STUDY PROTOCOL

REVISED Using a digital health intervention "INTERCEPT" to improve secondary prevention in coronary heart disease (CHD) patients: protocol for a mixed methods non-randomised feasibility study

[version 2; peer review: 2 approved]

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Abstract

Background

Digital health interventions (DHIs) are increasingly used for the secondary prevention of cardiovascular disease (CVD). The aim of this study is to determine the feasibility of "INTERCEPT", a co-designed DHI developed to improve secondary prevention in hospitalised coronary heart disease patients (CHD).

Methods

This non-randomised, pilot feasibility study with embedded process evaluation will be conducted with a sample of 40 patients in an acute hospital setting. Informed by behaviour change theory, INTERCEPT integrates a smartphone interface, health care professional portal, a fitness wearable and a blood pressure monitor. INTERCEPT is designed to support and motivate patients to set goals, self-monitor lifestyle and medical risk factors, and manage their medications, with

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the health care professional portal enabling monitoring and communication with patients. Using consecutive sampling, eligible patients will be recruited in two phases, a pre-implementation phase and an implementation phase. Commencing with pre-implementation (1 month duration), participants will not immediately receive INTERCEPT, however, they will be invited to receive INTERCEPT at 3 months follow-up. This will enable early learning about the processes of recruitment and conducting the assessment prior to full scale deployment of INTERCEPT in the next step implementation phase. During the implementation phase (2 months duration), participants will be invited to download INTERCEPT to their smartphone prior to hospital discharge. Qualitative interviews will be conducted among a subset of patients and health care professionals to gain a greater insight into their experience of using INTERCEPT. Primary outcomes will be assessed at baseline and 3-month follow-up. Using pre-defined feasibility criteria, including recruitment, retention and engagement rates, together with data on intervention acceptability, will determine the appropriateness of progressing to a definitive trial.

Discussion

This study will provide important insights to help inform the feasibility of conducting a definitive trial of "INTERCEPT" among coronary heart disease patients in a critical health care setting.

Keywords
Cardiovascular disease, digital health interventions, secondary prevention, feasibility, acceptability

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REVISED **Amendments from Version 1**

In response to reviewer feedback, some minor revisions have been made to the manuscript. The abstract has been updated to ensure consistency in wording used to describe the study design. The objectives of the study have been revised. Further clarity on the sampling strategy and selection criteria for the qualitative patient interviews is provided. Grammatical errors have been corrected and the study flow diagram has been refined to delineate between the pre-implementation and implementation phases.

Any further responses from the reviewers can be found at the end of the article

Introduction

Cardiovascular disease (CVD) is one of the leading causes of death and disability globally, with approximately 40% of events occurring in patients with pre-existing coronary heart disease (CHD)[1]. Comprehensive secondary prevention strategies, which involve behavioural lifestyle and medical risk factor management for patients with known CVD, can reduce CVD mortality, recurrent CVD hospital admissions, and improve overall quality of life[2]. Yet, despite these well-established benefits, standards of secondary prevention are sub-optimal, with international data from the EuroAspire V survey and national data from the IAspire survey highlighting that the majority of CHD patients are not meeting the recommended secondary prevention lifestyle and risk factor targets[3,4]. Furthermore, while guidelines recommend that secondary prevention should start as early as possible following diagnosis[5,6], referral to and uptake and accessibility of hospital-based, secondary prevention programmes such as cardiac rehabilitation(CR), remains persistently poor[4,7]. Therefore, to maximise uptake and participation rates, there is a need to look beyond traditional hospital-based CR programmes to more innovative, patient centred, delivery models, which focus on early initiation of prevention ideally within two weeks of the patients index event or hospitalisation[8]. Evidence suggests that early initiation of prevention during this critical time point, when the patient is more likely to be motivated and engaged leads to greater uptake and adherence of prevention and rehabilitation programmes[9,10].

Accelerated by the coronavirus disease 2019 (COVID-19) pandemic, there is increased recognition of the potential of digital health interventions (DHIs) to transform preventive care, with evidence suggesting improved CVD risk factor control, health related quality of life, medication adherence, enhanced self-management and shared decision making among patients with coronary heart disease[11–13]. Consequently, various International organisations such as the World Heart Federation, American Heart Association and the European Society of Cardiology recommend the use of digital interventions for the prevention and management of CVD[14–17]. Digital health is an evolving area with technologies encompassing electronic decision support tools, eHealth artificial intelligence, machine learning, telemedicine and mHealth (smart phone apps, wearables, text messaging). With 70% of the world's population using a smart phone[18], smart phone applications are an obvious choice to increase the reach of secondary prevention interventions. However, despite their exponential growth, uptake and usage of health apps by patients is low[19] and there have been limited studies evaluating health apps in critical care settings such as the coronary care unit[20]. Additional challenges of DHIs are that, the majority of apps are designed with minimal input from target end users, the degree to which they follow evidence-based guidelines is unclear, and there is lack of understanding of the systems required to support implementation and scalability of these apps[11,19].

