseforskning.etikkom.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Appendix 9

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Henriette Snilsberg	22845531	20.12.2018	2018/2201 REK sør-øst B
			Deres dato:	**Deres referanse:**
			06.11.2018	

Vår referanse må oppgis ved alle henvendelser

Elin Børøsund
Oslo universitetssykehus HF

2018/2201 Bruk av en eHelseløsning i langtidsoppfølging av pasienter med kronisk sykdom; InvolverMeg

Forskningsansvarlig: Oslo universitetssykehus HF
Prosjektleder: Elin Børøsund

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst B) i møtet 05.12.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hforsknl) § 10.

Prosjektomtale
Kronisk sykdom medfører ofte bekymring, usikkerhet og plagsomme symptomer som varierer i intensitet. Det er behov for behandling og oppfølging som tar hensyn til det. Til tross for et tydelig ønske fra myndighetene, er eHelseløsninger for mennesker med kronisk sykdom i liten grad implementert. I prosjektet er det utviklet en digital kommunikasjonsløsning som gir pasienter mulighet til å kartlegge symptomer/behov i forkant av konsultasjon ved sykehus, samt kunne sende sikre meldinger. Løsningen baseres på tidligere utviklede løsninger, forskning, og brukernes behov. Mål: Utforske bruk, implementering, erfaring og potensiell effekt av en løsning for kommunikasjon av symptomer/behov i forkant og mellom konsultasjoner. Studien består av to deler. Først vil det gjennomføres en pilotstudie med inntil 50 deltakere for å kartlegge deltakernes erfaringer med bruk av eHelseløsningen. Etter eventuelle justeringer vil det gjennomføres en observasjonsstudie med inntil 160 pasienter som får tilgang

Komiteens vurdering
I dette forskningsprosjektet ønsker man å se på hvordan bruken av en digital kommunikasjonsløsning for pasienter oppleves med mål om å utforske bruk, implementering, erfaring og potensiell effekt av en løsning for kommunikasjon av symptomer/behov i forkant og mellom konsultasjoner. Studien er delt i to, der det først skal utføres en pilotstudie med 50 deltakere, deretter en observasjonsstudie med 160 deltakere. I pilotstudien vil inklusjon av 50 deltakere gi tilstrekkelig feedback på funksjonalitet og innhold i eHelseløsningen, slik at nødvendige justeringer kan foretas før observasjonsstudien. Deltakerne vil i tillegg gi tilbakemelding på de benyttede spørreskjema ved 3 måneders målingen, slik at det kan foretas eventuelle justeringer relatert til skjemaenes egnethet for å besvare forskningsspørsmålene, samt forståelighet og byrde for deltakerne ved utfyllingen. 50 deltakere vil gi helsepersonell tilstrekkelig erfaring for å vurdere om rutiner for håndtering av eHelseløsningen bør endres.

I observasjonsstudien vil pasienters langtidsbruk, erfaring og potensiell effekt av eHelseløsningen

utforskes. Dette vil gi erfaring med løsningen i ulike faser av oppfølging av pasientgruppene. Det vil rekrutteres inntil 100 pasienter som følges opp i etterkant av nyretransplantasjon og inntil 60 pasienter med

ikke-hormonproduserende hypofyseadenom.

Rekruttering
Studien planlegger å inkludere Inntil 210 deltakere totalt. Deltakerne vil rekrutteres i forbindelse med at de er operert for et ikke-hormonproduserende hypofyseadenom og følges opp ved Seksjon for

spesiell endokrinologi ved Oslo Universitetsykehus (OUS) eller at de er nyretransplanterte som følges opp ved Nyremedisinsk avdeling ved OUS.) Alle deltakere vil være i alderen 18 år eller eldre.

Inntil 20 helsepersonell ved Seksjon for spesiell endokrinologi og Nyremedisinsk avdeling ved

OUS vil også rekrutteres.

Informasjons-og samtykkeskriv
Samtykke innhentes elektonisk via den nasjonale fellesløsningen for e-signatur fra Difi hvor nettskjema kan settes opp for å levere en sikker, brukervennlig og gyldig signeringsløsning til forskningformål. En lenke til det elektroniske samtykket vil sendes ut på sms eller epost til deltakere. Deltakerne må logge seg inn med høyeste sikkerhetsnivå (BankID/BuyPass, sikkerhetsnivå 4) for å signere digitalt. Signert skjema sendes så til prosjektets sikre lagringsområde i Tjenester for Sensitive Data ved UiO hvor de andre forskningsdataene lagres elektronisk. Dersom deltaker heller ønsker å signere på papir, så er dette også mulig. Det er utarbeide eget informasjons-og samtykekskriv til de ulike deltakergrupene, og disse synes å være dekkende for formålet med studien.

Forsvarlighet
Det er beskrevet at eHelseløsningen risikovurderes i samarbeid med Personvernombudet ved Oslo Universitetssykehus, og vil tilfredsstille alle krav til slike løsninger som sykehuset er ansvarlig for.

Data fra spørreskjema og data for bruksmønster av eHelseløsningen oppbevares på sikker server hos Tjenester for Sensitive Data (TSD) ved Universitetet i Oslo mens studien pågår. Når studien avsluttes vil data overføres til sikker server ved Oslo Universitetssykehus (OUS).

Opplysninger fra kartlegging og innhold i meldinger som er dokumentasjonspliktige vil kopieres inn i pasientjournalen av helsepersonell. Dette er informert om i informasjons- og samtykkeskrivet til deltakerne, og komiteen har ingen innvendinger til dette.

Det er i søknaden beskrevet at man ønsker å registrere de som takker nei til deltakelse for å kunne få innsikt i om det er grupper av mennesker denne typen eHelseøsninger ikke appellerer til, og om det er årsaker til å ikke ønske å delta som kan forebygges.

