

BMJ Open Assessing a nurse-assisted eHealth intervention posthospital discharge in adult patients with non-communicable diseases: a protocol for a feasibility study

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To cite: Morken IM, Wathne HB, Karlsen B, *et al.* Assessing a nurse-assisted eHealth intervention posthospital discharge in adult patients with non-communicable diseases: a protocol for a feasibility study. *BMJ Open* 2023;**13**:e069599. doi:10.1136/bmjopen-2022-069599

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-069599>).

Received 27 October 2022
Accepted 28 June 2023



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ABSTRACT

Introduction A growing number of patients with non-communicable diseases (NCDs), such as heart failure (HF) and colorectal cancer (CRC), are prone to comorbidity, a high rate of readmissions and complex healthcare needs. An eHealth intervention, however, could potentially ameliorate the increasing burdens associated with NCDs by helping to smoothen patient transition from hospital to home and by reducing the number of readmissions. This feasibility study therefore aims to assess the feasibility of a nurse-assisted eHealth intervention posthospital discharge among patients with HF and CRC, while also examining the preliminary clinical and behavioural outcomes of the intervention before initiating a full-scale randomised controlled trial. The recruitment ended in January 2023.

Methods and analysis Twenty adult patients with HF and 10 adult patients with CRC will be recruited from two university hospitals in Norway. Six hospital-based nurse navigators (NNs) will offer support during the transition phase from hospital to home by using a solution for digital remote care, Dignio Connected Care. The patients will use the MyDignio application uploaded to an iPad for 30 days postdischarge. The interactions between patients and NNs will then be assessed through direct observation and qualitative interviews in line with a think-aloud protocol. Following the intervention, semistructured interviews will be used to explore patients' experiences of eHealth support and NNs' experiences of eHealth delivery. The feasibility testing will also comprise a post-test of the Post-System Usability Questionnaire and pretesting of patient-reported outcomes questionnaires, as well as an inspection of user data collected from the software.

Ethics and dissemination The study has been approved by the Norwegian Centre for Research Data (ID.NO: 523386). All participation is based on informed, written consent. The results of the study will be published in open-access, peer-reviewed journals and presented at international and national scientific conferences and meetings.

INTRODUCTION

As a result of the COVID-19 pandemic crisis, eHealth solutions are more important than ever in providing timely and effective care

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Use of a complex intervention design.
- ⇒ Quantitative and qualitative methods that include a think-aloud approach will provide a comprehensive picture of feasibility.
- ⇒ The outcomes to be assessed in this study will inform the main randomised controlled trial to evaluate the effectiveness of the intervention.
- ⇒ The study is limited by its small sample size, meaning that the data it generates may not be generalisable to patients participating in similar interventions.

to the growing number of patients with non-communicable diseases (NCDs).¹⁻³ NCDs are non-infectious health conditions, also known as chronic diseases, that tend to be of long duration and are the leading cause of death worldwide, with cardiovascular diseases accounting for the majority of such deaths (17.9 million people annually), followed by cancer (9.3 million).⁴ Patients with heart failure (HF) and colorectal cancer (CRC) are prone to comorbidity, complex healthcare needs, a high rate of 30-day and 90-day readmissions,⁵⁻⁸ as well as an excessive Burden of Treatment (BoT).⁹⁻¹⁰ BoT describes the extra workload (ie, self-management tasks) that patients with serious long-term illnesses must undertake in order to live well and also covers the impact this workload has on well-being and quality of life (QoL).¹¹ A high treatment burden can lead to negative outcomes such as reduced QoL, psychological distress, non-adherence to treatment and hospital readmissions.¹¹⁻¹³ With eHealth, health management and patient engagement can be enhanced with remote digital care and virtual technology to deliver healthcare outside the confines of traditional healthcare facilities.¹⁴⁻¹⁶ Hence, to better support



self-management in NCD patients, eHealth solutions may be a viable option. Eysenbach (2001)¹⁷ defines eHealth as ‘health services and information delivered or enhanced through the Internet and related technologies’ (p. e20).¹⁷

