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Mobile Health Biometrics to prescribe immediate remote physical activity for enhancing uptake to cardiac rehabilitation (MOTIVATE-CR+): protocol for a randomised controlled feasibility trial

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ABSTRACT

Introduction: Cardiac Rehabilitation (CR) can reduce cardiovascular mortality and improve health related quality of life. In the United Kingdom patient uptake of CR remains low (52%), falling well short of the target in the 2019 NHS Long-term plan (85%). Mobile health (mHealth) technologies, offering biometric data to patients and healthcare professionals, may bridge the gap between supervised exercise and physical activity (PA) advice, enabling patients to engage in regular long-term physically active lifestyles. This randomised controlled trial (RCT) will evaluate the feasibility of mHealth technology when incorporated into a structured home-based walking intervention, in people with recent myocardial infarction.

Methods and analysis: This is a feasibility, assessor blinded, parallel group RCT. Participants will be allocated to either CR standard care (control group) or CR standard care + mHealth supported exercise counselling (mHealth group). Feasibility outcomes include; the number of patients approached, screened and eligible; the percentage of patients that decline CR (including reasons), agree to CR and consent to being part of the study; the percentage of patients that enroll in standard CR and reasons for drop out; and the percentage of participants that complete clinical, physical and psychosocial outcomes to identify a suitable primary outcome for a future definitive trial.

Ethics and dissemination: The trial was approved in the UK by the Northwest – Greater Manchester East Research Ethics Committee (22/NW/0301) and is being conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Results will be published in peer-reviewed journals and presented at national and international scientific meetings.

Trial registration numbers: ClinicalTrials.gov: NCT05774587

Key Words: mHealth, Cardiac Rehabilitation, Exercise, mobile technologies

Strengths and limitations of this study

- The MOTIVATE-CR+ intervention may increase the uptake of CR by bridging the gap between discharge and the start of supervised CR.
- The MOTIVATE CR+ intervention potentially allows patients that recently experienced a myocardial infarction to co-design a personalised and progressive walking programme with the support of an exercise specialist.
- The MOTIVATE CR+ intervention potentially enables participants to communicate regularly with an exercise specialist and gain feedback on the exercise they complete.
- The MOTIVATECR+ intervention is not embedded within current cardiac rehabilitation landscape, as such, future work will be needed to address how the intervention could fit within service structures.

Introduction

Cardiac Rehabilitation (CR) is a clinically- and cost-effective intervention, reducing cardiovascular (CV) mortality and unplanned hospital admissions in addition to improving health related quality of life [1-4]. Despite this, in the UK, the National Audit of Cardiac Rehabilitation (NACR) estimates that only 52% of eligible patients start CR (defined as uptake) [5]. A key milestone within the National Health Service (NHS) long-term plan is to increase uptake of CR from 52 to 85% by 2028 [6]. Reducing the time between hospital discharge and the start of CR in general is essential to meet this milestone; the current recommendation is <28 days post

discharge, but the range in clinical services is 3-111 days [5]. Failure to begin CR within 28 days reduces uptake, with recent data suggesting 10,753 patients per year do not take up CR due to a delay in service provision, equating to a loss of 3,936 years of life expectancy [7]. A possible solution to increase uptake of CR may be to bridge the gap between hospital discharge and the start of supervised CR with remote physical activity (PA) counselling supported by mHealth technology that provides biometric feedback and coaching to patients and health professionals.

The emergence of mobile technologies and wearable sensors has enabled real-world monitoring through mobile health biometrics (mHealth) [8]. Devices incorporating biometrics such as heart rate (HR) could be a potential solution to bridge the gap between general PA advice on discharge, and supervised exercise. HR monitors provide objective personalised data that account for age, body mass and fitness [9] and are related to exercise intensity regardless of the type of activity being performed [10]. Current research studies (https://www.motivateljmu.com/about) in healthy sedentary individuals, people with newly diagnosed type 2 diabetes and stage 4 CR have explored the acceptability and efficacy of exercise and PA counselling programmes supported by mHealth technologies that provide biometric feedback and coaching to patients and health professionals [8, 11]. Biometric data such as HR are recorded through a wrist worn fitness tracker to inform exercise counselling delivered by healthcare professionals. Recently, we have shown that the use of mHealth supported counselling leads to adherence of 113%±68 (participants exercised more often than prescribed) and is superior to self-directed web-based exercise in sedentary office workers at risk of cardiovascular disease [12].

Virtual home-based CR has emerged as an alternative to supervised in-person CR usually delivered in a hospital or leisure centre [13]. In the UK, self-directed virtual web-based exercise for CR has been developed but is not used as part of CR standard practice, and does not currently allow individualised exercise prescription, biometric monitoring, or coaching [14-16]. Studies have shown CR can be effectively delivered remotely using mHealth technologies with biometric monitoring [17, 18]. Whilst these studies were conducted to compare supervised in-person CR and remote CR, they demonstrated that mHealth technology is acceptable in this patient group [17, 18]. No study to date has examined whether remote CR with biometric monitoring, can be employed as an immediate post-hospital discharge intervention to increase uptake of CR.

Study aims

The primary aim is to conduct a feasibility study to evaluate a model where mHealth technology supports a remote home-based PA and counselling intervention immediately post hospital discharge to increase uptake to cardiac rehabilitation.

The specific objectives are:

1. Obtain patient demographics and screening, eligibility, recruitment and drop-out rates.
2. Estimate precision of outcome measures: uptake, time between discharge and start of Cardiac Rehabilitation (CR), adherence, cardiovascular (CV) risk profile, health related quality of life (HrQoL).
3. Assess acceptability of the mHealth PA and counselling intervention.

4. Assess feasibility and acceptability of outcome measurements and conducting an RCT.

5. Determine availability and completeness of economic data.

Methods and analyses

This is a feasibility, assessor blind, parallel group randomised control trial (RCT). Participants will be randomised to either CR standard care (active control group) or CR standard care + mHealth supported exercise counselling (mHealth intervention). Outcomes assessment will be completed twice; 1) immediately post hospital discharge, before any intervention, and 2) after CR (Figure 1). To minimise participant burden and ensure timely completion, outcome measures will be undertaken remotely. The trial protocol adheres to Recommendations for Interventional Trials and the Template for Intervention Description and replication guidelines [19, 20].

INSERT FIGURE 1 HERE

Study setting and recruitment plan

Recruitment (n=60) will take place at three UK CR sites; North-West England (n=20), West Midlands (n=20) and North-East England (n=20) commencing May 2023 for 12 months. The trial will end (last data collection from the last participant) in June 2024.The participant information sheet (PIS) will be added to hospital discharge packs, and patients will then be contacted via telephone by a CR team immediately post-discharge as part of routine care (within 48h). During this contact the CR team will discuss the study. If the patient expresses an interest in the study, the CR team will request verbal consent to pass contact details to the research team, who will

contact interested participants via telephone (or video call) to discuss the PIS (provided by CR team), ask any questions and confirm eligibility criteria. Participants will be consented and screened which involves a medical history, details of current medications, current PA and exercise behaviour (Figure 2).

Eligibility criteria

Eligible participants will have been referred to CR with a recent clinical diagnosis of myocardial infarction (MI) and have been discharged within the last five days.

Detailed inclusion criteria

- Participant is willing and able to give informed consent for participation in the study.
- Male or Female.
- Over 18 years old.
- Post MI.
- Post percutaneous coronary intervention (PCI) patients.
- Referred for CR.

Detailed exclusion criteria

- Acute or unstable health conditions
- Coronary artery bypass graft surgery
- Unable to participate in self-management programmes because of medical care needs.
- Absolute contraindications to exercise.
- Unable to operate or own mobile/smartphone devices/lack of internet access

- Declined CR standard care.
- Allergies to the watch materials.
- Atrial fibrillation or other arrhythmia preventing accurate heart rate.

INSERT FIGURE 2 HERE

Randomisation and blinding

Randomisation will be computer generated and the code held by an independent person blinded to the groups. Due to the nature of the intervention, blinding the participants is not possible. Following the initial screening process participants will be randomly allocated to the two study groups (active control or mHealth intervention) and informed by telephone/ email (patient preference).

Outcome measures

Primary Outcome

Outcome measures will be taken using remote 'home-based' solutions which do not require travel or in-person contact. Throughout the study, information will be collected on 1) the total number of patients screened, eligible, approached, 2) the % of patients that a) decline CR (including reasons for declining); b) agree to CR and c) consent to being part of the study; 3) the % of patients that take up standard CR following the mHealth intervention and reasons for drop out of CR before the end of the intervention (if provided); and 4) the % of participants that complete outcome assessments and reasons for drop out (if provided).

Secondary outcomes

Age, sex, ethnicity, reason for enrolment into CR, centre referred to, education and employment status will also be collected via an initial screening telephone call. Immediately following consent and randomisation, participants will be mailed (direct to patients preferred address) all necessary assessment resources including written and video guidance on how to complete the assessments (https://www.motivateljmu.com/cr.) within the 1-5 day timeframe. Participants will then receive a phone/video call from the research team to 1) discuss the testing protocol and allow patients to ask any questions they may have and 2) gain patients current medication information (current medications and dose) and ethnicity. On the day of testing, a member of the research team will be available via phone/video call to provide support where required. Using this approach, we expect participants to begin the mHealth intervention within a maximum of 5 days post discharge.