To address these challenges, we have developed a digital intervention known as "INTERCEPT", which aims to improve secondary prevention in CHD patients. Responding to the need for early initiation of prevention following an index event, the INTERCEPT intervention will be introduced to the patient at the time of their acute hospitalisation and before discharge. The intervention includes, (1) a smart phone app which aims to support and motivate patients to achieve a healthy lifestyle, manage their CVD risk factors to target, and improve adherence with cardio protective medications and (2) a web-based healthcare professional (HCP) portal, which will support remote monitoring of lifestyle, medical risk factor and medications and facilitates direct communication with the patient by a specialist cardiovascular nurse. To enable self-monitoring in real time INTERCEPT integrates with a fitness wearable and a blood pressure monitor.

To optimise INTERCEPT and its impact in terms of improving the standards of secondary CVD care, the development of INTERCEPT has been guided by the Medical Research Council (MRC) guidelines for the development and evaluation of complex interventions[21]. To ensure it meets the needs of the end user, INTERCEPT and the protocol for this feasibility study has been co-designed with key stakeholders including patients, healthcare professionals and software developers. Our next step in the intervention development process is to examine the feasibility of INTERCEPT in the real-world clinical setting. Acknowledging that feasibility is an overarching concept[22], specific feasibility domains such as the acceptability and usability of the intervention, recruitment capability, retention of study participants and study assessment procedures, will be examined, through our study objectives[23].

Aims & objectives

The overall aim of this study is to examine the feasibility of the INTERCEPT digital intervention, to help inform (a) further refinement of the intervention, and (b) to determine the feasibility of a definitive randomized controlled trial (RCT).

The primary objectives are to assess:

- The acceptability of INTERCEPT among patients and health care professionals through semi-structured interviews. Acceptability is defined as the extent to which people delivering or receiving a health care intervention consider it appropriate based on anticipated or

experienced cognitive and emotional responses to the intervention[24].

- Engagement with INTERCEPT by examining the extent (e.g. amount, frequency, duration, depth) of usage among patients.

The secondary objectives are to:

- Assess the feasibility of the study methods, by examining recruitment and retention rates assessment and data collection procedures and analysis methods

- Obtain preliminary data of the potential association of the INTERCEPT DHI with improved lifestyle, psychosocial and medical risk factors for CVD and adherence with cardio protective medications at 3 months

Methods

Study design

This is a non-randomised, pilot feasibility study, with an embedded process evaluation. Process evaluations aim to explain how complex interventions work, providing information on implementation process, the mechanisms of change (how does the intervention produce change) and contextual factors, all of which may influence study outcomes[25]. While the purpose of a process evaluation varies depending on the stage of intervention development, for this study it will play an important role in understanding the feasibility and acceptability of INTERCEPT and optimising its design in preparation for a larger scale effectiveness trial[21,25]. We will also deploy a mixed methods approach for this feasibility study, i.e., combining the strengths of both quantitative and qualitative methods. This will maximise what can be learnt from our feasibility study and thus inform a robust decision about next steps[23]. Given potential uncertainties around the feasibility of recruiting participants and deploying a DHI in a critical care setting such as the Coronary Care Unit (CCU) or Cardiothoracic Unit (CTU), this study will be conducted in 2 phases, a pre- implementation phase and an implementation phase. The pre-implementation phase will be one month long and we anticipate enrolling 15 participants during this time. While, participants in this phase will undergo the study assessment procedures, they will not immediately receive INTERCEPT, but they will be invited to receive INTERCEPT at 3 months follow-up. This will enable us to learn about the processes of recruitment and conducting the assessment prior to full scale technical deployment of INTERCEPT, which potentially will bring additional challenges.

The implementation phase will be two months long and we anticipate enrolling 25 participants during this time. Acknowledging that this is a non-randomised feasibility study, the CONSORT extension for reporting pilot randomised controlled trials will be used to guide reporting where applicable[26]

Study population & recruitment

The planned inclusion criteria are patients (≥18years) with a diagnosis of CHD. This includes acute coronary syndrome patients or those who have had elective percutaneous transluminal coronary angioplasty or coronary artery by-pass surgery. Patients must have a smart phone or tablet to enable download of the app, have access to email on this device and be able to provide written consent in English. The exclusion criteria are patients who are clinically unstable and are not planned for discharge home.

Using consecutive sampling eligible patients will be recruited to the study through the cardiology department (coronary care and cardiothoracic units) at University Hospital Galway. Nurses working in these units will inform patients of the study using an information flyer. Enrolment to the control group (pre-implementation phase) and intervention group (implementation phase) will be based on consecutive ACS patients admitted to hospital in defined date periods.

As this is a feasibility study no formal power calculations are required to determine sample size. Recommendations on the appropriate sample size for these types of studies vary greatly from 10–12 participants per group to between 24–50 per group[27]. We have chosen a sample size of 40 (15 pre-implementation, 25 implementation) based on similar studies and practical time frames[27,28]. For the qualitative semi-structured interviews, purposive sampling (i.e. the deliberate choice of a participant due to particular qualities they possess) will be used to recruit 10–15 patients and 6–8 health care professionals and researchers. There will be a specific focus on recruiting patients representative of a broad range of CHD diagnosis, age groups, gender and digital health literacy levels. The concept of information power, will be used to guide final sample size for the qualitative interviews. Information power indicates that the more information the sample holds, relevant to the actual study the lower the amount of participants required[29].