Nurses play a central role in remote digital care, such as by monitoring patients’ blood pressure, weight, heart rate, temperature and symptoms (eg, pain, fatigue and dizziness). They guide and support patients towards self-management by providing them with the analytical skills necessary to interpret bodily signals and take the appropriate measurements so as to prevent them from exacerbating their condition.¹⁸ This enables nurses and other care providers to provide timely, clinical intervention. Remote monitoring combined with eHealth support has proven efficient in increasing self-care and reducing costly readmissions, which can be critical and burdensome for patients.^{19 20} Self-management may be particularly challenging during transitional phases, for example, shifts from one life phase or status to another,²¹ such as the transition from hospital to home. Interventions specifically designed to close the transitional gap between hospital discharge and home, combining remote monitoring and eHealth, may have the potential to improve both timely clinical intervention and patient engagement in self-care, as well as to reduce readmissions and save on costs.^{20 22–27} Accordingly, this protocol proposes the feasibility assessment of nurse-assisted eHealth intervention consisting of remote monitoring of blood pressure, weight and heart rate for patients with HF, temperature and weight for patients with CRC, as well as symptoms for both patient groups in collaboration with a NN.

Developing, evaluating and implementing complex interventions, such as an innovative eHealth intervention, are essential for improving healthcare.^{28 29} Today, there are several theories that attempt to conceptualise and explain how new technologies are best developed, implemented and adopted as part of everyday healthcare. This research will draw on one such theory—the Normalisation Process Theory (NPT). NPT identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice.²⁸ The theory focuses on the work that individuals and groups do to ‘normalise’ an intervention and do so by identifying four theoretical constructs: (1) coherence, (2) cognitive participation, (3) collective action and (4) reflexive monitoring.³⁰ Moreover, NPT offers a consistent framework that can be used to describe and evaluate implementation potential, and, more importantly, to design and improve complex interventions.

The use of NPT has coalesced around two main types of studies—feasibility studies and process evaluations³⁰—and has also been used to consider complex interventions prior to the development of RCTs to test their effectiveness.³¹ Thus, NPT seems to serve as an appropriate framework for evaluating the feasibility of and the process of developing the current eHealth intervention.

In this article, we present a study protocol for the feasibility assessment of a nurse-assisted eHealth intervention

for patients with HF and CRC in transition from hospital to home. The overall objective is to determine whether this nurse-assisted eHealth intervention is feasible and acceptable to patients with HF and CRC who are in the process of transitioning from hospital discharge to home testing. Furthermore, we will examine the preliminary clinical and behavioural outcomes of the intervention. Thus, the study asks the following research questions: (1) What are patients’ and healthcare professionals’ initial experiences of the adoption of nurse-assisted eHealth intervention? (2) Which functions of nurse-assisted eHealth intervention will be deemed functional and usable, and which will require further development for successful implementation and further use in an RCT? (3) What are the patients’ experiences of eHealth as self-management support? and (4) What are the NNs’ experiences of healthcare delivery through technology? In addition, we aim to estimate the recruitment rate, patient adherence to the intervention and response rates of patient-reported outcomes (PROMS) expected to be used in the main project’s full-scale RCT, while examination of the SD of PROMS will be used to estimate sample size to the RCT.^{32–35}

METHODS AND ANALYSIS

Study design

We use the framework of complex interventions proposed by the UK Medical Research Council (MRC)²⁹ in order to assess the study’s feasibility. The study will be reported in accordance with the Consolidated Standards of Reporting Trials 2010 statement: extension to randomised pilot and feasibility trials.³⁶ Development of the eHealth intervention used for feasibility testing in this study was completed in 2021.³⁷ This feasibility study is already in progress, having started in December 2021. The recruitment ended in January 2023 and the expected study completion is November 2023. The study detailed in this protocol constitutes the first of two phases in a main project: (1) a feasibility study and (2) an RCT. The outcomes assessed in this study will inform the main RCT in evaluating the effectiveness of the intervention. The feasibility assessment will consider the usability of the nurse-assisted eHealth interventions while also determining whether the eHealth intervention is appropriate for further testing and evaluating its effectiveness.³⁸ This feasibility study is a non-randomised study in which all participants will receive the nurse-assisted eHealth intervention. The design of the study is combined with a 30-day test period of the eHealth intervention in the patient’s home environment. This study will comprise both qualitative and quantitative methods following testing of the eHealth intervention among patients with HF and CRC and NNs. Qualitative data collection using interview, field observations and an exploratory and observational think-aloud approach³⁹ will be carried out in this study to explore the patients’ and nurses’ initial impressions of using eHealth interventions. Moreover, to further assess the acceptability and usefulness of the intervention, a quantitative,

descriptive approach will be adopted. A pretest–post-test of the questionnaires expected to be used in the RCT will also be performed. In order to examine the SD of PROMS for use in sample size calculation to the RCT, Lancaster *et al* (2004) recommend the general rule of thumb of 30 patients or greater.³⁵