Table 1: Primary objectives and outcome measures

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective		
Our overall objective is to test the feasibility of an evidence-based intervention prior to evaluation in a future randomised control trial (RCT).	Information will be collected on: 1. The number of patients screened, eligible and approached. 2. The percentage of patients that: a) decline CR (including reasons for declining) b) agree to CR and c) consent to being part of the study 3. the percentage of patients that take up standard CR and reasons for drop out; and	1 - 4) Ongoing throughout the intervention

	4. the percentage of participants that complete outcome assessments and reasons for drop out.	
Secondary Objective		
1) Estimate precision of potential outcome measures required for sample size estimations for the definitive RCT.	Six potential outcome measures will be assessed: **1) Adherence to exercise** a. Adherence to structured exercise b. Pre and post intervention exercise questionnaire (GLTEQ) c. Objectively assessed physical activity **2) Body composition** a. Height + weight b. Waist circumference **3) Blood pressure** **4) Blood lipids and HbA1c** a. Total cholesterol b. HDL c. Triglycerides d. HbA1c **5) Health related quality of life** a. MacNew Heart disease health related quality of life b. The Behavioural Regulation in Exercise Questionnaire c. Patient Rapport with Counsellor Questionnaire	1) a. Ongoing throughout the intervention b. During initial and outcome assessments c. 7 days post CR 2-5) During initial and outcome assessments
2) Evaluate the acceptability of the intervention to patients, assessing the feasibility of implementing the intervention.	1) Post-intervention patient qualitative data (semi-structured interviews) investigating: a. The acceptability of the intervention components and barriers and facilitators to the intervention b. Acceptability of the recruitment and randomisation process c. Acceptability of the measurement instruments	Post CR (Purposive sampled subset)
3) Determine availability and completeness of economic data	1. level EQ-5D 2. Questionnaire assessing healthcare usage in the last 12 weeks	1-2) Post CR

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Exercise adherence and habitual PA

Adherence to home-based exercise prescription is difficult to measure using one method. Accordingly, the feasibility of three outcome measures will be assessed:

1. Device-derived assessment of exercise sessions: the number of planned structured exercise sessions completed along with the duration and intensity of each session will be assessed via optical HR monitoring (photoplethysmography). The mHealth group will use the Polar Ignite 2 fitness watch and the Polar Verity sense optical HR monitor (Polar Electro, Finland) provided as part of the intervention. The active control group will be provided with a Polar Verity Sense optical HR monitor for the duration of the trial, to wear during planned structured exercise sessions (e.g., structured CR session). The Polar Verity Sense records HR but gives no real-time/historical feedback to participants. As such active control participants will be blinded to the HR throughout.

2. Device-derived PA: key metrics of PA will be assessed using a wrist-worn triaxial accelerometer (GENEActiv, Activinsights, Kimbolton, Cambridge, UK) during the final 7 days of the intervention period immediately after follow-up testing. Before sending to the participant, the accelerometer will be initialised and set by the research team to start and finish recording at specific dates. Data will be downloaded using manufacturers' software and processed in R (R Core Team,Vienna, Austria) using the open-source GGIR software package (http://cran.r-project.org).

3. Survey-reported exercise behaviour will be evaluated using the Godin Leisure Time Exercise Questionnaire (GLTEQ) at baseline and post-intervention. The questionnaire will be administered using an online platform (Qualtrics, Provo, UT) survey.

Baseline and post intervention testing

Testing will take place in the morning between 6am and 10am and should take approx. 45 minutes. Participants will be fasted overnight and instructed to abstain from caffeine, alcohol, and moderate/ vigorous exercise the day before testing. Participants will be asked to drink a glass of water immediately before the measures are taken.

Anthropometrics

Participants will be sent a measuring tape (Seca 201, Germany) to be used for assessing height and waist circumference. Waist circumference will be measured in triplicate at the level of the umbilicus. Previous work suggests a strong correlation between self-measured and technician-measured height and weight (Salter, UK) [21] and waist circumference, measured at the umbilicus [22].

Blood pressure

Patients will be asked to rest in a seated position for 10 minutes before measuring their blood pressure using an automated blood pressure monitor validated by the British and Irish Hypertension Society (UK, Salter BPA-9200-GB; Canada, Bios BD215). Patients will wrap the blood pressure cuff around their non-dominant arm. Blood pressure will then be measured in triplicate, leaving 1 minute between successive measurements. Self-measured blood pressure is a validated approach for monitoring blood pressure, endorsed by the American Heart Association and American Medical Association [23].

Blood sampling

Patients will then collect a 500ul blood sample from a finger prick, using a self-administered commercial blood collection kit, via Royal Devon and Exeter NHS Foundation Trust (MonitorMyHealth.org.uk) in accordance with pre-defined procedures. Patients will be asked to post the envelope on the same day as collection. Due to the time sensitive nature of the sample patients will be sent a text/email (patient preference) to remind them to post the sample. Blood samples will be posted by participants to the Royal Devon and Exeter NHS Foundation Trust. Samples will be analysed for HbA1c, total cholesterol, HDL cholesterol and triglycerides by the Clinical Chemistry department at the Royal Devon and Exeter Hospital. Donor information will not be available to the team at Royal Devon and Exeter Hospital as samples will be sent using pseudonymised sample codes only, however members of the research team will be able to identify donors via participant numbers. Internal pilot data from the Exeter Clinical Laboratory demonstrates that capillary blood sampling reveals good agreement with standard venous sampling.

Patient Questionnaires

All patients will complete online versions of 1) the 5-level EuroQol-5 Dimensions, 2) a study specific questionnaire assessing healthcare use over the previous 12-weeks, 3) the Godin Leisure Time Exercise Questionnaire (GLTEQ), 4) the heart disease health related quality of life (MacNew) questionnaire and 5) the Behavioural Regulation in Exercise Questionnaire version 2 (BREQ-2). The questionnaires will be completed using qualtrics by assessor blind to group allocation. Patients will be encouraged to complete the questionnaires immediately after testing. Should

questionnaires not be completed reminders will be sent (text/email dependent on patient preference) following 1 and 3 days. If need be, we will offer to do the questionnaires over the phone or secure video conferencing with patients.

Semi-structured interviews

Table 2: interview schedule and aims

Interview	Group sampled	Number sampled	Sampling	Date	Aim
Post-intervention feedback on the mHealth intervention	mHealth Intervention only	2-3 each site (total n=12-20)	Minimum inclusion of at least one self-identified male and female in each group	Approximately 1 week after CR completion	Guided discussion will aim to learn about experiences (barriers, facilitators, actual use of tech and coach, receptivity to coach, perceived appropriateness, suggestions for improvement but also exercise prescription and counselling).
Post intervention feedback on the acceptibility of the research process	mHealth Intervention Active Control	2-3 each site 2-3 each site (total n=12-20)	Minimum inclusion of at least one self-identified male and female in each group	Approximately 1 week after CR completion	Guided discussion will aim to learn about experiences (willingness to do again, refer others, perceived appropriateness, respect, dignity, confidentiality, suggestions for improvement) with recruitment, randomization and the research process.

Process evaluation

A detailed process evaluation will examine the acceptability and feasibility of the intervention and evaluation methods. Semi-structured interviews will be conducted post intervention (table 2):

1. Post-intervention feedback on the intervention.
2. Post-intervention feedback on acceptability of the research process.

All interviews will be conducted by another individual on the research team via telephone or video call according to participant preference and will be structured using a topic guide.

Qualitative analysis

Interviews will be audio / video recorded and transcribed verbatim, deductively coded and analysed using the theoretical domains framework enabling challenges and facilitators within the intervention to be identified [24]. Transcriptions will be thematically analysed [25] and coded either manually or using NVivo V.12TM software. Data will be thematically analysed using reflexive thematic analysis recommendations such as data familiarisation, generating initial themes, coding and finalising patterns of shared meanings underpinned by a central concept, and writing up using data extracts interspersed with researcher interpretations [25]. Although the data themes will be created deductively the patterns of shared meaning will be inductively generated from the data themselves allowing interpretation and researcher contextual awareness to be discussed [25]. Member checking will be the final step in analysis, ensuring that interviewed participants have the opportunity to confirm researcher interpretation and add comments that will be incorporated into

the final analysis [26]. Our aim is to develop a comprehensive understanding of the intervention acceptability, implementation and mechanisms of impact.

Economic assessment

At baseline and post-intervention all participants will complete the EuroQol-5 Dimension questionnaire and a study-specific questionnaire assessing healthcare usage in the last 12 weeks (GP services, specialist care, ambulatory clinics in hospital, physiotherapy and medicines). During the interventions, researcher time per participant will also be recorded in both groups.

Interventions

An initial intervention meeting will be scheduled via preferred virtual platform. All subsequent intervention meetings will be held using this platform. Either a Polar Verity sense HR monitor (standard CR care) or Polar Ignite 2 and Polar Verity sense HR monitor (exercise counselling + mHealth + standard CR care) will be posted to the patient following randomisation (contained within parcel for assessment equipment). Patients in the exercise counselling + mHealth + standard CR care group will also be provided with instructions to download the Polar Flow – Sync & Analyze application from the App Version 6 30.06.22 Store (IOS devices) or Google Play (Android devices). The app will be initialised in the 1st exercise counselling session.