Komiteen godkjenner dette forutsatt det kun registreres informasjon om *alder* og *kjønn* på vedkommende som takker nei, samt at det ikke etterspørres hvorfor de takker nei til deltakelse med mindre dette er noe som vedkommende oppgir spontant.

Komiteen mener det vil være nyttig at prosjektet gjennomføres. Komiteen godkjenner prosjektet slik det nå foreligger.

Vedtak
REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven § 10.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Tillatelsen gjelder til 01.01.2029.Av dokumentasjonshensyn skal opplysningene likevel bevares inntil

01.01.2034. Forskningsfilen skal oppbevares atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Sluttmelding og søknad om prosjektendring
Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Eventuell klage sendes til REK sør-øst B. Klagefristen er tre uker fra mottak av dette brevet.

Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Komiteens avgjørelse var enstemmig.

Med vennlig hilsen

Ragnhild Emblem
Professor, dr. med.
leder REK sør-øst B

Henriette Snilsberg
komitésekretær

Kopi til:
lise.solberg.nes@rr-research.no
Oslo universitetssykehus HF ved øverste administrative ledelse: oushfdlgodkjenning@ous-hf.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst B	Marianne Bjørnerem	22845531	22.01.2020	15893
			Deres referanse:	

Elin Børøsund

15893 Bruk av en eHelseløsning i langtidsoppfølging av pasienter med kronisk sykdom; InvolverMeg

Forskningsansvarlig: Oslo universitetssykehus HF

Søker: Elin Børøsund

REKs vurdering

Vi viser til endringsmelding for ovennevnte forskningsprosjekt mottatt 13.01.20. Søknaden er behandlet av sekretariatet på delegert fullmakt fra REK sør-øst B, med hjemmel i helseforskningsloven § 11.

Tidligere referansenummer: 2018/2201.

Endringene innebærer

1. Nye prosjektmedarbeidere; Marianne Ollivier og Elise Flakk Nordang, begge fra Oslo Universitetssykehus HF.

2. Forkortet oppfølgingsstudie fra 12 til 6 måneder. Dette ble endret på grunn av forsinkelser med den tekniske løsningen og for at PhD-stipendiaten skal kunne fullføre til planlagt tid.

3. For å inkludere et tilstrekkelig antall deltakere med ikke-hormonproduserende hypofyseadenom i studien skal også ikke-opererte spørres i tillegg til de opererte.

4. Revidering av informasjonsskriv:
- Klargjøring av prosedyrer.
- Revidering i henhold til endringene beskrevet i endringsmeldingen.

5. Spørreskjemaet HLQ skal nå benyttes ved 3 og 6 måneder i tillegg til ved baseline.

Vedlagt endringsmeldingen lå oppdatert informasjonsskriv og protokoll. Protokoll med markerte endringer ble sendt inn via e-post 16.01.20.

Vurdering

Sekretariatet i REK har vurdert de omsøkte endringene, og har ingen forskningsetiske innvendinger til endringene slik de er beskrevet i skjema for prosjektendring.

Vedtak

Godkjent

REK har gjort en forskningsetisk vurdering av endringene i prosjektet, og godkjenner prosjektet slik det nå foreligger, jf. helseforskningsloven § 11.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad, endringssøknad, oppdatert protokoll og de bestemmelser som følger av helseforskningsloven med forskrifter.

Med vennlig hilsen

Jacob C. Hølen
Sekretariatsleder REK sør-øst

Marianne Bjørnerem
Rådgiver
REK sør-øst B

Kopi sendt til: Forskningsansvarlig institusjon

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst B	Ingrid Dønåsen	22845523	25.09.2020	15893
			Deres referanse:	

Elin Børøsund

15893 Bruk av en eHelseløsning i langtidsoppfølging av pasienter med kronisk sykdom; InvolverMeg

Forskningsansvarlig: Oslo universitetssykehus HF

Søker: Elin Børøsund

REKs vurdering

REK viser til endringsmelding innsendt 10.09.2020 for prosjekt 15893 (2018/2201). Søknaden er behandlet av sekretariatet REK sør-øst på fullmakt fra REK sør-øst B, med hjemmel i helseforskningsloven § 11.

REK har vurdert følgende endringer:

- Ny versjon av forskningsprotokoll. Grunnet Covid-19 situasjonen så ønsker prosjektleder å utvide metoden for gjennomføring av intervju i studien.
De vil å ha mulighet til å gjennomføre individuelle intervju med pasienter (via telefon) og helsepersonell (ansikt til ansikt eller via telefon) istedet for fokusgruppe hvor der mange møtes fysisk, der dette er hensiktsmessig av smittevernhensyn.

REK har vurdert den omsøkte endringen og har ingen forskningsetiske innvendinger til de endringer som er beskrevet i skjema for prosjektendring.

Vedtak

Godkjent

REK godkjenner med hjemmel i helseforskningsloven § 11 annet ledd at prosjektet videreføres i samsvar med det som fremgår av søknaden om prosjektendring og i samsvar med de bestemmelser som følger av helseforskningsloven med forskrifter.

Dersom det skal gjøres ytterligere endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende ny endringsmelding til REK.
Av dokumentasjonshensyn skal opplysningene oppbevares i 5 år etter prosjektslutt.

Opplysningene skal deretter slettes eller anonymiseres. Opplysningene skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en datafil.
Prosjektet skal sende sluttmelding til REK, se helseforskningsloven § 12, senest 6 måneder etter at prosjektet er avsluttet.