The eHealth intervention

The eHealth intervention uses an existing software platform (Dignio Connected Care),⁴⁰ which will be accessible for patients (MyDignio) and NNs (DignioPrevent) using a web-enabled tablet (ie, an iPad). DignioPrevent is a digital patient journal accessed via a secure website and used for remote follow-up of patients (www.dignio.com). MyDignio is an application for smartphones or tablets (www.dignio.com).

The Dignio platform's functions for self-management support were available for individual tailoring, and, as a result of the main project's development study, the functions and content were customised to the two patient populations for relevant digital communication with the NNs. Registered nurses engaged as NNs will offer support during the transition phase from hospital to home through DignioPrevent with the objectives of providing feedback on monitoring results and improving patient outcomes, thus facilitating patients in participating in self-management tasks. The patients will be instructed by the NN regarding how to use the MyDignio application and monitoring devices after providing informed consent at the hospital ward. The patients will be encouraged to measure their body weight (both HF and CRC patients), temperature (only CRC patients) and blood pressure and heart rate (only HF patients) by using the monitoring devices at least once a day at approximately the same time, thus minimising daily variance caused by meals, micturition and bowel movement. Before the monitoring begins, warning thresholds for body weight, blood pressure, pulse and temperature will be determined for each patient. Telephone contact details to access technical support will also be included in case the participants require additional assistance or encounter technical difficulties. The NN will contact each patient 24–48 hours after discharge to answer any questions about using the tablet and the monitoring devices. Furthermore, the NN will follow-up on the patients, when necessary, over a period of 30 days at home.

Study setting

The study includes participants with HF and CRC from two university hospitals in Norway (study site A and study site B). Study site A is a university hospital in the western part of Norway. It is a local hospital for a population of approximately 370 000 inhabitants. Study site B is a university hospital in the middle part of Norway. It is the local hospital for 327 574 inhabitants and has regional functions for approximately 730 000 inhabitants (as of September 2020).

Eligibility of study participants

To test the eHealth intervention, 20 patients with HF will be recruited from hospital cardiology wards at both study sites. Ten patients treated for CRC will be recruited from a gastrosurgical ward at study site A.

Eligible patients with HF are aged ≥ 18 years, ejection fraction $\leq 40\%$ and able to speak and write Norwegian. Exclusion criteria for this group of patients include patients on a waiting list for a heart transplant, those who require a Left Assist Ventricular Device, and those with a life expectancy < 6 months.

Eligible patients with CRC, meanwhile, are aged ≥ 18 years, are being surgically treated for either colon or rectal cancer, CRC DUKE's class 1–3 (curative) and are able to speak and write Norwegian. Exclusion criteria for CRC patients will be metastatic cancer, a Clavien-Dindo Surgical Complication Score of > 3 and acute medical crisis. Exclusion criteria for both patient groups are mental illness, cognitive impairment, planned discharge to a nursing home and participation in other intervention studies.

Eligible nurses are the dedicated NNs. The NNs are experienced hospital nurses with clinical skills required to identify and monitor the healthcare requirements of patients with HF and CRC.

Recruitment of participants

The patient recruitment strategy will involve selecting participants from the hospital inpatient departments. The hospital department patient list will be screened for study selection criteria by the involved study personnel. If patients are eligible, they will be informed by the study personnel either in writing or orally. The patients will be provided with an information letter detailing study aims, intervention content and delivery, collection of personal information and confidentiality of data management. If patients are interested in participating, they can contact the study personnel in the clinic. Written informed consent will be obtained from all patients.