Participants will be given written and verbal instruction regarding contraindications to exercise and will be asked to confirm they are not experiencing any of these prior to their exercise session. If participants are experiencing any of these symptoms, then

they must not exercise and inform the research team. Participants will be randomised into one of two groups:

1.CR standard care control group: Participants will follow CR standard care. Participants have contact (e.g. telephone/virtual and/or home visit) with the CR team between discharge and beginning CR. They will begin structured exercise at the time provided by the CR service, the structured exercise service consists of 1-2 supervised exercise sessions per week for 8-12 weeks at the clinical or community centre. Exercise sessions are circuit-based, cardiovascular and strength exercise of light to moderate intensity (40-70% heart rate reserve (HRR)). Participants can wear an unblinded HR monitor during structured exercise provided by the CR service. As part of the study, they will also always wear the blinded verity sense optical HR monitor provided by the research team.

2. mHealth supported Exercise counselling +CR standard care experimental group (Table 3): Participants will co-design a personalised and progressive home-based walking program, with support from the exercise specialist, that starts immediately following hospital discharge and study measures, and continues as an adjunct once/if structured exercise CR begins. To assist with the transition to independent exercise and to promote long-term adherence, participants will receive 4 virtual exercise counselling sessions. The first, held within 5 days of discharge, will be used to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant and time-bound) PA plan. During this initial phase, participants will be prescribed an individualised (initial duration and intensity of sessions and rate of progression) walking plan. Once structured exercise CR has begun, a second session will be held to discuss progress

and refine goals with the aim of progressing the programme. At this time, home-based walking sessions will be performed alongside structured exercise CR sessions to increase adherence in daily life. A third meeting will be held 1 month into CR to discuss progress. A final meeting will occur at the end of CR to review progress and strategies to maintain exercise and PA. Each participant's exercise program will differ, but the aim will be to increase exercise intensity and duration throughout the programme with the goal of achieving 150-minutes of moderate intensity exercise per week, when combined with structured exercise CR sessions. HR zones of 40-70% will be calculated using the Karvonen HRR formula [27] as identified in The British Association for Cardiovascular Prevention and Rehabilition (BACPR) guidelines [28].

3. Behaviour change intervention: Our mHealth technology supported PA and counselling intervention, MOTIVATE, is designed based on the principles of the COM-B model of behaviour change (capability, opportunity, motivation, and behaviour) [29]. An analysis of the intervention components showed that MOTIVATE addressed capability by suitably screening participants and identifying barriers and motivators through goal setting during exercise counselling sessions, alongside increasing the participant's confidence when completing remotely monitored exercise sessions. Opportunity has been identified through the use of remote feedback and monitoring via text messages. Motivation was addressed using motivational interviewing technique processes, in addition to the removal of the barrier of travelling to an exercise facility, and in combination with using goal setting and feedback text messages.

Table 3: Details of counselling intervention

Date	Details

Consultation 1	Prior to intervention	Initial meeting to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant and time-bound) plan and develop the walking programme.
Consultation 2	At the start of CR	Progress/adapt the walking programme where applicable
Consultation 3	1-month into CR	Patient feedback/refinement of walking programme with the aim of progressing the programme further.
Consultation 4 progress.	Post intervention	Patient feedback and review of Discussion on strategies for maintaining exercise and PA

The experimental intervention will be supported by 3 mHealth elements: 1. Online coaching platform for exercise specialist: (Polar Flow for Coach https://flow.polar.com/coach) within the platform the exercise specialist will build the co-designed exercise programme, specifying the agreed number of sessions per week and prescribing the duration and intensity of each phase i.e., warm up, workout and cool-down. Structured exercise CR sessions will also be recorded so these can be tracked. Throughout the intervention the online platform will also provide the research fellow access to the participant data including; daily PA, HR during exercise, rate of perceived exertion RPE (CR-10 scale [30]) and written comments on exercise sessions.

2. Smart phone app: (Polar Flow – Sync & Analyze) participants will access their walking programme, use the app to track their exercise and PA achievements. All

data recorded by the fitness tracker (see details below) will be avaliable within the app, and participants will use the app to provide feedback on each exercise session; including a session RPE (CR-10 scale) and a written comment.

3. Fitness watch (Polar Ignite 2, Polar Electro): the Polar Ignite 2 fitness watch features a triaxial accelerometer and optical HR monitor. Participants will access pre-set exercise sessions, designed by the exercise specialist, on the device. The prescribed duration and intensity, via HR zones, will be displayed in real time on the watch throughout the exercise session. The watch will also provide live visual and haptic (vibration) alerts, coaching participants to execute the session as prescribed. Progress towards a personalised daily PA target will also be displayed throughout the day on the watch screen. All data recorded on the watch will be synchronised with both the smartphone app and the online platform. For the remainder of the walking intervention (including during CR), messages will be sent weekly. Participants will be able to respond to these comments and programmes will be updated if necessary.

Ongoing communication

Data from the mHealth elements, including participant comments, will be used to facilitate ongoing personalised feedback. During the first month, participants will be asked to provide a RPE and written comments following all exercise sessions, using the smart phone app. The comment will relate to the appropriateness of the session duration and intensity and their enjoyment of the walking programe. After each recorded exercise session, the exercise specialist will then use the participant feedback to send a personalised text message in response to the session. Based on this feedback, the exercise specialist will update the walking programme as

appropriate via the online platform. The aim of this initial 1 month period is to refine the exercise sessions to ensure particiapnts have a programme that meets their current fitness and lifestyle requirements. Following exercise counselling 3 participants will receive weekly text messages from their exercise specialist until the end of the intervention period.

Exercise specialist

The role of exercise specialist will be assumed by a post-doctoral research fellow in the UK (a Registration Council for Clinical Physiologists registered Clinical Exercise Physiologist with PhD in exercise science). The same exercise specialist will provide support to both arms of the trial.

Study withdrawal

Each participant has the right to withdraw from the study at any time with no obligation to provide a reason. If provided, reasons for withdrawal will be retained so that a full consort diagram can be generated, but personal data will be disposed of. In addition, participants may be withdrawn from the study by the research team at any time if the research team considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Withdrawal of Consent
- Loss to follow up

Withdrawal from the study will not result in exclusion of the participant's data from analysis, including audio recordings that have already been transcribed as all of this data will be pseudonymised. Withdrawn participants will not be replaced. Participants will be asked reasoning behind withdrawal either via email or phone call. The reason will be recorded in the study file. Participants are free to give no reason.

Serious adverse event reporting and management

Participants will be asked if an adverse event (AE) has occurred during the exercise counselling sessions at the start of CR and end of CR, plus during ongoing text message support. Should an AE be reported, an independent clinician will assess the event and the end outcome using the Serious Adverse Events (SAE) Report Form. The Chief Investigator (CI) will then report the event to the sponsor using the SAE Letter Template. Serious adverse events are defined as any adverse event at any stage in the research participation of the study which:

- results in death
- is life threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly/ birth defect

Life-threatening refers to an event in which the participant was at risk of death at the time of event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Expected adverse events include:

- Development of unstable angina
- Cough and Colds

- Flu
- Muscle aches and pains
- Muscle strains
- Indigestion
- Constipation
- COVID-19

Data management

Direct access to data will be granted to the research team, authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. Paper data will be stored in a locked cabinet at LJMU, only accessible to the PI and Post-Doctoral Fellow. An electronic file containing the link between participants' name and study number will be stored in a password protected file and only be accessible to the PI and Post-Doctoral Fellow. A paper copy of this file will also be stored in a locked cabinet in the principal investigator's office at LJMU. Audio / video recordings which contain personal data will be recorded on a password protected device and transferred to password protected storage and deleted from the recording device. All patients will be given a pseudonymised study code. This code will be used for all stored data including transcripts of interviews and audio recordings. Published quotes will be pseudonymised using this code. Pseudonymised data will be transferred between investigators using an internet-based data transfer portal. This data will reside in a secure server with access restricted to allocated staff. Only the LJMU study team will have access to personal identifiable information.

Interviews will be transcribed and analysed by the team study team at Liverpool John Moores University. Our intended policy is that the study team should have exclusive use of the data for a period of 12 months or until the data is published. Data will be shared with named collaborators during this time. Following this data will be publicly available through the LJMU Data Repository, published under a permissive re-use license. A CC BY NC license will be applied to openly available data, this creative commons license permits others to distribute, and build upon the work for non-commercial purposes.

Sample size calculation

As this is a feasibility study a formal power calculation is not appropriate. The sample size was based on published good practice recommendations for pilot/feasibility studies [31].The proportion of eligible patients who consent to participate will be presented by site and overall, along with the proportions in each intervention group completing each follow-up assessment and the reasons for withdrawal. Descriptive characteristics and outcome data will be summarised overall and by intervention group, as mean (standard deviation) for normally distributed continuous variables, median (interquartile range) for non-normally distributed continuous variables, and number (percentage) for categorical variables.