Vi ber om at alle henvendelser sendes inn via vår saksportal: : https://rekportalen.no
Vennligst oppgi vårt referansenummer i korrespondansen.
Med vennlig hilsen

Jacob C. Hølen
Sekretariatsleder REK sør-øst

Elin Evju Sagbakken
Seniorrådgiver og komitesekretær
REK sør-øst B

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst B	Ingrid Dønåsen	22845523	26.11.2020	15893
			Deres referanse:	

Elin Børøsund

15893 Bruk av en eHelseløsning i langtidsoppfølging av pasienter med kronisk sykdom; InvolverMeg

Forskningsansvarlig: Oslo universitetssykehus HF

Søker: Elin Børøsund

REKs vurdering

Tidligere REK-referanse: 2018/2201

Viser til søknad om endringsmelding mottatt 23.11.20. Søknaden er behandlet av sekretariatet i REK sør-øst på delegert fullmakt fra REK sør-øst B, med hjemmel i helseforskningsloven § 11.

Endringene innebærer tilføring av ny prosjektmedarbeider:

- Christine Rygg, Innholdskonsulent, Oslo universitetssykehus HF

Vurdering

REK har vurdert de omsøkte endringene, og har ingen forskningsetiske innvendinger til endringene slik de er beskrevet i skjema for prosjektendring.

Vedtak

Godkjent

REK har gjort en forskningsetisk vurdering av endringene i prosjektet, og godkjenner prosjektet slik det nå foreligger, jf. helseforskningsloven § 11.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Tillatelsen er gitt under forutsetning av at prosjektendringen gjennomføres slik det er beskrevet i prosjektendringsmeldingen og endringsprotokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://rekportalen.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: rek-sorost@medisin.uio.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Jacob C. Hølen
Sekretariatsleder REK sør-øst

Silje Hansen
Førstekonsulent

Kopi sendes forskningsansvarlig institusjon og eventuelle medbrukere som er gitt tilgang til prosjektet i REK-portalen.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK sør-øst B. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst B, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering.

Vil du delta i et forskningsprosjekt for utvikling og brukertesting av en eHelseløsning for personer med ikke-hormonproduserende hypofysesvulst?

eHelseløsning betyr her elektronisk kartlegging av symptomer og mulighet til bruk av sikker e-post for oppfølging og veiledning av helsepersonell.

Du forespørres om deltakelse fordi du får behandling og oppfølging etter å ha kirurgisk fjernet en ikke-hormonproduserende hypofysesvulst. For å delta må du være over 18 år, samt beherske norsk skriftlig og muntlig, samt ha tilgang til egen BankID, BuyPass eller Comfides.

Bakgrunn og hensikt

Å leve med langvarige helseutfordringer påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. Det er behov for behandling og oppfølging som i større grad tar hensyn til det.

Hensikten med prosjektet er å utvikle en eHelseløsning hvor brukerne kan registrere symptomer før konsultasjon på sykehus og hva de ønsker å snakke med helsepersonell om. Løsningen kan gjøre det lettere å be om informasjon og veiledning for å håndtere plagene den enkelte erfarer. I tillegg kan endringer i sykdomsutvikling bli mer synlig både for brukeren og helsepersonell. Å styrke opplevelsen av å mestre livet med helseutfordringer kan bidra til økt livskvalitet og redusere stress relatert til sykdom.

Hva innebærer studien for deg?

Vi trenger kunnskap om hva som er viktig og nyttig for deg i ditt daglige liv og i møte med helsepersonell. Deltagelse i studien innebærer at du kan bidra med idéer og tilbakemeldinger på løsningens utforming, innhold og å teste den. For enkelte vil det være aktuelt å delta både i intervju og arbeidsgruppe, samt å teste løsningen. For andre vil det bare være aktuelt å delta i et intervju. Hva som passer, vil bli avtalt med hver enkelt deltager. Du vil også bli bedt om å fylle ut et skjema med bakgrunnsopplysninger om deg selv.

Intervju:
Intervjuet gjennomføres av en forsker og/eller prosjektmedarbeider og tar cirka 45-60 minutter. Det vil bli tatt lydopptak.

Arbeidsgruppen:
Gruppen varer mellom 1-3 timer (inkludert pause) og vil bestå av andre personer med ikke-hormonproduserende hypofysesvulst, IT-utviklere og prosjektmedarbeidere, og ledes av en forsker. Det tas lydopptak og skrives referat fra møtene for å sikre at vi får med alle innspill.

Brukertesting:
Brukertestingen tar mellom 1-2 timer (inkludert pause). Under testingen vil du sitte med en PC, et nettbrett eller en smarttelefon. Du vil få ulike oppgaver for at vi skal se hvordan du bruker løsningen.

Vi vil filme fingerbevegelsene dine på brettet (ikke ansiktet) og tar opp lyd for å få så mye informasjon ut av testingen som mulig.

Mulige fordeler og ulemper for deg

Studien medfører ingen kostnader for deg og det er ingen risiko forbundet med studien. Det er få ulemper knyttet til deltakelse i prosjektet. Noen vil kanskje oppleve det som slitsomt å delta i intervju og grupper, men vi vil legge inn pauser underveis dersom du trenger det. Total medgått tid kan også oppleves som en ulempe. Din deltakelse vil bidra til viktig kunnskap om hvordan en eHelseløsning bør se ut for å passe til behovet til personer med ikke-hormonproduserende hypofysesvulst.

Informasjonen om deg og resultat av studien

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.03.27. Resultat fra studien kan bli publisert i norske og internasjonale tidsskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av studien når dette publiseres. Du vil få se den ferdige løsningen når den er utviklet. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til prosjektadministrator eller prosjektleder.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i utvikling av løsningen eller brukt i vitenskapelige publikasjoner. Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Senter for pasientmedvirkning og samhandlingsforskning, Oslo universitetssykehus HF:

- Berit Seljelid (91 15 32 52) Prosjektadministrator, phd- student/sykepleier
- Elin Børøsund (23 06 60 10) Prosjektleder, seniorforsker/sykepleier

Forsikring og økonomi

Du er forsikret på samme måte som ved ordinære opphold/konsultasjoner ved sykehus.