INTERCEPT intervention

INTERCEPT is a complex intervention, which aims to promote self-management and to support patients to achieve a healthy lifestyle, manage CVD risk factors, and improve adherence with cardio protective medications. Developed for the Irish healthcare context, by the Irish National Institute for Prevention and CVD Health, INTERCEPT includes, a smart phone app which integrates with a web-based, health care professional portal, a fitness wearable and blood pressure monitor. INTERCEPT has been co-designed by a core team of health care professionals (nurse specialists, physiotherapists, dietitians, psychologists, cardiologists, and a pharmacist) researchers, software developers and patients from the Croí (an Irish heart and stroke patient organisation) public and patient involvement (PPI) panel. An iterative and participatory approach to the design process was adopted using online workshops conducted between May 2021 and December 2022. This involved identification of the guiding principles, content and design features, developing a working prototype of the app, followed by a beta version which was pilot tested among the project team and reviewed for clarity of language, ease of navigation

and functionality. To anticipate and interpret intervention usage, user acceptance testing with patients who had a recent cardiac event (<2 years) was conducted.

A full description of the intervention components are presented in *Extended data*[30]. In summary, these include: tailored goal setting to motivate and support healthy lifestyle changes; a health tracker to support self-monitoring of physical activity, mood, healthy eating, medications, blood pressure, cholesterol and glucose levels; educational resources to increase knowledge and awareness of healthy lifestyle changes and adherence with cardio-protective medications and notifications to prompt engagement with the INTERCEPT. The HCP portal is designed to support remote monitoring and communication with patients. Through informed consent, a CVD Nurse Specialist will monitor patient engagement with the INTERCEPT through the portal dashboard. This data includes tracking of lifestyle and medical risk factors, goal setting and use of medication reminders. As the I-App has been designed as a self-management tool the nurse will only initiate contact with the patient, when self-reported outcomes are outside guideline recommended targets, for example if blood pressure is high. In line with a protocol, the patient will then be advised to follow-up with their GP or Cardiologist.

Given the strong focus of INTERCEPT in supporting and changing health behaviours its development has been informed by social cognitive theory[31] and select behaviour change techniques from the taxonomy of behaviour change techniques (BCTs)[32]. An illustration of how the components and features of the intervention are aligned with behavioural change techniques, proposed mechanism of actions and outcomes is presented in INTERCEPT logic model (can be reviewed in *Extended data*[14]).

Study procedures

All patients will undergo a baseline assessment prior to hospital discharge.This will include: demographics (including age, sex, ethnicity, education); medical history; measurement of health behaviours (physical activity using the International Physical Activity questionnaire (IPAQ) short form[33] and diet using the Mediterranean Diet Score[34]); weight, height and waist; blood pressure; lipids; blood glucose and HbA1c; digital health literacy (eHealth Literacy Scale)[35]; medication adherence (MARS-5)[36] and psychosocial health (using 3 instruments: the Hospital Anxiety and Depression Scale (HADS)[37], Health Related Quality of Life (HRQoL)[38], and the General Self-Efficacy Scale (GSE Scale))[39].

During the implementation phase patients will be invited to download INTERCEPT to their smartphone. They will be supported by a study nurse who will explain how to use INTERCEPT. Participants will also be given a hard copy user manual, which will provide detailed instructions for using I-App. Patients will receive a blood pressure monitor (Withings BPM), a fitness wearable (Withings Pulse HR) and weighing scales, all of which will integrate with INTERCEPT using bluetooth technology. Together with INTERCEPT, this equipment will support the patients in monitoring and tracking their lifestyle and medical risk factors. With their informed consent, the nurse will track the data they record on INTERCEPT through the web-based nurse portal on a daily basis from Monday to Friday. The nurse will provide appropriate prompts to seek professional help, as required, through their own general practitioner.

A second in person follow up assessment will be conducted 3 months after the first assessment, following the patient's discharge from hospital. At this assessment, patients who were enrolled during the pre-implementation phase will be offered access to INTERCEPT and the supporting devices (Fitness wearable, blood pressure monitor and weighing scales) for a period of 3 months. Figure 1 illustrates the flow of participants throughout the study.

To explore the acceptability of I-App, semi-structured interviews will take place with a subset of patients and health care professionals at 3-month follow-up. The interview guides can be reviewed in *Extended data*[14]. These interviews will provide an in-depth understanding of their perspectives of INTERCEPT, exploring attitudes, usability and satisfaction. Furthermore, the interviews will help explore the relationship between mechanisms of behaviour change, the implementation of I-App and the context within which it is being implemented. Using a convergent approach both quantitative and qualitative data will be collected during the same stage of the research and will be merged to create a more comprehensive interpretation of the data[23]. However, if implementation barriers arise during the study, for example if participants withdraw from using INTERCEPT soon after receiving it, the timing of the interviews will be reviewed, to ensure data capture. Mixed methods guidance recommends this approach as it helps to inform refinement to the recruitment strategy[23]. To ensure quality of reported qualitative results, the consolidated criteria for reporting qualitative research (COREQ) will be used[40].

Outcomes

Outcomes will be assessed at baseline (time point 1, T1) and at 3 months (time point 2, T2). Table 1 provides a summary of the outcomes, associated measures and time points, which correspond to the primary and secondary study objectives.