Patient and public involvement

Participants were not involved in the development of the protocol and research questions. However, user representatives from the National Association for Heart and Lung Diseases (LHL) and the 'Norwegian Association for Ostomy, Reservoir and Gastrointestinal Cancer' (NORILCO) have been actively involved in this project since its early planning stages, as well as in discussions regarding study design, including the choice of outcome measures and an evaluation of the ethics of participating in the study.

Outcomes

Feasibility

Study feasibility will be assessed by participant recruitment (enrolment as a proportion of eligible participants) and retention (the proportion of participants who completed all assessments). Participants retention will further on be



assessed as follows: (1) engagement with the intervention as measured by adherence to monitoring devices and to the symptom checklist; and (2) by examining delivery as intended (as per protocol) through the use of digital devices, background data and NNs' perceptions of how patients received the intervention components. This will be captured after the patients have completed the intervention so as to keep a record of how actual delivery was received in relation to the planned delivery (eg, if a participant required extra time or further support).

Acceptability and utility

Qualitative feasibility data collection

The qualitative data collection focuses primarily on the design, navigation, functionality, delivery, content, availability/possibility of help, usefulness and personal relevance of the eHealth interventions. To ensure that the e-Health intervention is providing functions that users need (eg, utility), it is essential to be attentive to its quality of a user's experience when interacting with functions (eg, usability),³⁴ keeping in mind its intended users (eg, patients and nurses), task (eg, medication, temperature, weight and blood pressure management, free-text data entry or patient record search) and environment (eg, ward and home environment).⁴¹ This will be accessed through direct observation and qualitative interviews with patients and NNs from both study sites, as well as observation of some patients using a think-aloud method shortly after discharge.^{42 43} Think-aloud methods involve participants thinking aloud as they are performing a set of specified tasks. Participants are asked to say whatever comes into their mind as they complete the task. This might include what they are looking at, thinking, doing and feeling. This gives observers an insight into the participant's cognitive processes.⁴³ In addition, the researcher will also ask more

specific questions such as: How did you find the design/layout of MyDignio—How easy did you find it to understand the content of MyDignio?—Was the structure of the platform easy/difficult to understand—was it easy to find and navigate?—Does the platform feature the necessary functions or is there something missing?—How did you find the use of MyDignio technically speaking? The thinking-aloud method is widely regarded as a frequently used method for testing most aspects of usability.^{43–46} The data will be analysed using components from the NPT.²⁷ In order to explore patients' experiences of eHealth as self-management support, semistructured interviews with the patients will be performed after they have completed the intervention. The NNs, meanwhile, will be interviewed and asked to share their experiences of digital follow-up care using a semistructured interview guide after completing a 30-day follow-up period with all the patients recruited.

Quantitative feasibility data collection

Intervention acceptability and utility will also be assessed by a self-report questionnaire, the Post-Study System Usability Questionnaire (PSSUQ),⁴⁷ which is completed at 30 days. This is a 16-item instrument that will assess participants' perceived satisfaction of a website, software, system or product at the end of a study or intervention.

In addition, aggregated number-based data of use will be collected from the software DignioPrevent, displaying patients' registrations and the NNs responses as well as the interaction between patients and NNs in the form of chats and video consultations.

Pretest and post-test of PROMS (patient-reported outcomes)

The quantitative data collection process will also test the survey battery intended for the planned RCT. The pretest

Table 1 Measures in participant surveys

Outcomes	Measurements	Number of items	Baseline survey	Follow-up survey	References
Acceptability and utility	The Post-Study System Usability Questionnaire	16		x	Lewis (2011) ⁴⁷
Perceived self-efficacy to self-manage HF and CRC	Self-Efficacy for Managing Chronic Disease	6	X	x	Lorig <i>et al</i> (2001) ⁵¹
Patient-reported BoT	Patient Experience with Treatment and Self-management (PETS) scale (Medical information, Monitoring health, Medications and Medical appointments)	24	X	x	Eton <i>et al</i> (2010) ⁵² Norwegian version: Husebo <i>et al</i> (2018) ⁵³
Health-related Quality of Life (HrQoL)	EuroQoL EQ-5D-5L questionnaire	5	X	x	Brooks (1996) ⁵⁴
Collaboration with healthcare interventions	CollaboRATE	3	X	x	Elwyn <i>et al</i> (2013) ⁵⁵
Support from health professionals	Constructive support from health professionals	13	X	x	Karlsen <i>et al</i> (2004) ⁵⁶ Ofstedal <i>et al</i> (2010) ⁵⁷

BoT, Burden of Treatment; CRC, colorectal cancer; HF, heart failure.

will be performed by asking patients to fill out questionnaires at the hospital ward at baseline (ie, hospital discharge), and at the end of the 30-day eHealth follow-up (post-test). The post-test data collection will be performed during an end-of-intervention appointment either at the hospital or in the patient's home. Questionnaire data will be collected by using an application that includes an integrated solution for collecting sensitive data.