Det vil bli gitt kompensasjon for reise og tidsbruk i form av gavekort på 250 kr for hvert oppmøte. Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Prosjektet er godkjent av Personvernombudet ved Oslo universitetssykehus HF (20178/9223).

Oslo universitetssykehus

NORSK SYKEPLEIERFORBUND

Samtykke til deltakelse i forskningsprosjektet:

Utvikling og brukertesting av en eHelseløsning for personer med ikke-hormonproduserende hypofysesvulst

Jeg er villig til å delta i prosjektet

Sted og dato	Deltakers signatur
	Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato	Signatur
	Rolle i prosjektet

Oslo universitetssykehus

NORSK SYKEPLEIERFORBUND

Vil du delta i et forskningsprosjekt for utvikling og brukertesting av en eHelseløsning for nyretransplanterte?

eHelseløsning betyr her elektronisk kartlegging av symptomer og mulighet til bruk av sikker e-post for oppfølging og veiledning av helsepersonell.

Du forespørres om deltakelse fordi du får behandling og oppfølging etter nyretransplantasjon. For å delta må du være over 18 år, samt beherske norsk skriftlig og muntlig, samt ha tilgang til egen BankID, BuyPass eller Comfides.

Studiens bakgrunn og hensikt

Å leve med langvarige helseutfordringer påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. Det er behov for behandling og oppfølging som i større grad tar hensyn til det.

Hensikten med prosjektet er å utvikle en eHelseløsning hvor brukerne kan registrere symptomer før konsultasjon på sykehus og hva de ønsker å snakke med helsepersonell om. Løsningen kan gjøre det lettere å be om informasjon og veiledning for å håndtere plagene den enkelte erfarer. I tillegg kan endringer i sykdomsutvikling bli mer synlig både for brukeren og helsepersonell. Å styrke opplevelsen av å mestre livet med helseutfordringer kan bidra til økt livskvalitet og redusere stress relatert til sykdom.

Hva innebærer studien for deg?

Vi trenger kunnskap om hva som er viktig og nyttig for deg i ditt daglige liv og i møte med helsepersonell. Deltagelse i studien innebærer at du kan bidra med idéer og tilbakemeldinger på løsningens utforming, innhold og å teste den. For enkelte vil det være aktuelt å delta både i intervju og arbeidsgruppe, samt å teste løsningen. For andre vil det bare være aktuelt å delta i et intervju. Hva som passer, vil bli avtalt med hver enkelt deltager. Du vil også bli bedt om å fylle ut et skjema med bakgrunnsopplysninger om deg selv.

Intervju:
Intervjuet gjennomføres av en forsker og/eller prosjektmedarbeider og tar cirka 45-60 minutter. Det vil bli tatt lydopptak.

Arbeidsgruppe:
Gruppen varer mellom 1-3 timer (inkludert pause) og vil bestå av andre nyretransplanterte, IT-utviklere og prosjektmedarbeidere, og ledes av en forsker. Det tas lydopptak og skrives referat fra møtene for å sikre at vi får med alle innspill.

Brukertesting:
Brukertestingen tar mellom 1-2 timer (inkludert pause). Under testingen vil du sitte med en PC, et nettbrett eller en smarttelefon. Du vil få ulike oppgaver for at vi skal se hvordan du bruker løsningen. Vi vil filme fingerbevegelsene dine på brettet (ikke ansiktet) og tar opp lyd for å få så mye informasjon ut av testingen som mulig.

Mulige fordeler og ulemper for deg

Studien medfører ingen kostnader for deg og det er ingen risiko forbundet med studien. Det er få ulemper knyttet til deltakelse i prosjektet. Noen vil kanskje oppleve det som slitsomt å delta i intervju og grupper, men vi vil legge inn pauser underveis dersom du trenger det. Total medgått tid kan også oppleves som en ulempe. Din deltakelse vil bidra til viktig kunnskap om hvordan en eHelseløsning bør se ut for å passe til behovet til nyretransplanterte.

Informasjonen om deg og resultat av studien

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.03.27. Resultat fra studien kan bli publisert i norske og internasjonale tidsskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av studien når dette publiseres. Du vil få se den ferdige løsningen når den er utviklet. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til prosjektadministrator eller prosjektleder.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i utvikling av løsningen eller brukt i vitenskapelige publikasjoner. Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Senter for pasientmedvirkning og samhandlingsforskning, Oslo universitetssykehus HF:

- Berit Seljelid (91 15 32 52) Prosjektadministrator, phd- student/sykepleier
- Elin Børøsund (23 06 60 10) Prosjektleder, seniorforsker/sykepleier

Forsikring og økonomi

Du er forsikret på samme måte som ved ordinære opphold/konsultasjoner ved sykehus.

Det vil bli gitt kompensasjon for reise og tidsbruk i form av gavekort på 250 kr for hvert oppmøte. Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Prosjektet er godkjent av Personvernombudet ved Oslo universitetssykehus HF (20178/9223).

Oslo universitetssykehus

NORSK SYKEPLEIERFORBUND

Samtykke til deltakelse i forskningsprosjektet:

Utvikling og brukertesting av en eHelseløsning for nyretransplanterte

Jeg er villig til å delta i prosjektet

Sted og dato	Deltakers signatur
	Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato	Signatur
	Rolle i prosjektet

Oslo universitetssykehus

Forespørsel om deltagelse i forskningsprosjektet

InvolverMeg

Vil du delta i et forskningsprosjekt som gjennomføres ved Oslo universitetssykehus hvor du får teste en digital kommunikasjonsløsning for kontakt med helsepersonell?

Du forespørres om deltakelse fordi du får behandling og oppfølging av et ikke-hormonproduserende hypofyseadenom ved Seksjon for spesiell endokrinologi, Oslo universitetssykehus. For å delta må du være over 18 år, beherske norsk skriftlig og muntlig, ha egen BankID, samt smarttelefon eller nettbrett.