Progression criteria

Progression to a definitive trial will be determined by pre-defined "Stop/Amend/Go progression criteria"[41] which have been developed through study team consensus. Beyond examining quantitative measures of recruitment and retention we have incorporated qualitative methods to ensure a more comprehensive understanding of the feasibility of implementing INTERCEPT in a critical care setting is obtained. These criteria are outlined in Table 2. In addition, the decision to progress will be informed by the acceptability of INTERCEPT to both patients and health care professionals and suggested refinements to the intervention will be reviewed prior to progression.

Data analysis

Qualitative analysis. Qualitative data will be initially analysed using thematic analysis, following which the Theoretical Framework of Acceptability (TFA) will be deductively applied.

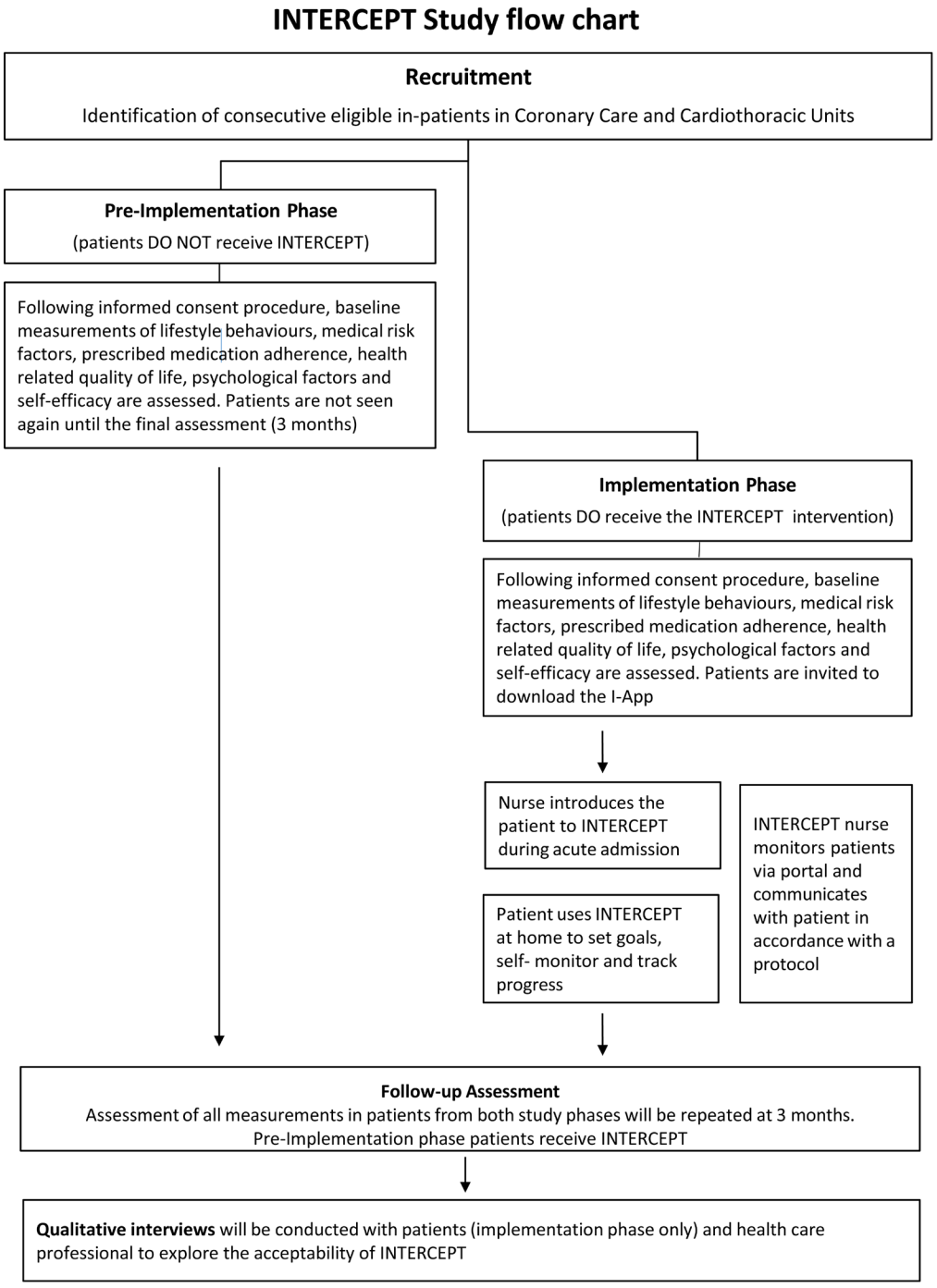

Figure 1. Intercept study flow.

The TFA is designed to assess acceptability across seven constructs: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy and is recommended for use in feasibility studies[24]. A definition of these constructs is provided in Table 3. Interviews will be transcribed verbatim and analysis will be supported by use of NVivo, a qualitative data analysis software package. Two members of the research team will code the data and will assess the information power of the sample. These two individuals, together with the study team including the PPI group, will work collaboratively to interpret the findings.

Table 1. Summary of outcome measures.