Trial oversight

The quality of the study will be assured through the series of management groups. The trial will be overseen by a Trial Steering Committee (TSC) and operated on a day-to-day basis by a Trial Delivery Group (TDG). The TSC will comprise of experienced academic experts (research team) and patients, but does not require

and therefore will not have an independent chair. The TSC will meet quarterly to discuss progress. The role of the TSC is to provide overall supervision of the trial. In particular, the TSC will concentrate on the progress of the trial, adherence to the protocol, participant safety and consideration of new information. The TSC must be in agreement with the final protocol and, throughout the trial, will take responsibility for major decisions such as need to change the protocol for any reason, monitoring and supervising the progress of the trial, reviewing relevant information from other sources and informing and advising the TDG on all aspects of the trial.

The TDG will comprise of the same research team and will hold monthly meetings to discuss progress. The responsibilities of the TDG will include:

1. Report to the TSC.
2. Maintain the Trial Master File.
3. Confirm all approvals are in place before the start of the trial at a site.
4. Provide study materials.
5. Data management centre.
6. Give collaborators regular information about the progress of the study.
7. Respond to any questions (e.g., from collaborators) about the trial.
8. Ensure data security and quality and observe data protection laws.
9. Safety reporting.
10. Ensure trial is conducted in accordance with Good Clinical Practice (GCP).
11. Statistical analysis.
12. Publication of trial results.

Patient and public involvement (PPI)

PPI work was conducted with patients participating in stage 4 CR at one of the sites. Patients (n=9) were given the programmed mHealth technology to use for 12 weeks. Exercise intensity was successfully prescribed and monitored using HR, including in those on beta-blockers, in this group. Eight of 9 patients described the intervention as very/extremely helpful in increasing their exercise levels, citing the improved communication with their CR specialists and feedback given by the watch during exercise as facilitators.

One patient representative will be invited on the trial steering committee. They will advise on study information materials to recruit participants to the study. At the end of the project our patient representatives will contribute to the reporting of the study through reading and reviewing the 'lay' sections of the report. They will also be involved in dissemination of research findings through reviewing literature outlining the results before they are circulated.

Ethics and dissemination

The trial protocol has received favourable opinion from the Greater Manchester East Research Ethics Committee (22/NW/0301) in the UK. Upon study completion, the chief investigator owns the data. On completion of the study, the data will be analysed, and results will be disseminated via publication in clinical and physiological journals, presented at National and International conferences and in the form of feedback sheets or perhaps local articles. Participants will not be identifiable from the results of the study. Pseudonymised data from this study will be made available for sharing with other investigators, after publication of the study's key papers. Data will be shared through the LJMU Data Repository (http://opendata.ljmu.ac.uk/). This is a secure institutional data repository, which is searchable on the www, it is

managed by Library Services. A DOI will be generated for datasets as they are deposited to the repository. Data will be stored in this repository for a minimum of 10 years or for 10 years from the last date of access.

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Competing interests

None

Patient consent for publication

None

Data statement

Author contributions

HJ, AC, KH, LT, GMc, GM and MC initiated the study design. HJ, GMc, GM, LT and MC are grant holders. All authors contributed to refinement of the protocol and approved the final manuscript. The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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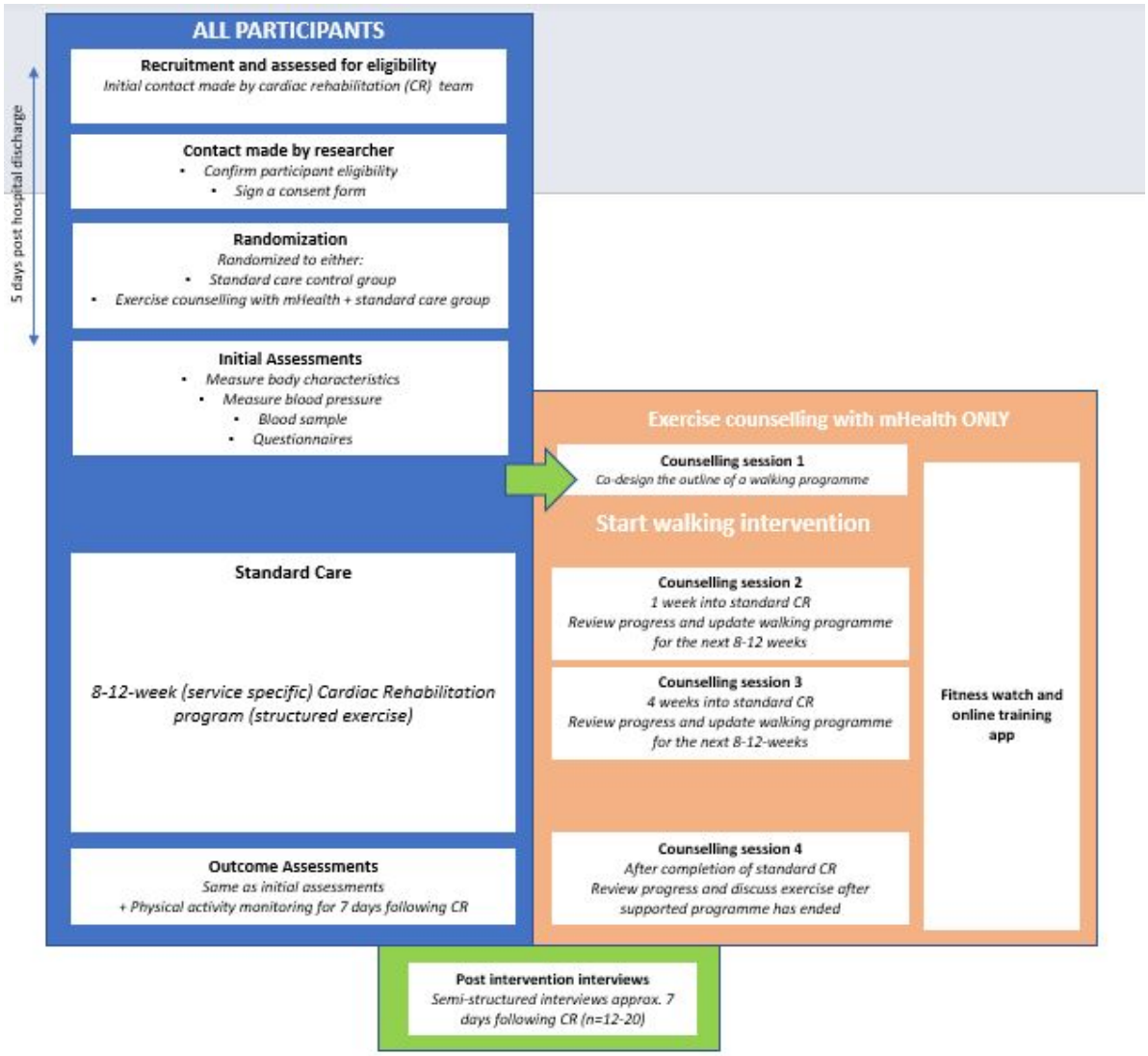

Figure 1: Study flow diagram and participant pathway

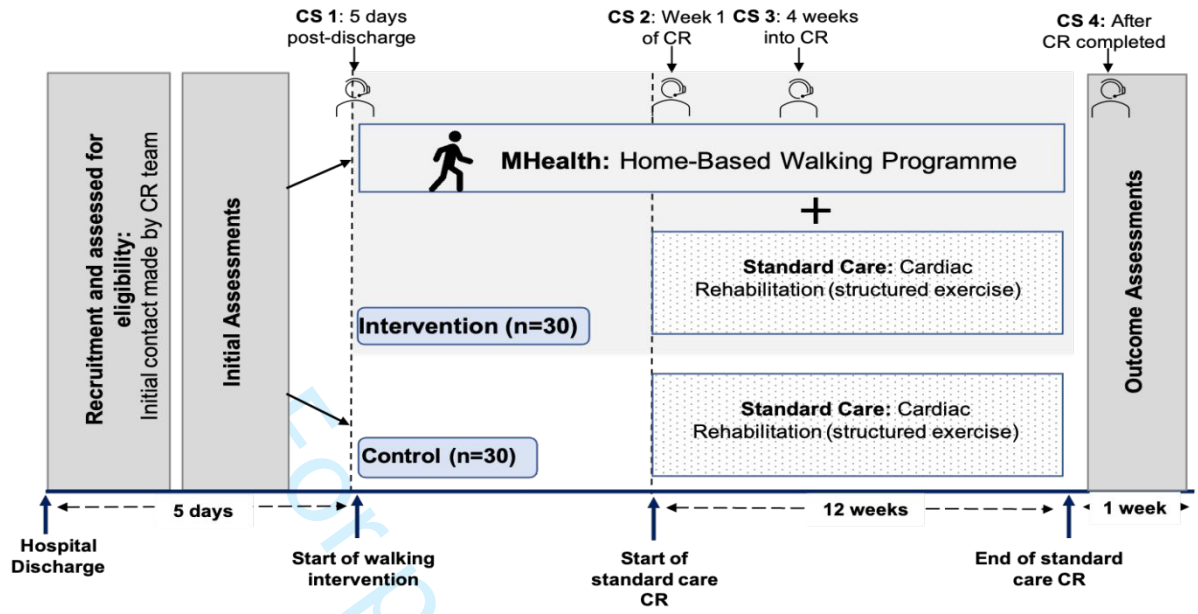

Figure 2: Schematic of the experimental design. Abbreviations: CR; cardiac rehabilitation, n; number, CS; counselling session.

Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORTreporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title and Abstract			
Title	#1a	Identification as a randomized trial in the title.	1
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	1
Introduction			

Background and objectives	#2a	Scientific background and explanation of rationale	3-5
Background and objectives	#2b	Specific objectives or hypothesis	5-10
Methods			
Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	6
Trial design	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	#4a	Eligibility criteria for participants	7-8
Participants	#4b	Settings and locations where the data were collected	6
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	16-20
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	9-10
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	#7a	How sample size was determined.	24

Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization - Sequence generation	#8a	Method used to generate the random allocation sequence.8	6-8
Randomization - Sequence generation	#8b	Type of randomization; details of any restriction (such as blocking and block size)	6-8
Randomization - Allocation concealment mechanism	#9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-8
Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	6-8
Blinding	#11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	6-8
Blinding	#11b	If relevant, description of the similarity of interventions	16-20
Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	9-11,15-16

Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow diagram (strongly recommended)	#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	N/A
Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	N/A
Recruitment	#14a	Dates defining the periods of recruitment and follow-up	N/A
Recruitment	#14b	Why the trial ended or was stopped	N/A
Baseline data	#15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	#16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	N/A
Outcomes and estimation	#17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A
Outcomes and estimation	#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A

Ancillary analyses	#18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	N/A
Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	N/A
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A
Registration	#23	Registration number and name of trial registry	2-3
Other information			
Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A
Registration	#23	Registration number and name of trial registry	2-3
Protocol	#24	Where the full trial protocol can be accessed, if available	N/A

Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	25

BMJ Open

Mobile Health Biometrics to prescribe immediate remote physical activity for enhancing uptake to cardiac rehabilitation (MOTIVATE-CR+): protocol for a randomised controlled feasibility trial

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Mobile Health Biometrics to prescribe immediate remote physical activity for enhancing uptake to cardiac rehabilitation (MOTIVATE-CR+): protocol for a randomised controlled feasibility trial

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ABSTRACT

Introduction: Cardiac Rehabilitation (CR) can reduce cardiovascular mortality and improve health related quality of life. In the United Kingdom patient uptake of CR remains low (52%), falling well short of the target in the 2019 NHS Long-term plan (85%). Mobile health (mHealth) technologies, offering biometric data to patients and healthcare professionals, may bridge the gap between supervised exercise and physical activity (PA) advice, enabling patients to engage in regular long-term physically active lifestyles. This randomised controlled trial (RCT) will evaluate the feasibility of mHealth technology when incorporated into a structured home-based walking intervention, in people with recent myocardial infarction.

Methods and analysis: This is a feasibility, assessor blinded, parallel group randomised control trial (RCT). Participants will be allocated to either CR standard care (control group) or CR standard care + mHealth supported exercise counselling (mHealth intervention group). Feasibility outcomes will include; the number of patients approached, screened and eligible; the percentage of patients that decline CR (including reasons for declining), agree to CR and consent to being part of the study; the percentage of patients that enroll in standard CR and reasons for drop out; and the percentage of participants that complete clinical, physical and psychosocial outcomes to identify a suitable primary outcome for a future definitive trial.

Ethics and dissemination: The trial was approved in the UK by the Northwest – Greater Manchester East Research Ethics Committee (22/NW/0301) and is being conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Results will be published in peer-reviewed journals and presented at national and international scientific meetings.

Trial registration numbers: ClinicalTrials.gov: NCT05774587

Introduction

Cardiac Rehabilitation (CR) is a clinically- and cost-effective intervention, reducing cardiovascular (CV) mortality and unplanned hospital admissions in addition to improving health related quality of life [1-4]. Despite this, in the UK, the National Audit of Cardiac Rehabilitation (NACR) estimates that only 52% of eligible patients start CR (defined as uptake) [5]. A key milestone within the National Health Service (NHS) long-term plan is to increase uptake of CR from 52 to 85% by 2028 [6]. Reducing the time between hospital discharge and the start of CR in general is essential to meet this milestone; the current recommendation is <28 days post discharge, but the range in clinical services is 3-111 days [5]. Failure to begin CR within 28 days reduces uptake, with recent data suggesting 10,753 patients per year do not take up CR due to a delay in service provision, equating to a loss of 3,936 years of life expectancy [7]. A possible solution to increase uptake of CR may be to bridge the gap between hospital discharge and the start of supervised CR with remote physical activity (PA) counselling supported by mHealth technology that provides biometric feedback and coaching to patients and health professionals.

The emergence of mobile technologies and wearable sensors has enabled real-world monitoring through mobile health biometrics (mHealth) [8]. Devices incorporating biometrics such as heart rate (HR) could be a potential solution to bridge the gap between general PA advice on discharge, and supervised exercise. HR monitors provide objective personalised data that account for age, body mass and fitness [9] and are related to exercise intensity regardless of the type of activity being performed [10]. Current research studies (https://www.motivateljmu.com/about) in healthy sedentary individuals, people with newly diagnosed type 2 diabetes and stage 4 CR have explored the acceptability

and efficacy of exercise and PA counselling programmes supported by mHealth technologies that provide biometric feedback and coaching to patients and health professionals [8, 11]. Biometric data such as HR are recorded through a wrist worn fitness tracker to inform exercise counselling delivered by healthcare professionals. Recently, we have shown that the use of mHealth supported counselling leads to adherence of 113%±68 (participants exercised more often than prescribed) and is superior to self-directed web-based exercise in sedentary office workers at risk of cardiovascular disease [12].

Virtual home-based CR has emerged as an alternative to supervised in-person CR usually delivered in a hospital or leisure centre [13]. In the UK, self-directed virtual web-based exercise for CR has been developed but is not used as part of CR standard practice, and does not currently allow individualised exercise prescription, biometric monitoring, or coaching [14-16]. Studies have shown CR can be effectively delivered remotely using mHealth technologies with biometric monitoring [17, 18]. Whilst these studies were conducted to compare supervised in-person CR and remote CR, they demonstrated that mHealth technology is acceptable in this patient group [17, 18]. No study to date has examined whether remote CR with biometric monitoring, can be employed as an immediate post-hospital discharge intervention to increase uptake of CR.

Study aims

The primary aim is to conduct a feasibility study to evaluate a model where mHealth technology supports a remote home-based PA and counselling intervention immediately post hospital discharge to increase uptake to cardiac rehabilitation.

The specific objectives are:

1. Obtain patient demographics and screening, eligibility, recruitment and drop-out rates.
2. Estimate precision of outcome measures: uptake, time between discharge and start of Cardiac Rehabilitation (CR), adherence, cardiovascular (CV) risk profile, health related quality of life (HrQoL).
3. Assess acceptability of the mHealth PA and counselling intervention.
4. Assess feasibility and acceptability of outcome measurements and conducting an RCT.
5. Determine availability and completeness of economic data.

Methods and analyses

This is a feasibility, assessor blind, parallel group randomised control trial (RCT) registration number: ClinicalTrials.gov: NCT05774587. Participants will be randomised to either CR standard care (active control group) or CR standard care + mHealth supported exercise counselling (mHealth intervention). Outcomes assessment will be completed twice; 1) immediately post hospital discharge, before any intervention, and 2) after CR (Figure 1). To minimise participant burden and ensure timely completion, outcome measures will be undertaken remotely. The trial protocol adheres to Recommendations for Interventional Trials and the Template for Intervention Description and replication guidelines [19, 20].

INSERT FIGURE 1 HERE

Study setting and recruitment plan

Recruitment (n=60) will take place at three UK CR sites; North-West England (n=20), West Midlands (n=20) and North-East England (n=20) commencing May 2023 for 12 months. The trial will end (last data collection from the last participant) in June 2024.The participant information sheet (PIS) will be added to hospital discharge packs, and patients will then be contacted via telephone by a CR team immediately post-discharge as part of routine care (within 48h). During this contact the CR team will discuss the study. If the patient expresses an interest in the study, the CR team will request verbal consent to pass contact details to the research team, who will contact interested participants via telephone (or video call) to discuss the PIS (provided by CR team), ask any questions and confirm eligibility criteria. Participants will be consented and screened which involves a medical history, details of current medications, current PA and exercise behaviour (Figure 2).

Eligibility criteria

Eligible participants will have been referred to CR with a recent clinical diagnosis of myocardial infarction (MI) and have been discharged within the last five days.

Detailed inclusion criteria

- Participant is willing and able to give informed consent for participation in the study.
- Male or Female.
- Over 18 years old.
- Post MI.
- Post percutaneous coronary intervention (PCI) patients.
- Referred for CR.

Detailed exclusion criteria

- Acute or unstable health conditions
- Coronary artery bypass graft surgery
- Unable to participate in self-management programmes because of medical care needs.
- Absolute contraindications to exercise.
- Unable to operate or own mobile/smartphone devices/lack of internet access
- Declined CR standard care.
- Allergies to the watch materials.
- Atrial fibrillation or other arrhythmia preventing accurate heart rate.

INSERT FIGURE 2 HERE

Randomisation and blinding

Randomisation will be computer generated and the code held by an independent person blinded to the groups to maintain allocation concealment according to the SPIRIT guidelines [19]. Due to the nature of the intervention, blinding the participants is not possible. Following the initial screening process participants will be randomly allocated to the two study groups (active control or mHealth intervention) and informed by telephone/ email (patient preference).