Å leve med langvarig sykdom påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. Dette forskningsprosjektet vil teste en digital kommunikasjonsløsning for kontakt mellom pasient og helsepersonell. Deltagerne får mulighet til 1) å kartlegge symptomer og behov, før konsultasjon på sykehuset. I tillegg får de benytte en 2) sikker e-posttjeneste for oppfølgning og veiledning av helsepersonell mellom konsultasjonene.

Forskningsprosjektet skal teste hvordan det er å benytte den digitale kommunikasjonsløsningen og om spørreskjemaene deltagerne får er forståelige, samt hvordan det er å få digital oppfølgning fra helsepersonell. Dette vil bidra til viktig kunnskap om hva en digital kommunikasjonsløsning skal inneholde og hvordan bruken av digitale tjenester kan styrke oppfølgingen av personer med langvarig sykdom.

Hva innebærer prosjektet for deg?

Før du kan ta i bruk kommunikasjonsløsningen må du svare på noen spørsmål om deg selv og hvordan du har det i forbindelse med sykdom og behandling. Det skjer ved at du får tilsendt en lenke til et spørreskjema i sms eller e-post. Ved å følge lenken fyller du ut spørsmålene elektronisk. Dette vil ta ca 15 minutter. 3 og 6 måneder etter at du fikk tilgang til kommunikasjonsløsningen vil du få noen av de samme spørsmålene som før oppstart, samt spørsmål om hvordan det har vært å benytte kommunikasjonsløsningen. Dette vil ta ca 10-15 minutter. Vi ber om din tillatelse til å innhente data om hvordan du bruker kommunikasjonsløsningen (hva som benyttes, hvor ofte og hvilke spørsmål som stilles). Dette er opplysninger som hentes fra systemloggen.

Bruken av kommunikasjonsløsningen kommer i tillegg til den oppfølgingen du får i dag. Noen dager før avtalt konsultasjon på sykehuset vil du få tilsendt en lenke via e-posttjenesten i MinJournal. Varsel om dette kommer på sms eller eventuelt den epost-adressen du har registert i MinJournal. For å svare må du logge på med bruk av BankID i MinJournal. I innboksen vil det ligge en e-post med en lenke du kan følge for å fylle ut en kartlegging av dine symptomer og behov. Kartleggingen gir også en mulighet for å prioritere hva som er viktig for deg å snakke om med helsepersonell i konsultasjonen. Kartlegging og prioritering mottas og leses av helsepersonell før konsultasjonen. Om du skulle glemme å fylle ut kartleggingen kan det komme en påminnelse på sms eller e-post før konsultasjonen. E-posttjenesten i MinJournal benyttes for å sende spørsmål og motta svar mellom

Oslo universitetssykehus

deg og helsepersonell. Du må ikke benytte e-posttjenesten ved behov for øyeblikkelig helsehjelp. Innhold i kartlegginger og meldinger som vurderes som journalverdig av helsepersonell vil bli ført inn i pasientjournal.

Etter en kort innføring i bruk av kommunikasjonsløsningen kan du bruke den når du har behov for det og så lenge forskningsprosjektet pågår, minst 6 måneder.

Du kan bli invitert til å delta i et fokusgruppeintervju sammen med 5-7 andre deltagere som har benyttet den digitale kommunikasjonsløsningen etter 3 - 6 måneders bruk. Dette vil avtales nærmere. Deltagelse i fokusgruppe er helt frivillig, vil ta mellom 60-90 minutter og påvirker ikke muligheten til å bruke kommunikasjonsløsningen. Hensikten med dette er å dele erfaringene med å bruke løsningen. I fokusgruppen vil det bli benyttet lydopptak for å sikre at vi får med alle innspill.

Mulige fordeler og ulemper for deg

Forskningsprosjektet medfører ingen kostnader for deg og det er ingen risiko forbundet med å delta. Det kan oppleves som positivt å få mulighet til å stille spørmål til helsepersonell ved bruk av meldingstjenesten. Det kan også oppleves som en fordel å få anledning til å prioritere hva du har behov for å snakke om i konsultasjonene med helsepersonell. Det er få ulemper knyttet til deltakelse i prosjektet. Noen vil kanskje oppleve det som slitsomt å besvare alle spørsmålene som blir sendt ut. Total medgått tid til å besvare spørsmålene kan også oppleves som en ulempe.

Hva skjer med opplysninger om deg?

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder Elin Børøsund og medlemmer av forskningsteamet som har tilgang til denne listen, og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.01.29 Resultat fra studien kan bli publisert i norske og internasjonale tidskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av forskningsprosjektet når dette publiseres. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til Elin Børøsund og Berit Seljelid. Enkelte tidskrift kan kreve å få tilgang til orginaldata, dette vil si anonymiserte svar fra spørreskjema og bruk av løsningen. Vi ber om din tillatelse til dette.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, vil du få tilstendt en lenke på sms eller e-post hvor du kan samtykke til deltagelse ved bruk av BankID, eventuelt kan du undertegne samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre oppfølgning og behandling. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre

Oslo universitetssykehus

opplysningene allerede er brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Elin Børøsund, tlf: 22 89 43 57, Elin.Borosund@rr-research.no

Forsikring og økonomi

Du er forsikret på samme måte som ved ordinære opphold/konsultasjoner ved sykehus.

Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning (Saksnr. hos REK 2018/2201)

Etter ny personopplysningslov har behandlingsansvarlig Oslo universitetssykehus og prosjektleder Elin Børøsund et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6a og artikkel 9 nr. 2 og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Personvernombudet.

Kontaktopplysninger

Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Avdeling for digital helseforskning, Oslo universitetssykehus HF:

- Elin Børøsund, prosjektleder, seniorforsker
  Tlf: 22 89 43 57
  E-post: Elin.Borosund@rr-research.no
- Berit Seljelid, prosjektadministrator, Phd- stipendiat
  Tlf: 91 15 32 52
  E-post: Berit.Seljelid@rr-research.no

Du kan ta kontakt med Oslo universitetssykehus sitt personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet.