Objectives	Measures/approaches	Time points
Primary		
Acceptability of I-App to patients and healthcare professionals	• Semi structured interviews guided by the theoretical framework of acceptability*	T2
Engagement and usability of I-App among patients*	• Using web analytics, app usage data including logs of interactions (date and time of use, modules viewed and time spent on them) and user-entered data (for example blood pressure readings or goals set) will be measured. • System Usability Scale (SUS)[42]. This scale provides a measure of the person's subjective perceptions of the usability of a system over a short period of time. It assesses the components of usability, effectiveness and efficiency and satisfaction according to the user and context of use.	T2 T2
Secondary		
Lifestyle	**Smoking cessation**: self-reported and validated by breath carbon monoxide using the Bedfont Smokerlyser (Micro+) **Mediterranean Diet Score**: self-reported using the 14 item Mediterranean Diet Questionnaire **Physical Activity and exercise**: IPAQ short form **Weight**: • Change in weight in those overweight or obese (as defined by body mass index) at hospital admission using SECA 701 digital scales • Change in waist reduction in those centrally obese (waist circumference) at hospital admission using a metal tape measure	T1 & T2 T1 & T2 T1 & T2 T1 & T2
Medical risk factors	• % Blood pressure < 130/80mmHg and < 140/80 mmHg • % Low-density lipoprotein (LDL) cholesterol< 1.4 mmol/l • % HbA1c < 53mmol/mol • % Fasting blood glucose ≤ 6 mmol/l	T1 & T2 T1 & T2
Cardio protective medications	Beliefs about and adherence with medications will be measured using the Medication Adherence Report Scale(MARS-5)	T1 & T2
Psychosocial	• Health related quality of life using HeartQoL • Anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) • General Self-Efficacy Scale	T1 & T2 T1 & T2 T1 & T2
Feasibility of a definitive trial of the INTERCEPT	Acceptability and suitability of the study procedures will be assessed through: • No of eligible patients invited to participate in the study • No of patients who enrolled in the study • % of enrolled patients who attended 3 month follow-up semi-structured interviews with both patients and health care professionals	T2

*Acceptability, usability and engagement of INTERCEPT will be measured among participants in the implementation phase only.

Table 2. Intercept progression criteria.

	Go - proceed with RCT	Amend – proceed with changes	Stop - do not proceed unless changes are possible.
Feasibility of patient recruitment.	>75% of the target sample (n=40) size are recruited in four months.	30–74% of the sample size are recruited in 3 months.	<30% of the sample size are recruited in 3 months.
Feasibility of patient retention	>80% of enrolled patients attend 3 month follow-up.	60–80% of enrolled patients attend 3 month follow-up	<60% of enrolled patients attend 3 month follow-up.
Feasibility of intervention implementation	Delivery of intervention judged strongly feasible by qualitative data.	Delivery of intervention judged possibly feasible by qualitative data.	Delivery of intervention judged not feasible by qualitative data.

Table 3. Theoretical Framework of Acceptability Constructs[24].

Theoretical Framework of Acceptability (TFA) Constructs	Definition
Affective attitude	How an individual feels about the intervention, after taking part.
Burden	The amount of effort that was required to participate in the intervention.
Ethicality	The extent to which the intervention has good fit with an individual's value system.
Opportunity costs	The benefits, profits or values that were given up to engage in the intervention.
Perceived effectiveness	The extent to which the intervention is perceived to have achieved its intended purpose.
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention.
Intervention coherence	The extent to which the participant understands the intervention and how it works.

Quantitative analysis. Descriptive statistics will be used to report on baseline demographics, clinical data, I-App usability and usage data. Continuous variables will be presented as means with standard deviations and categorical variables in absolute frequencies with percentages. As this is a feasibility study, we do not aim to assess statistical significance between the pre-implementation and implementation phase. However to obtain preliminary data on the possible association of INTERCEPT with improved lifestyle, psychosocial and medical risk factors for CVD at 3 months we will examine outcomes between baseline and end of study assessment. Changes in categorical variables will be assessed by the McNemar test and the paired t-test or Mann-Whitney will be used for continuous variables. Recruitment and retention rates will be reported on and presented using the CONSORT flow diagram[43]. All statistical analysis will be conducted using Stata. 16.

Ethics
Ethical approval for this study was granted by the Clinical Research Ethics Committee at Galway University Hospitals (C.A. 2913) on the 16th of March 2023. Informed consent will be obtained following explanation of the study and the provision of the patient information leaflet. All participants will be informed of their right to withdraw from the study at any time without giving a reason.

Public and Patient Involvement
Patient and Public Involvement (PPI) input from the Croí (heart and stroke patient organisation) panel has been embedded in this study from the outset. The PPI panel, which includes 5 contributors (4 female) with lived experience of CVD have been involved in the co-design of the Intercept intervention, proving input across all stages of the design process. For this specific study they attended two 1.5 hour meetings (one online and one in person) providing advice on the recruitment strategy, technology deployment and the study materials including the study flyer, patient information leaflet, consent form and topic guides for the qualitative interviews. It is anticipated that future contributions will include supporting data analysis of the qualitative interviews, interpreting the results of these interviews and advising on communication and dissemination of research outcomes.

Data management
All data will be managed in line with general data protection regulation (GDPR) requirements: data minimisation, storage limitation, transparency, integrity and confidentiality. A data protection impact assessment has been prepared and will be reviewed before the study commences, and as necessary over the course of the study.