An overview of outcome measures is presented in [table 1](#).

All scales are generic and applicable to the two patient groups. Patient demographics, including variables of gender, age, education, work and living situation, will be collected from questionnaire, while diagnoses of other health conditions will be collected from hospital medical records.

Data storage

All data will be stored in the services for sensitive data (TSD) solution, which is administered by the University of Oslo (UiO) and provides a platform for secure data collection, storage and analysis of sensitive research data.

Data analysis plan

Qualitative analysis plan

The interviews will be audio-recorded and transcribed. Each data set (ie, transcripts, written field notes and observational data) will be analysed through thematic content analysis using tools from NPT²⁸ as well as through the think-aloud method of assessing usability, which consists of coding user comments for relevance to usability criteria and then grouping them according to themes such as data entry, user-interface consistency and comprehension.³⁸ Sorting and analysing of data will be performed manually without using a software (eg, Saldana, 2009⁴⁸).

Quantitative analysis plan

We will use IBM SPSS Statistics V.28 (IBM, 2022) to perform descriptive analyses of demographic variables and usability data (numbers, percentage, means and ranges). In addition, the number of patient registrations in MyDignio, the NNs' response rates and the percentage rates of recruitment, retention and questionnaire completion will be calculated. Moreover, measures of central tendency and variability will be computed for continuous measures. The results from these analyses will then quantify important sample characteristics as well as proportions and means of the feasibility and acceptability measures.

Ethics and dissemination

Ethical considerations

Approval was obtained from the Norwegian Centre for Research Data (NSD) (ID.NO: 523386) and the participating hospitals' Privacy Appeals Board. The Regional Ethics Committee (REC) deemed the current feasibility study to be exempt (ID.NO: 242405). The study will be conducted according to the Helsinki Declaration,⁴⁹ REC and the research guidelines from Stavanger University

Hospital (SUS) and St Olavs Hospital, Trondheim University Hospital and ethical and legal requirements according to the European General Data Protection Regulation (GDPR) No. 679, of 27 April 2016.⁵⁰

The participants will be recruited voluntarily and receive information about confidentiality, anonymity and the right to withdraw themselves from the study at any time. All participation is based on informed, written consent. The data collected will only be used for the purpose of the project. The participants will have the right to access the registered information and to have any errors in the information corrected. All information will be processed without the inclusion of any directly recognisable information (ie, coded information). A code will link the participant to the registered information through a list of names accessible only to the project manager. The data collected from patients will be stored in the TSD platform until 2028. All data with personal identifying information (ie, the code list) will be stored in a secure research server at the hospitals separate from the data material at the TSD server.

Risk and vulnerability analysis

A risk and vulnerability analysis of the customised Dignio Connected Care platform, including a Data Protection Impact Assessment, was performed as part of the research ethics assessment conducted by the NSD. The assessment included an examination of any calculated potential threat to the organisation's network (study site A and study site B) and vulnerabilities within its network and information systems.

The advantages of the project, which include developing new knowledge on content and the administration of a digital health intervention tailored to the patient populations of interest, may outweigh the possible disadvantages of the project.

Disseminations

The results from this study will be presented at international and national scientific conferences as well as in peer-reviewed scientific journals. The results will also be shared with the stakeholders of the project through patient organisation channels, at seminars for relevant healthcare personnel and as popular-science contributions via local media and social media.

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Acknowledgements We thank professor Carl May, professor Edvin Bru and professor Anna Strömberg for involvement in study conceptualisation and development of intervention content.

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Funding This work was supported by the Norwegian Research Council grant number (301472) and the University of Stavanger, Norway.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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