- Personvernombud ved Oslo universitetssykehus
  Tlf. 915 02 770
  E-post: personvern@ous-hf.no

Oslo universitetssykehus

Samtykke til deltakelse i forskningsprosjektet InvolverMeg:

Testing av en digital kommunikasjonsløsning for personer med et ikke- hormonproduserende hypofyseadenom som får oppfølgning av spesialisthelsetjenesten.

Jeg er villig til å delta i prosjektet

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato

Signatur

Rolle i prosjektet

Vil du delta i et forskningsprosjekt for utvikling og brukertesting av en eHelseløsning for kommunikasjon mellom helsepersonell og personer med ikke-hormonproduserende hypofyseadenom?

eHelseløsning betyr her elektronisk kartlegging av symptomer og mulighet til bruk av sikker e-post for oppfølging og veiledning av helsepersonell. Du forespørres om deltakelse fordi du er helsepersonell som har inngående kjennskap til overnevnte pasientgruppe.

Studiens bakgrunn og hensikt

Å leve med langvarige helseutfordringer påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. Det er behov for behandling og oppfølging som i større grad tar hensyn til det.

Hensikten med prosjektet er å utvikle en eHelseløsning hvor brukerne kan registrere symptomer før konsultasjon på sykehus og hva de ønsker å snakke med helsepersonell om. Løsningen kan gjøre det lettere å be om informasjon og veiledning for å håndtere plagene den enkelte erfarer. I tillegg kan endringer i sykdomsutvikling bli mer synlig både for brukeren og helsepersonell. Vi har behov for kunnskap om hvilke symptomer, utfordringer og behov helsepersonell erfarer at overnevnte pasientgruppe har, i tillegg til hvilke behov helsepersonell opplever i møte med pasientene.

Hva innebærer studien for deg?

Vi trenger kunnskap om hva som er viktig og nyttig for deg i møte med pasientgruppen. Deltagelse i studien innebærer at du kan bidra med idéer og tilbakemeldinger på løsningens utforming, innhold og å teste den. For enkelte vil det være aktuelt å delta både i intervju og arbeidsgruppe, samt å teste løsningen. For andre vil det bare være aktuelt å delta i et intervju. Hva som passer, vil bli avtalt med hver enkelt deltager.

Intervju:
Intervjuet gjennomføres av en forsker og/eller prosjektmedarbeider og tar cirka 45-60 minutter. Det vil bli tatt lydopptak.

Arbeidsgruppe:
Gruppen varer mellom 1-3 timer (inkludert pause) og vil bestå av annet helsepersonell fra feltet, IT-utviklere og prosjektmedarbeidere, og ledes av en forsker. Det tas lydopptak og skrives referat fra møtene for å sikre at vi får med alle innspill.

Brukertesting:
Brukertestingen tar mellom 1-2 timer (inkludert pause). Under testingen vil du sitte med en PC, et nettbrett eller en smarttelefon. Du vil få ulike oppgaver for at vi skal se hvordan du bruker løsningen. Vi vil filme fingerbevegelsene dine på brettet (ikke ansiktet) og tar opp lyd for å få så mye informasjon ut av testingen som mulig.

Mulige fordeler og ulemper for deg

Studien medfører ingen kostnader for deg og det er ingen risiko forbundet med studien. Det er få ulemper knyttet til deltakelse i prosjektet. Noen vil kanskje oppleve det som slitsomt å delta i intervju og grupper, men vi vil legge inn pauser underveis dersom du trenger det. Total medgått tid kan også oppleves som en ulempe. Din deltakelse vil bidra til viktig kunnskap om hvordan en eHelseløsning bør se ut for å passe til behovet til pasientene og helsepersonell.

Informasjonen om deg og resultat av studien

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.03.27. Resultat fra studien kan bli publisert i norske og internasjonale tidsskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av studien når dette publiseres. Du vil få se den ferdige løsningen når den er utviklet. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til prosjektadministrator eller prosjektleder.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i utvikling av løsningen eller brukt i vitenskapelige publikasjoner. Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Senter for pasientmedvirkning og samhandlingsforskning, Oslo universitetssykehus HF:

- Berit Seljelid (91 15 32 52) Prosjektadministrator, phd- student/sykepleier
- Elin Børøsund (92 66 71 61) Prosjektleder, seniorforsker/sykepleier

Økonomi

Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Prosjektet er godkjent av Personvernombudet ved Oslo universitetssykehus HF (20178/9223).

Oslo universitetssykehus

NORSK SYKEPLEIERFORBUND

Samtykke til deltakelse i forskningsprosjektet:

Utvikling og brukertesting av en eHelseløsning for kommunikasjon mellom helsepersonell og personer med ikke-hormonproduserende hypofyseadenom

Jeg er villig til å delta i prosjektet

Sted og dato	Deltakers signatur
	Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato	Signatur
	Rolle i prosjektet

Vil du delta i et forskningsprosjekt for utvikling og brukertesting av en eHelseløsning for kommunikasjon mellom helsepersonell og nyretransplanterte?

eHelseløsning betyr her elektronisk kartlegging av symptomer og mulighet til bruk av sikker e-post for oppfølging og veiledning av helsepersonell. Du forespørres om deltakelse fordi du er helsepersonell som har inngående kjennskap til overnevnte pasientgruppe.

Studiens bakgrunn og hensikt

Å leve med langvarige helseutfordringer påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. Det er behov for behandling og oppfølging som i større grad tar hensyn til det.