Plans for dissemination of the study outcomes
A knowledge exchange and dissemination plan has been developed with key project stakeholders including the Croí PPI panel. Accordingly, study outcomes will be published in a peer-reviewed journal and will be presented at relevant national and international conferences. Given the relevance of the study to national priorities regarding chronic disease prevention, findings will be shared with the Health Service Executive (HSE) leads for the Integrated Care Programme for the Prevention and Management of Chronic Disease, the National Heart Programme and the Digital Transformation team. Outcomes will be shared with other key stakeholders including patient organisations such as Croí, hospital and community cardiology and rehabilitation teams, study participants and members of the public.

Study status
At the time of publication, recruitment to this study had commenced (June 2023).

Discussion
This study protocol describes the methods used to assess the feasibility of a trial of "INTERCEPT" a mobile Health app linked to a HCP portal and wearable technology to improve secondary prevention in CHD patients. Guidelines recommend that secondary prevention should start as early as

possible after a cardiac event[5,6]. However in reality, referral and uptake of secondary prevention interventions such as CR remains persistently poor and often is very delayed. INTERCEPT aims to bridge this important care gap by providing CHD patients with early access to a digital secondary prevention intervention at the time of their diagnosis and prior to their discharge from hospital. By examining the acceptability and usability of INTERCEPT among a sample of these patients, it will enable us to further refine INTERCEPT intervention to optimise its acceptability, use and effectiveness prior to moving to a definitive RCT. Moreover, by applying the pre-defined "Stop/Amend/Go" progression criteria this will provide transparent and objective justification on the appropriateness of moving to a larger trial.

There are some potential challenges associated with this study. Firstly, the time frame for recruitment is short as many CHD patients are discharged back to the referring hospital within 24 hours or home within 48 hours. This offers a limited window to conduct the initial assessment and to support the patient with downloading INTERCEPT. Through engagement with key stakeholders, including CCU/CTU nurses and cardiology staff, we have attempted to address this challenge by refining the recruitment strategy, baseline assessment procedures and including a pre-implementation phase, which may lead to subsequent refinements. Secondly, the field-based researchers and healthcare professionals involved in this study have limited experience in digital health intervention research and therefore may encounter challenges related to the technical aspects of deploying INTERCEPT. To overcome these challenges, we have collaboratively developed a guidance document, provided hands-on training, and have put in place a technical support helpline.

As the majority of DHI research for the secondary prevention of CVD is conducted in outpatient settings, this study will contribute to the evidence base related to the feasibility of introducing a DHI to CHD patients in a critical care setting at the time of diagnosis and before hospital discharge. Furthermore, through the application of a mixed methods approach, a comprehensive, nuanced and context specific understanding of the potential feasibility and acceptability issues will be generated, which will help inform decisions regarding a definitive trial of INTERCEPT.

Data availability statement

Underlying data

No underlying data are associated with this article.

Extended data

Open Science Framework: INTERCEPT. https://doi.org/10.17605/OSF.IO/85CV4[30].

This project contains the following extended data:

- Consent form_ healthcare professional and researcher
- Consent form–Patient V2
- INTERCEPT Intervention components
- INTERCEPT logic model
- Interview topic guides
- PIL-Healthcare professional and researcher
- PIL-Patient V2

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 06 February 2025

https://doi.org/10.21956/hrbopenres.15410.r45222

✔ **Stefan Tino Kulnik**
Ludwig Boltzmann Institute for Digital Health and Prevention, Lindhofstrasse 22, 5020, Salzburg,, Austria

I thank the authors for incorporating my suggestions.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Digital Health (dHealth), Mobile Health (mHealth), Cardiac Rehabilitation, Secondary Prevention of Cardiovascular Disease, Physiotherapy, Complex Interventions

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 26 February 2024

https://doi.org/10.21956/hrbopenres.15075.r37825

✔ **Stefan Tino Kulnik**
Ludwig Boltzmann Institute for Digital Health and Prevention, Lindhofstrasse 22, 5020, Salzburg,, Austria

Peer review

Using a digital health intervention “INTERCEPT” to improve secondary prevention in coronary heart disease (CHD) patients: protocol for a mixed methods non-randomised feasibility study
Gibson I, Jennings C, Neubeck L, Corcoran M, Wood D, Sharif F, Hynes L, Murphy AW et al.

Thank you for inviting my peer review of this study protocol, describing a non-randomised pilot feasibility study with embedded process evaluation. The authors have developed a digital health intervention (INTERCEPT, I-App) to support patients with coronary heart disease in the secondary prevention and self-management of their cardiovascular condition.

This is a well-written and comprehensive study protocol, incorporating relevant methodological literature (MRC framework for complex interventions, behaviour change techniques taxonomy) and reporting standards (CONSORT, COREQ), and providing additional study documentation in the online extended data repository (Open Science Framework).

I only have very minor comments for the authors‘ consideration, which are all intended to support the clarity of the report and to add some details for readers‘ information and completeness:

In the abstract, I suggest using the same wording to describe the study design as in the main text, i.e., a non-randomised, pilot feasibility study with embedded process evaluation (as opposed to „…will be conducted using a mixed methods process evaluation“). Also in the abstract, the description of the timing/duration of the pre-implementation and implementation phases is not so clear – perhaps this can be re-worded.

Introduction: „eHealth (electronic health records)“ could be read as eHealth = electronic health records, while eHealth encompasses a wider range of modalities/interventions.