Outcome measures

Primary Outcome

Outcome measures (Table 1) will be taken using remote 'home-based' solutions which do not require travel or in-person contact. Throughout the study, information will be collected on 1) the total number of patients screened, eligible, approached, 2) the % of patients that a) decline CR (including reasons for declining); b) agree to CR and c) consent to being part of the study; 3) the % of patients that take up standard CR following the mHealth intervention and reasons for drop out of CR before the end of the intervention (if provided); and 4) the % of participants that complete outcome assessments and reasons for drop out (if provided).

Secondary outcomes

Age, sex, ethnicity, reason for enrolment into CR, centre referred to, education and employment status will also be collected via an initial screening telephone call. Immediately following consent and randomisation, participants will be mailed (direct to patients preferred address) all necessary assessment resources including written and video guidance on how to complete the assessments (https://www.motivateljmu.com/cr.) within the 1-5 day timeframe. Participants will then receive a phone/video call from the research team to 1) discuss the testing protocol and allow patients to ask any questions they may have and 2) gain patients current medication information (current medications and dose) and ethnicity. On the day of testing, a member of the research team will be available via phone/video call to provide support where required. Using this approach, we expect participants to begin the mHealth intervention within a maximum of 5 days post discharge.

Table 1: Primary objectives and outcome measures

Objectives	Outcome Measures	Timepoint(s) of evaluation of this

		outcome measure (if applicable)
Primary Objective		
Our overall objective is to test the feasibility of an evidence-based intervention prior to evaluation in a future randomised control trial (RCT).	Information will be collected on: 1. The number of patients screened, eligible and approached. 2. The percentage of patients that: a) decline CR (including reasons for declining) b) agree to CR and c) consent to being part of the study 3. the percentage of patients that take up standard CR and reasons for drop out; and 4. the percentage of participants that complete outcome assessments and reasons for drop out.	1 - 4) Ongoing throughout the intervention
Secondary Objective		
1) Estimate precision of potential outcome measures required for sample size estimations for the definitive RCT.	Six potential outcome measures will be assessed: **1) Adherence to exercise** a. Adherence to structured exercise b. Pre and post intervention exercise questionnaire (GLTEQ) c. Objectively assessed physical activity **2) Body composition** a. Height + weight b. Waist circumference **3) Blood pressure** **4) Blood lipids and HbA1c** a. Total cholesterol b. HDL/LDL c. Triglycerides d. HbA1c **5) Health related quality of life** a. MacNew Heart disease health related quality of life	1) a. Ongoing throughout the intervention b. During initial and outcome assessments c. 7 days post CR 2-5) During initial and outcome assessments

	b. The Behavioural Regulation in Exercise Questionnaire c. Patient Rapport with Counsellor Questionnaire	
2) Evaluate the acceptability of the intervention to patients, assessing the feasibility of implementing the intervention.	1) Post-intervention patient qualitative data (semi-structured interviews) investigating: a. The acceptability of the intervention components and barriers and facilitators to the intervention b. Acceptability of the recruitment and randomisation process c. Acceptability of the measurement instruments	Post CR (Purposive sampled subset)
3) Determine availability and completeness of economic data	1. level EQ-5D 2. Questionnaire assessing healthcare usage in the last 12 weeks	1-2) Post CR

Exercise adherence and habitual PA

Adherence to home-based exercise prescription is difficult to measure using one method. Accordingly, the feasibility of three outcome measures will be assessed:

1. Device-derived assessment of exercise sessions: the number of planned structured exercise sessions completed along with the duration and intensity of each session will be assessed via optical HR monitoring (photoplethysmography). The mHealth group will use the Polar Ignite 2 fitness watch and the Polar Verity sense optical HR monitor (Polar Electro, Finland) provided as part of the intervention. The active control group will be provided with a Polar Verity Sense optical HR monitor for the duration of the trial, to wear during planned structured exercise sessions (e.g., structured CR session). The Polar Verity Sense records HR but gives no real-time/historical feedback to participants. As such active control participants will be blinded to the HR throughout.

2. Device-derived PA: key metrics of PA will be assessed using a wrist-worn triaxial accelerometer (GENEActiv, Activinsights, Kimbolton, Cambridge, UK)

during the final 7 days of the intervention period immediately after follow-up testing. Before sending to the participant, the accelerometer will be initialised and set by the research team to start and finish recording at specific dates. Data will be downloaded using manufacturers' software and processed in R (R Core Team,Vienna, Austria) using the open-source GGIR software package (http://cran.r-project.org).

3. Survey-reported exercise behaviour will be evaluated using the Godin Leisure Time Exercise Questionnaire (GLTEQ) at baseline and post-intervention. The questionnaire will be administered using an online platform (Qualtrics, Provo, UT) survey.

Baseline and post intervention testing

Testing will take place in the morning between 6am and 10am and should take approx. 45 minutes. Participants will be fasted overnight and instructed to abstain from caffeine, alcohol, and moderate/ vigorous exercise the day before testing. Participants will be asked to drink a glass of water immediately before the measures are taken.

Anthropometrics

Participants will be sent a measuring tape (Seca 201, Germany) to be used for assessing height and waist circumference. Waist circumference will be measured in triplicate at the level of the umbilicus. Previous work suggests a strong correlation between self-measured and technician-measured height and weight (Salter, UK) [21] and waist circumference, measured at the umbilicus [22].

Blood pressure

Patients will be asked to rest in a seated position for 10 minutes before measuring their blood pressure using an automated blood pressure monitor validated by the British and Irish Hypertension Society (UK, Salter BPA-9200-GB; Canada, Bios BD215). Patients will wrap the blood pressure cuff around their non-dominant arm. Blood pressure will then be measured in triplicate, leaving 1 minute between successive measurements. Self-measured blood pressure is a validated approach for monitoring blood pressure, endorsed by the American Heart Association and American Medical Association [23].

Blood sampling

Patients will then collect a 500ul blood sample from a finger prick, using a self-administered commercial blood collection kit, via Royal Devon and Exeter NHS Foundation Trust (MonitorMyHealth.org.uk) in accordance with pre-defined procedures. Patients will be asked to post the envelope on the same day as collection. Due to the time sensitive nature of the sample patients will be sent a text/email (patient preference) to remind them to post the sample. Blood samples will be posted by participants to the Royal Devon and Exeter NHS Foundation Trust. Samples will be analysed for HbA1c, total cholesterol, HDL/LDL cholesterol and triglycerides by the Clinical Chemistry department at the Royal Devon and Exeter Hospital. Donor information will not be available to the team at Royal Devon and Exeter Hospital as samples will be sent using pseudonymised sample codes only, however members of the research team will be able to identify donors via participant numbers. Internal pilot data from the Exeter Clinical Laboratory demonstrates that capillary blood sampling reveals good agreement with standard venous sampling.

Patient Questionnaires

All patients will complete online versions of 1) the 5-level EuroQol-5 Dimensions, 2) a study specific questionnaire assessing healthcare use over the previous 12-weeks, 3) the Godin Leisure Time Exercise Questionnaire (GLTEQ), 4) the heart disease health related quality of life (MacNew) questionnaire and 5) the Behavioural Regulation in Exercise Questionnaire version 2 (BREQ-2). The questionnaires will be completed using qualtrics by assessor blind to group allocation. Patients will be encouraged to complete the questionnaires immediately after testing. Should questionnaires not be completed reminders will be sent (text/email dependent on patient preference) following 1 and 3 days. If need be, we will offer to do the questionnaires over the phone or secure video conferencing with patients. No cardiovascular assessments will take place due to the remote nature of the testing and the lack of monitoring available for participants during any sub-maximal physical exertion.

Semi-structured interviews

Table 2: Details of semi-structured interviews

Interview	Group sampled	Number sampled	Sampling	Date	Aim
Post-intervention feedback on	mHealth Intervention only	2-3 each site (total n=12-20)	Minimum inclusion of at least one self-	Approximately 1 week after CR completion	Guided discussion will aim to learn about experiences (barriers, facilitators, actual use of tech and coach, receptivity to coach,

the mHealth intervention			identified male and female in each group		perceived appropriateness, suggestions for improvement) with the intervention (both technological aspects but also exercise prescription and counselling).
Post intervention feedback on the acceptibility of the research process	mHealth Intervention Active Control	2-3 each site 2-3 each site (total n=12-20)	Minimum inclusion of at least one self-identified male and female in each group	Approximately 1 week after CR completion	Guided discussion will aim to learn about experiences (willingness to do again, refer others, perceived appropriateness, respect, dignity, confidentiality, suggestions for improvement) with recruitment, randomization and the research process.

Process evaluation

A detailed process evaluation will examine the acceptability and feasibility of the intervention and evaluation methods. Semi-structured interviews will be conducted post intervention (table 2):

1. Post-intervention feedback on the intervention.
2. Post-intervention feedback on acceptability of the research process.

All interviews will be conducted by another individual on the research team via telephone or video call according to participant preference and will be structured using a topic guide.