Hensikten med prosjektet er å utvikle en eHelseløsning hvor brukerne kan registrere symptomer før konsultasjon på sykehus og hva de ønsker å snakke med helsepersonell om. Løsningen kan gjøre det lettere å be om informasjon og veiledning for å håndtere plagene den enkelte erfarer. I tillegg kan endringer i sykdomsutvikling bli mer synlig både for brukeren og helsepersonell. Vi har behov for kunnskap om hvilke symptomer, utfordringer og behov helsepersonell erfarer at overnevnte pasientgruppe har, i tillegg til hvilke behov helsepersonell opplever i møte med pasientene.

Hva innebærer studien for deg?

Vi trenger kunnskap om hva som er viktig og nyttig for deg i møte med pasientgruppen. Deltagelse i studien innebærer at du kan bidra med idéer og tilbakemeldinger på løsningens utforming, innhold og å teste den. For enkelte vil det være aktuelt å delta både i intervju og arbeidsgruppe, samt å teste løsningen. For andre vil det bare være aktuelt å delta i et intervju. Hva som passer, vil bli avtalt med hver enkelt deltager.

Intervju:
Intervjuet gjennomføres av en forsker og/eller prosjektmedarbeider og tar cirka 45-60 minutter. Det vil bli tatt lydopptak.

Arbeidsgruppe:
Gruppen varer mellom 1-3 timer (inkludert pause) og vil bestå av annet helsepersonell fra feltet, IT-utviklere og prosjektmedarbeidere, og ledes av en forsker. Det tas lydopptak og skrives referat fra møtene for å sikre at vi får med alle innspill.

Brukertesting:
Brukertestingen tar mellom 1-2 timer (inkludert pause). Under testingen vil du sitte med en PC, et nettbrett eller en smarttelefon. Du vil få ulike oppgaver for at vi skal se hvordan du bruker løsningen. Vi vil filme fingerbevegelsene dine på brettet (ikke ansiktet) og tar opp lyd for å få så mye informasjon ut av testingen som mulig.

Mulige fordeler og ulemper for deg

Studien medfører ingen kostnader for deg og det er ingen risiko forbundet med studien. Det er få ulemper knyttet til deltakelse i prosjektet. Noen vil kanskje oppleve det som slitsomt å delta i intervju og grupper, men vi vil legge inn pauser underveis dersom du trenger det. Total medgått tid kan også oppleves som en ulempe. Din deltakelse vil bidra til viktig kunnskap om hvordan en eHelseløsning bør se ut for å passe til behovet til nyretransplanterte og helsepersonell.

Informasjonen om deg og resultat av studien

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.03.27. Resultat fra studien kan bli publisert i norske og internasjonale tidsskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av studien når dette publiseres. Du vil få se den ferdige løsningen når den er utviklet. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til prosjektadministrator eller prosjektleder.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i utvikling av løsningen eller brukt i vitenskapelige publikasjoner. Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Senter for pasientmedvirkning og samhandlingsforskning, Oslo universitetssykehus HF:

- Berit Seljelid (91 15 32 52) Prosjektadministrator, phd- student/sykepleier
- Elin Børøsund (92 66 71 61) Prosjektleder, seniorforsker/sykepleier

Økonomi

Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Prosjektet er godkjent av Personvernombudet ved Oslo universitetssykehus HF (20178/9223).

Oslo universitetssykehus

NORSK SYKEPLEIERFORBUND

Samtykke til deltakelse i forskningsprosjektet:

Utvikling og brukertesting av en eHelseløsning for kommunikasjon mellom helsepersonell og nyretransplanterte

Jeg er villig til å delta i prosjektet

Sted og dato	Deltakers signatur
	Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato	Signatur
	Rolle i prosjektet

Oslo universitetssykehus

Forespørsel om deltagelse i forskningsprosjektet

InvolverMeg

Vil du delta i et forskningsprosjekt som gjennomføres ved Oslo universitetssykehus for å teste og og ta i bruk en digital kommunikasjonsløsning for kontakt med pasienter?

Du forespørres om deltakelse fordi du er helsepersonell som følger opp enten nyretransplanterte eller personer med ikke-hormonproduserende hypofyseadenom som får oppfølgning og behandling ved Oslo universitetssykehus. For å delta må du enten være ansatt ved Nyremedisinsk avdeling eller Seksjon for spesiell endokrinologi.

Å leve med langvarig sykdom påvirker alle områder av livet. Mange opplever bekymring og usikkerhet i tillegg plagsomme symptomer som varierer i intensitet. I dette forskningsprosjektet vil vi teste og ta i bruk en digital kommunikasjonsløsning hvor pasienter får mulighet til å 1) kartlegge symptomer og behov før konsultasjon på sykehuset og 2) benytte en sikker e-posttjeneste for oppfølging og veiledning av helsepersonell mellom konsultasjonene.

Den første delen av forskningsprosjektet gjennomføres som en pilotstudie hvor hensikten er å pilotteste hvordan det er å benytte den digitale kommunikasjonsløsningen, om spørreskjemaene pasientene besvarer er forståelige, samt om rutiner for å sende ut og benytte kartleggingen og besvare meldinger fungerer etter hensikten. Den andre andre delen av forskningsprosjektet gjennomføres som en observasjonsstudie over lengre tid hvor hensikten er å se på om bruken av kommunikasjonsløsningen påvirker hvordan deltagerne har det og hvordan det er å få digital oppfølging fra helsepersonell. Dette vil bidra til viktig kunnskap om hva en digital kommunikasjonsløsning skal inneholde og hvordan bruken av digitale tjenester kan styrke oppfølgingen av personer med langvarig sykdom.

Hva innebærer studien for deg?

Før oppstart vil du bli bedt om å fylle ut et skjema med noen spørsmål om deg selv og din yrkesbakgrunn. Etter 3-6 måneder i piloten, samt etter at observasjonsstudien er gjennomført vil du få et spørreskjema om hvordan det har vært å benytte kommunikasjonsløsningen. Dette vil ta 1-2 minutter. Vi ber om din tillatelse til å innhente data om hvordan du bruker kommunikasjonsløsningen (hvor ofte og hvordan meldinger besvares). Dette er opplysninger som hentes fra systemloggen.