Aims & objectives: Recruitment and retention rates are included under the primary objective „to assess the acceptability of the I-App intervention“, but recruitment and retention better fit with the secondary objective „to assess the feasibility of the study methods“ (which also describes recruitment and retentention). To assess the acceptability of the I-App intervention, perhaps the wording „uptake and engagement with the I-App“ would be preferable? I would suggest the same for Table 1, where the first three bullet points (number eligible, number enrolled, number completing follow-up) better fit with the last objective „Feasibility of a definitive trial“.

Recruitment: I’m unsure that this is „convenience sampling“, since, as I understand it, all consecutive patients on the respective wards will be systematically screened for eligibility. Convenience sampling to me would describe a less systematic approach.
Purposive sampling for qualitative interviews: Could the authors add examples for particular selection criteria, e.g., representation of both genders, surgical and non-surgical treatment, good and poor engagement with the I-App, etc. Specify „The concept of information power will be used to guide final sample size for qualitative interviews.“

I-App intervention: I would assume that the I-App intervention has been developed specifically for the Irish healthcare context. Could the authors add some detail, e.g., what context was the intervention developed for, from which contexts were the co-design contributers, and what were the dates (year/s) for the development phase.

Study procedures: For completeness, please specify and reference the data collection instruments

for physical activity, diet, digital health literacy and quality of life here in the main text. Please reference IPAQ in table 1; typo „luetooth technology“; please add how frequently the nurse will track I-App users‘ data, e.g. weekly, daily, etc.; For how long will patients from the pre-implementation group be allowed to use the I-App after the 3-months follow-up? Specify „audio-recorded semi-structured interviews“; specify „To ensure quality of reported qualitative results, the consolidated…“

Data analysis: State whether interview recordings will be transcribed.

Figure 1: I wonder how the timing of the pre-implementation phase and implementation phase could be visualised, so that the flow diagram reads unambiguously. At the moment, readers might think that this is one and the same cohort of patients progressing through both phases. Perhaps 2 parallel strands/columns for the 2 phases, both leading to the final assessment box, and staggered to indicate the different recruitment periods? It would be helpful to state „first month of recruitment“ for the pre-implementation phase, and „second and third months of recruitement“ for the implementation phase; and to include T1 and T2 in the flow diagram.

Table 2, row „Feasibility of patient recruitment“: in three months rather than in four months?

Discussion: Sentence „Guidelines recommend that…“ is missing a word; „Stop/Amend/Go is missing a quotation mark.

I noticed that acronyms are sometimes not spelled out at first use (DHI, GDPR), and sometimes spelled out after they have already been defined (PPI, DHI).

Extended data: In the description of the I-App, it would be helpful to provide screenshots for each view/function. With regard to the healthcare professionals‘ dashboard, please describe whether healthcare professionals can communicate with patients through the app („in-app“) or via communication channels outside of the app (telephone, etc.).

In the description of the logic model, it would be helpful to add a figure legend, including an explanation of the numbering of the behaviour change techniques (presumably these refer to categories of the taxonomy of behaviour change techniques). I noticed that the outcomes in the logic model do not include reduction in the occurrence of cardiovascular events and re-hospitalisation or reduction in mortality – was this a deliberate decision (and why)?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Digital Health (dHealth), Mobile Health (mHealth), Cardiac Rehabilitation, Secondary Prevention of Cardiovascular Disease, Physiotherapy, Complex Interventions

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 21 Nov 2024

Irene Gibson

We thank the reviewer for taking the time to provide such a thorough and helpful review of the manuscript. The comments have been most useful and we are confident that our revised submission has improved by addressing them. A point-by-point response to each of these comments is provided as follows:

1. **In the abstract, I suggest using the same wording to describe the study design as in the main text, i.e., a non-randomised, pilot feasibility study with embedded process evaluation (as opposed to „…will be conducted using a mixed methods process evaluation"). Also in the abstract, the description of the timing/duration of the pre-implementation and implementation phases is not so clear – perhaps this can be re-worded.**

We have revised the abstract in line with these suggestions, thank you.

1. **Introduction: „eHealth (electronic health records)" could be read as eHealth = electronic health records, while eHealth encompasses a wider range of modalities/interventions.**

To avoid potential confusion, we have removed reference to electronic health records.

1. **Aims & objectives: Recruitment and retention rates are included under the primary objective „to assess the acceptability of the I-App intervention", but recruitment and retention better fit with the secondary objective „to assess the feasibility of the study methods" (which also describes recruitment and retentention). To assess the acceptability of the I-App intervention, perhaps the wording „uptake and engagement with the I-App" would be preferable? I would suggest the same for Table 1, where the first three bullet points (number eligible, number enrolled, number completing follow-up) better fit with the last objective „Feasibility of a definitive trial".**

We agree, recruitment and retention rates align better with the secondary objectives of the study "assessing the feasibility of study methods". We have updated the objectives and Table 1 to reflect this change.

1. **Recruitment: I'm unsure that this is „convenience sampling", since, as I understand it, all consecutive patients on the respective wards will be systematically screened for eligibility. Convenience sampling to me would describe a less systematic approach.**

Thank you for highlighting this important point. We have replaced all references to convenience sampling with consecutive sampling, to accurately reflect our approach to sampling.