Qualitative analysis

Interviews will be audio / video recorded and transcribed verbatim, deductively coded and analysed using the theoretical domains framework enabling challenges and facilitators within the intervention to be identified [24]. Transcriptions will be thematically analysed [25] and coded either manually or using NVivo V.12TM software. Data will be thematically analysed using reflexive thematic analysis recommendations such as data familiarisation, generating initial themes, coding and finalising patterns of shared meanings underpinned by a central concept, and writing up using data extracts interspersed with researcher interpretations [25]. Although the data themes will be created deductively the patterns of shared meaning will be inductively generated from the data themselves allowing interpretation and researcher contextual awareness to be discussed [25]. Member checking will be the final step in analysis, ensuring that interviewed participants have the opportunity to confirm researcher interpretation and add comments that will be incorporated into the final analysis [26]. Our aim is to develop a comprehensive understanding of the intervention acceptability, implementation and mechanisms of impact.

Economic assessment

At baseline and post-intervention all participants will complete the EuroQol-5 Dimension questionnaire and a study-specific questionnaire assessing healthcare usage in the last 12 weeks (GP services, specialist care, ambulatory clinics in hospital, physiotherapy and medicines). During the interventions, researcher time per participant will also be recorded in both groups.

Interventions

An initial intervention meeting will be scheduled via preferred virtual platform. All subsequent intervention meetings will be held using this platform. Either a Polar Verity sense HR monitor (standard CR care) or Polar Ignite 2 and Polar Verity sense HR monitor (exercise counselling + mHealth + standard CR care) will be posted to the patient following randomisation (contained within parcel for assessment equipment). Patients in the exercise counselling + mHealth + standard CR care group will also be provided with instructions to download the Polar Flow – Sync & Analyze application from the App Version 6 30.06.22 Store (IOS devices) or Google Play (Android devices). The app will be initialised in the 1st exercise counselling session.

Participants will be given written and verbal instruction regarding contraindications to exercise and will be asked to confirm they are not experiencing any of these prior to their exercise session. If participants are experiencing any of these symptoms, then they must not exercise and inform the research team. Participants will be randomised into one of two groups:

1.CR standard care control group: Participants will follow CR standard care. Participants have contact (e.g. telephone/virtual and/or home visit) with the CR team between discharge and beginning CR. They will begin structured exercise at the time provided by the CR service, the structured exercise service consists of 1-2 supervised exercise sessions per week for 8-12 weeks at the clinical or community centre. Exercise sessions are circuit-based, cardiovascular and strength exercise of light to moderate intensity (40-70% heart rate reserve (HRR)). Participants can wear an unblinded HR monitor during structured exercise provided by the CR service. As part of the study, they will also always wear the blinded verity sense optical HR monitor provided by the research team.

2. mHealth supported Exercise counselling +CR standard care experimental group (Table 3): Participants will co-design a personalised and progressive home-based walking program, with support from the exercise specialist, that starts immediately following hospital discharge and study measures, and continues as an adjunct once/if structured exercise CR begins. To assist with the transition to independent exercise and to promote long-term adherence, participants will receive 4 virtual exercise counselling sessions. The first, held within 5 days of discharge, will be used to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant and time-bound) PA plan. During this initial phase, participants will be prescribed an individualised (initial duration and intensity of sessions and rate of progression) walking plan. Once structured exercise CR has begun, a second session will be held to discuss progress and refine goals with the aim of progressing the programme. At this time, home-based walking sessions will be performed alongside structured exercise CR sessions to increase adherence in daily life. A third meeting will be held 1 month into CR to discuss progress. A final meeting will occur at the end of CR to review progress and strategies to maintain exercise and PA. Each participant's exercise program will differ, but the aim will be to increase exercise intensity and duration throughout the programme with the goal of achieving 150-minutes of moderate intensity exercise per week, when combined with structured exercise CR sessions. HR zones of 40-70% will be calculated using the Karvonen HRR formula [27] as identified in The British Association for Cardiovascular Prevention and Rehabilition (BACPR) guidelines [28].

3. Behaviour change intervention: Our mHealth technology supported PA and counselling intervention, MOTIVATE, is designed based on the principles of the COM-B model of behaviour change (capability, opportunity, motivation, and behaviour) [29]. An analysis of the intervention components showed that MOTIVATE addressed capability by suitably screening participants and identifying barriers and motivators through goal setting during exercise counselling sessions, alongside increasing the participant's confidence when completing remotely monitored exercise sessions. Opportunity has been identified through the use of remote feedback and monitoring via text messages. Motivation was addressed using motivational interviewing technique processes, in addition to the removal of the barrier of travelling to an exercise facility, and in combination with using goal setting and feedback text messages.

Table 3: Details of counselling intervention

Consultation Number	Date	Details
Consultation 1	Prior to intervention	Initial meeting to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant and time-bound) plan and develop the walking programme.
Consultation 2	At the start of CR	Progression/adaptation of the Personal walking programme.
Consultation 3	1-month into CR	Patient feedback and refinement of the walking programme with the aim of progressing the programme further.
Consultation 4	Post-intervention	Patient feedback and review of progress. Discussion on strategies for maintaining exercise and PA

The experimental intervention will be supported by 3 mHealth elements: 1. Online coaching platform for exercise specialist: (Polar Flow for Coach https://flow.polar.com/coach) within the platform the exercise specialist will build the co-designed exercise programme, specifying the agreed number of sessions per week and prescribing the duration and intensity of each phase i.e., warm up, workout and cool-down. Structured exercise CR sessions will also be recorded so these can be tracked. Throughout the intervention the online platform will also provide the research fellow access to the participant data including; daily PA, HR during exercise, rate of perceived exertion RPE (CR-10 scale [30]) and written comments on exercise sessions.

2. Smart phone app: (Polar Flow – Sync & Analyze) participants will access their walking programme, use the app to track their exercise and PA achievements. All data recorded by the fitness tracker (see details below) will be avaliable within the app, and participants will use the app to provide feedback on each exercise session; including a session RPE (CR-10 scale) and a written comment.

3. Fitness watch (Polar Ignite 2, Polar Electro): the Polar Ignite 2 fitness watch features a triaxial accelerometer and optical HR monitor. Participants will access pre-set exercise sessions, designed by the exercise specialist in line with BACPR guidelines and Frequency, Intensity, Time and Type (FITT) principles, on the device. The prescribed duration and intensity, via HR zones, will be displayed in real time on the watch throughout the exercise session. The watch will also provide live visual and haptic (vibration) alerts, coaching participants to execute the session as prescribed. Progress towards a personalised daily PA target will also be displayed throughout the day on the watch screen. All data recorded on the watch will be synchronised with both the smartphone app and the online platform. For the

remainder of the walking intervention (including during CR), messages will be sent weekly. Participants will be able to respond to these comments and programmes will be updated if necessary.

Ongoing communication

Data from the mHealth elements, including participant comments, will be used to facilitate ongoing personalised feedback. During the first month, participants will be asked to provide a RPE and written comments following all exercise sessions, using the smart phone app. The comment will relate to the appropriateness of the session duration and intensity and their enjoyment of the walking programe. After each recorded exercise session, the exercise specialist will then use the participant feedback to send a personalised text message in response to the session. Based on this feedback, the exercise specialist will update the walking programme as appropriate via the online platform. The aim of this initial 1 month period is to refine the exercise sessions to ensure particiapnts have a programme that meets their current fitness and lifestyle requirements. Following exercise counselling 3 participants will receive weekly text messages from their exercise specialist until the end of the intervention period.

Exercise specialist

The role of exercise specialist will be assumed by a post-doctoral research fellow in the UK (a Registration Council for Clinical Physiologists registered Clinical Exercise Physiologist with PhD in exercise science). The same exercise specialist will provide support to both arms of the trial.

Study withdrawal

Each participant has the right to withdraw from the study at any time with no obligation to provide a reason. If provided, reasons for withdrawal will be retained but personal data will be disposed of. In addition, participants may be withdrawn from the study by the research team at any time if the research team considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Withdrawal of Consent
- Loss to follow up

Withdrawal from the study will not result in exclusion of the participant's data from analysis, including audio recordings that have already been transcribed as all of this data will be pseudonymised. Withdrawn participants will not be replaced. Participants will be asked reasoning behind withdrawal either via email or phone call. The reason will be recorded in the study file. Participants are free to give no reason.

Serious adverse event reporting and management

Participants will be asked if an adverse event (AE) has occurred during the exercise counselling sessions at the start of CR and end of CR, plus during ongoing text message support. Should an AE be reported, an independent clinician will assess the event and the end outcome using the Serious Adverse Events (SAE) Report Form. The Chief Investigator (CI) will then report the event to the sponsor using the

SAE Letter Template with suitable outcomes required before continuation of study.

Serious adverse events are defined as any adverse event at any stage in the research participation of the study which:

- results in death
- is life threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly/ birth defect

Life-threatening refers to an event in which the participant was at risk of death at the time of event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Expected adverse events include:

- Development of unstable angina
- Cough and Colds
- Flu
- Muscle aches and pains
- Muscle strains
- Indigestion
- Constipation
- COVID-19

Data management

Direct access to data will be granted to the research team, authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. Paper data will be stored in a

locked cabinet at LJMU, only accessible to the PI and Post-Doctoral Fellow. An electronic file containing the link between participants' name and study number will be stored in a password protected file and only be accessible to the PI and Post-Doctoral Fellow. A paper copy of this file will also be stored in a locked cabinet in the principal investigator's office at LJMU. Audio / video recordings which contain personal data will be recorded on a password protected device and transferred to password protected storage and deleted from the recording device. All patients will be given a pseudonymised study code. This code will be used for all stored data including transcripts of interviews and audio recordings. Published quotes will be pseudonymised using this code. Pseudonymised data will be transferred between investigators using an internet-based data transfer portal. This data will reside in a secure server with access restricted to allocated staff. Only the LJMU study team will have access to personal identifiable information.