En lenke med til kartleggingen må sendes pasientene ved å bruke e-posttjenesten i MinJournal noen tid før avtalt konsultasjon. For å få sendt og hentet ut kartlegginger, samt besvare spørsmål som er kommet inn via e-posttjenesten avdelingens fellespostkasse i MinJournal, må du logge på som klinikker på sykehus-PC. E-posttjenesten kan benyttes for å sende spørsmål og svar mellom deg og pasientene. E-posttjenesten skal ikke benyttes ved behov for øyeblikkelig helsehjelp. Innhold i kartlegginger og meldinger som vurderes som journalverdig, må klippes og limes inn i pasientjournal (DIPS).

Oslo universitetssykehus

Etter en kort innføring i bruk av kommunikasjonsløsningen kan du bruke den så lenge forskningsprosjektet pågår, ca 2,5 år.

Du kan bli invitert til å delta i 1-2 fokusgruppeintervju sammen med 5-7 andre deltagere (helsepersonell) som har benyttet den digitale kommunikasjonsløsningen i pilotperioden, samt når observasjonsstudien er gjennomført. Dette vil avtales nærmere. Deltagelse i fokusgruppe er helt frivillig, vil ta mellom 60-90 minutter og påvirker ikke muligheten til å bruke kommunikasjonsløsningen. Hensikten med dette er å få mulighet til å komme med innspill til hvordan løsningen kan forbedres og å dele erfaringene med å bruke løsningen. I fokusgruppen vil det bli benyttet lydopptak for å sikre at vi får med alle innspill.

Mulige fordeler og ulemper for deg

Forskningsprosjektet medfører ingen kostnader for deg og det er ingen risiko forbundet med å delta i det. Det kan oppleves som en fordel å få mulighet til å sende svar til pasienter ved bruk av en sikker meldingstjenesten. Det kan også oppleves som positivt å få kjennskap til hvilke forventninger pasienten har til konsultasjonen ved å se hvilke prioriteringer pasientene har gjort. Bruk av kommunikasjonsløsningen kan også medføre færre telefonhenvendelser, og redusere antall avbrudd i arbeidshverdagen. Det er få ulemper knyttet til deltakelsen i prosjektet. Noen vil kanskje oppleve det som slitsomt og tidkrevende å delta i fokusgruppeintervju, men vi vil legge inn pauser underveis dersom du trenger det. Andre kan synes at det tar ekstra tid å se på kartlegginger samt besvare meldinger fra pasientene.

Informasjonen om deg og resultat av studien

Informasjonen, som registreres om deg, skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder Elin Børøsund og medlemmer av forskningsteamet som har tilgang til denne listen, og som kan finne tilbake til deg.

All informasjon om deg vil bli anonymisert etter at studien er avsluttet, senest 01.01.29. Resultat fra studien kan bli publisert i norske og internasjonale tidskrift og på konferanser. Det vil ikke være mulig å identifisere deg i resultatene av forskningsprosjektet når dette publiseres. Etter hvert som resultatene av prosjektet publiseres, kan kopier og artikler fås ved henvendelse til Elin Børøsund og Berit Seljelid. Enkelte tidskrift kan kreve å få tilgang til orginaldata, dette vil si anonymiserte svar fra spørreskjema og bruk av løsningen. Vi ber om din tillatelse til dette.

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta så kan du undertegne samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for ditt arbeidsforhold ved avdelingen. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene

allerede er brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder Elin Børøsund;
Tlf: 22 89 43 57,
Epost: Elin.Borosund@rr-research.no

Forsikring og økonomi

Studien er finansiert av midler fra Norsk Sykepleieforbund og Oslo universitetssykehus HF. Det er ingen interessekonflikter å melde.

Godkjenning

Regional komité for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning (Saksnr. hos REK 2018/2201).

Etter ny personopplysningslov har behandlingsansvarlig Oslo universitetssykehus og prosjektleder Elin Børøsund et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6a og artikkel 9 nr. 2 og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Personvernombudet.

Kontaktopplysninger

Dersom du har spørsmål til prosjektet, kan du kontakte følgende ansatte ved Avdeling for digital helseforskning, Oslo universitetssykehus HF:

- Elin Børøsund, prosjektleder, seniorforsker
  Tlf: 22 89 43 57
  E-post: Elin.Borosund@rr-research.no
- Berit Seljelid, prosjektadministrator, Phd- stipendiat
  Tlf: 91 15 32 52
  E-post: Berit.Seljelid@rr-research.no

Du kan ta kontakt med Oslo universitetssykehus sitt personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet.

- Personvernombud ved Oslo universitetssykehus HF
  Tlf. 915 02 770
  E-post: personvern@ous-hf.no

Oslo universitetssykehus

Samtykke til deltakelse i forskningsprosjektet InvolverMeg:

Pilottesting og bruk av en digital kommunikasjonsløsning for helsepersonell som følger opp personer med langvarig sykdom og behov for oppfølgning av spesialisthelsetjenesten.

Jeg er villig til å delta i prosjektet

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato

Signatur

Rolle i prosjektet

Errata list

Page	Line	Original text	Type of correction	Corrected text
18	24	...communication (42) However…	Cor	…communication (42). However…
24	32	…decisionmaking,..	Cor	…decision making,..
25	17	…provider and providers…	Cor	…providers, and providers…
51	17	…(i.e., ‘samvalg’)…	Celtf	…(i.e., ‘samvalg’)…
56	22	…(Brooke, 1996)…	Cor	…(165)…
77	12	…(160)(Polit & Beck, 2021)…	Cor	…(160)…
79	9	…(Hartasanchez et al, 2022)…	Cor	…(36)...
79	13	…(Qu et al, 2023)…	Cor	…(214)…