1. **Purposive sampling for qualitative interviews: Could the authors add examples for particular selection criteria, e.g., representation of both genders, surgical and non-surgical treatment, good and poor engagement with the I-App, etc. Specify „The concept of information power will be used to guide final sample size for qualitative interviews."**

This is a great suggestion. We have now elaborated on the selection criteria for the qualitative patient interviews, which includes reference to all of the above points.

1. **I-App intervention: I would assume that the I-App intervention has been developed specifically for the Irish healthcare context. Could the authors add some detail, e.g., what context was the intervention developed for, from which contexts were the co-design contributers, and what were the dates (year/s) for the development phase.**

Thanks for another helpful suggestion. These additional details, including the origins of INTERCEPT have now been provided.

1. **Study procedures: For completeness, please specify and reference the data collection instruments for physical activity, diet, digital health literacy and quality of life here in the main text. Please reference IPAQ in table 1; typo „luetooth technology"; please add how frequently the nurse will track I-App users' data, e.g. weekly, daily, etc.; For how long will patients from the pre-implementation group be allowed to use the I-App after the 3-months follow-up? Specify „audio-recorded semi-structured interviews"; specify „To ensure quality of reported qualitative results, the consolidated..."**

While the data collection instruments were outlined in table 1, to respond to this comment and improve the clarity of the paper we have updated the study procedures text to include this information. In addition, we provide details on the frequency of monitoring the HCP portal and INTERCEPT usage after the 3 month follow-up. Suggested text changes to offer greater clarity on the semi-structured interviews and use of the COREQ have also been included and the typo has been corrected.

1. **Data analysis: State whether interview recordings will be transcribed.**

Thanks, we have added this additional detail in under qualitative analysis.

1. **Figure 1: I wonder how the timing of the pre-implementation phase and implementation phase could be visualised, so that the flow diagram reads unambiguously. At the moment, readers might think that this is one and the same cohort of patients progressing through both phases. Perhaps 2 parallel**

strands/columns for the 2 phases, both leading to the final assessment box, and staggered to indicate the different recruitment periods? It would be helpful to state „first month of recruitment" for the pre-implementation phase, and „second and third months of recruitement" for the implementation phase; and to include T1 and T2 in the flow diagram.

This is an excellent suggestion and we have now revised the flow diagram to delineate between the pre-implementation and implementation phases.

1. **Table 2, row „Feasibility of patient recruitment": in three months rather than in four months?**

The table has been updated to reflect the 3-month follow-up period.

1. **Discussion: Sentence „Guidelines recommend that…" is missing a word; „Stop/Amend/Go is missing a quotation mark.**

Thank you for highlighting these grammatical errors, which have now been corrected.

1. **I noticed that acronyms are sometimes not spelled out at first use (DHI, GDPR), and sometimes spelled out after they have already been defined (PPI, DHI).**

These grammatical errors have been corrected, throughout the manuscript

1. **Extended data: In the description of the I-App, it would be helpful to provide screenshots for each view/function. With regard to the healthcare professionals' dashboard, please describe whether healthcare professionals can communicate with patients through the app („in-app") or via communication channels outside of the app (telephone, etc.).**

We welcome this great suggestion, however we deliberately did not include screen shots as they have been incorporated in a separate publication, which describes the co-design and development of INTERCEPT. This publication is currently under review. We have provided additional detail on health care professional communication in the extended data.

1. **In the description of the logic model, it would be helpful to add a figure legend, including an explanation of the numbering of the behaviour change techniques (presumably these refer to categories of the taxonomy of behaviour change techniques). I noticed that the outcomes in the logic model do not include reduction in the occurrence of cardiovascular events and re-hospitalisation or reduction in mortality – was this a deliberate decision (and why)?**

Thanks again for your very helpful attention to detail. For the logic model we have now added a figure legend, which offers greater clarity on the BCTs. You raise an important point regarding outcomes, however the behavioural and biomedical outcomes included in the logic model relate to the expected mechanisms of action of the INTERCEPT components. There is significant evidence to show that these outcomes can significantly reduce the incidence of repeat CV events and death. For next step evaluation of effectiveness, it is likely that we will assess 30-day hospital readmissions, however we anticipate that a much longer-term follow-up, would be required to observe meaningful reductions in repeat CVD events and overall mortality.

Competing Interests: No competing interests were disclosed.

Reviewer Report 12 October 2023

https://doi.org/10.21956/hrbopenres.15075.r36520

Geraldine Lee
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A well thought study protocol using a mixed methods approach. The protocol is detailed and including digital technology (i.e. Smartphone) along with HCP portal with BP monitor and fitness monitor is a novel approach. The phases with pre-implementation and implementation are justified and recruited numbers realistic. The only issue is that when patients experience an acute event, they are often overwhelmed and may decline the study. It is important that a close eye is kept on numbers declining the study.

The inclusion criteria are acceptable and primary objectives are appropriate. The goal setting for participants is good and it will be interesting to see the level of engagement and whether participants maintain engagement for the duration of the study. The interviews with HCPs and participants will be beneficial in identifying issues that would have potentially been missed by using a purely quantitative approach.

A well written protocol that will provide useful data on early engagement with patients after an acute CVD event.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiovascular disease, risk factor modification, behaviour change in chronic diseases, nursing, mixed methods, lived experience.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.