Interviews will be transcribed and analysed by the team study team at Liverpool John Moores University. Our intended policy is that the study team should have exclusive use of the data for a period of 12 months or until the data is published. Data will be shared with named collaborators during this time. Following this data will be publicly available through the LJMU Data Repository, published under a permissive re-use license. A CC BY NC license will be applied to openly available data, this creative commons license permits others to distribute, and build upon the work for non-commercial purposes.

Sample size calculation

As this is a feasibility study a formal power calculation is not appropriate. The sample size was based on published good practice recommendations for pilot/feasibility studies with the median value for feasibility studies (36 participants per arm) reported in an audit of pilot and feasibility trials registered in the UK clinical research network [31, 32].The proportion of eligible patients who consent to participate will be presented by site and overall, along with the proportions in each intervention group completing each follow-up assessment and the reasons for withdrawal. Descriptive characteristics and outcome data will be summarised overall and by intervention group, as mean (standard deviation) for normally distributed continuous variables, median (interquartile range) for non-normally distributed continuous variables, and number (percentage) for categorical variables.

Trial oversight

The quality of the study will be assured through the series of management groups. The trial will be overseen by a Trial Steering Committee (TSC) and operated on a day-to-day basis by a Trial Delivery Group (TDG). The TSC will comprise of experienced academic experts (research team) and patients, but does not require and therefore will not have an independent chair. The TSC will meet quarterly to discuss progress. The role of the TSC is to provide overall supervision of the trial. In particular, the TSC will concentrate on the progress of the trial, adherence to the protocol, participant safety and consideration of new information. The TSC must be in agreement with the final protocol and, throughout the trial, will take responsibility for major decisions such as need to change the protocol for any reason, monitoring and supervising the progress of the trial, reviewing relevant information from other sources and informing and advising the TDG on all aspects of the trial.

The TDG will comprise of the same research team and will hold monthly meetings to discuss progress. The responsibilities of the TDG will include:

1. Report to the TSC.
2. Maintain the Trial Master File.
3. Confirm all approvals are in place before the start of the trial at a site.
4. Provide study materials.
5. Data management centre.
6. Give collaborators regular information about the progress of the study.
7. Respond to any questions (e.g., from collaborators) about the trial.
8. Ensure data security and quality and observe data protection laws.
9. Safety reporting.
10. Ensure trial is conducted in accordance with Good Clinical Practice (GCP).
11. Statistical analysis.
12. Publication of trial results.

Patient and public involvement (PPI)

PPI work was conducted with patients participating in stage 4 CR at one of the sites. Patients (n=9) were given the programmed mHealth technology to use for 12 weeks. Exercise intensity was successfully prescribed and monitored using HR, including in those on beta-blockers, in this group. Eight of 9 patients described the intervention as very/extremely helpful in increasing their exercise levels, citing the improved communication with their CR specialists and feedback given by the watch during exercise as facilitators.

One patient representative will be invited on the trial steering committee. They will advise on study information materials to recruit participants to the study. At the end

of the project our patient representatives will contribute to the reporting of the study through reading and reviewing the 'lay' sections of the report. They will also be involved in dissemination of research findings through reviewing literature outlining the results before they are circulated.

Ethics and dissemination

The trial protocol has received favourable opinion from the Greater Manchester East Research Ethics Committee (22/NW/0301) in the UK. Upon study completion, the chief investigator owns the data. On completion of the study, the data will be analysed, and results will be disseminated via publication in clinical and physiological journals, presented at National and International conferences and in the form of feedback sheets or perhaps local articles. Participants will not be identifiable from the results of the study. Pseudonymised data from this study will be made available for sharing with other investigators, after publication of the study's key papers. Data will be shared through the LJMU Data Repository (http://opendata.ljmu.ac.uk/). This is a secure institutional data repository, which is searchable on the www, it is managed by Library Services. A DOI will be generated for datasets as they are deposited to the repository. Data will be stored in this repository for a minimum of 10 years or for 10 years from the last date of access.

Strengths and limitations

- The MOTIVATE-CR+ intervention may increase the uptake of CR by bridging the gap between discharge and the start of supervised CR.

- The MOTIVATE CR+ intervention potentially allows patients that recently experienced a myocardial infarction to co-design a personalised and progressive walking programme with the support of an exercise specialist.
- The MOTIVATE CR+ intervention potentially enables participants to communicate regularly with an exercise specialist and gain feedback on the exercise they complete.
- The MOTIVATECR+ intervention is not embedded within current cardiac rehabilitation landscape, as such, future work will be needed to address how the intervention could fit within service structures.

Contributors

HJ, AC, KH, LT, GMc, GM and MC initiated the study design. HJ, GMc, GM, LT and MC are grant holders. All authors contributed to refinement of the protocol and approved the final manuscript.

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Competing interests

None

Patient consent for publication

None

Author contributions

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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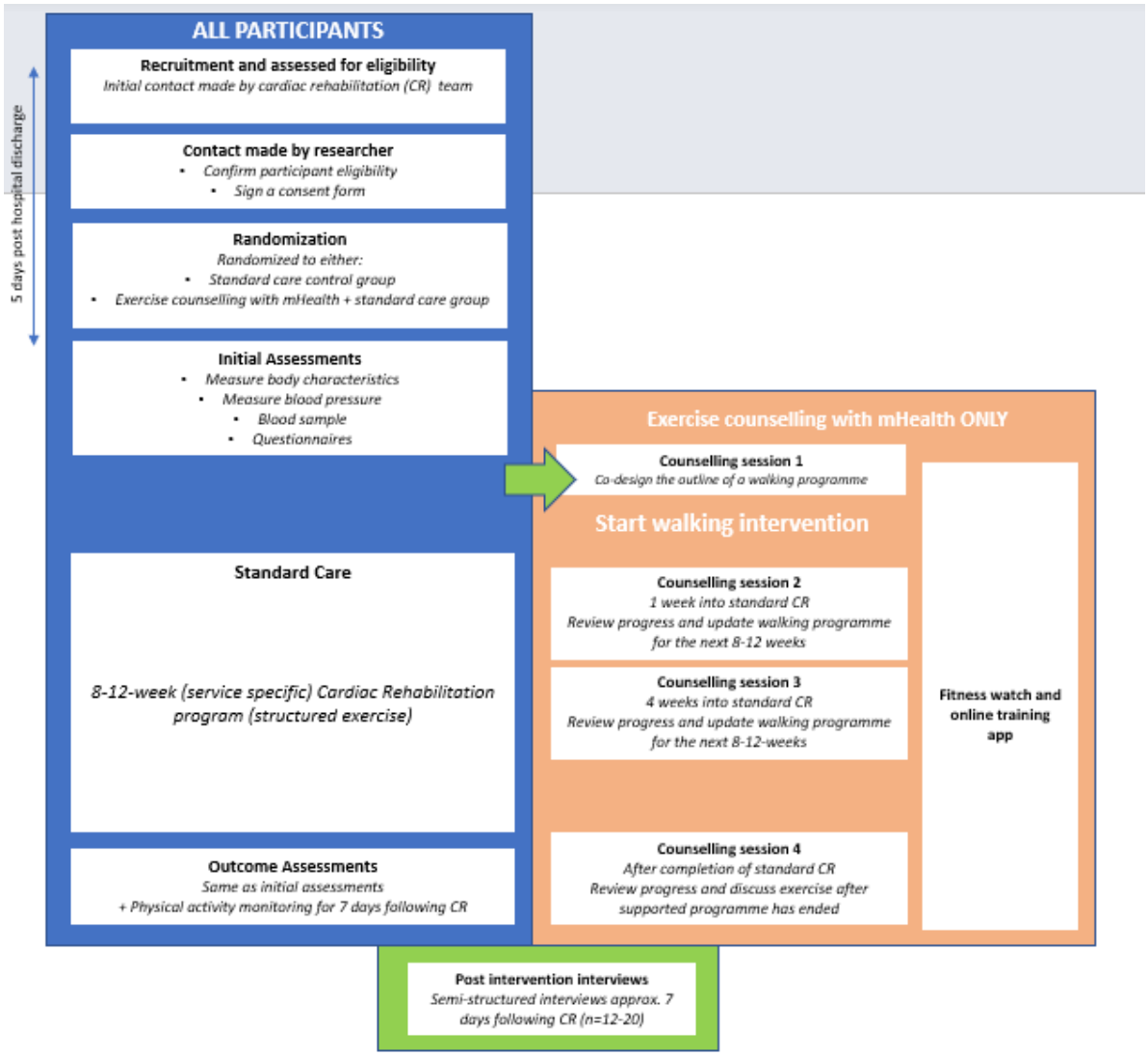

Figure 1: Study flow diagram and participant pathway

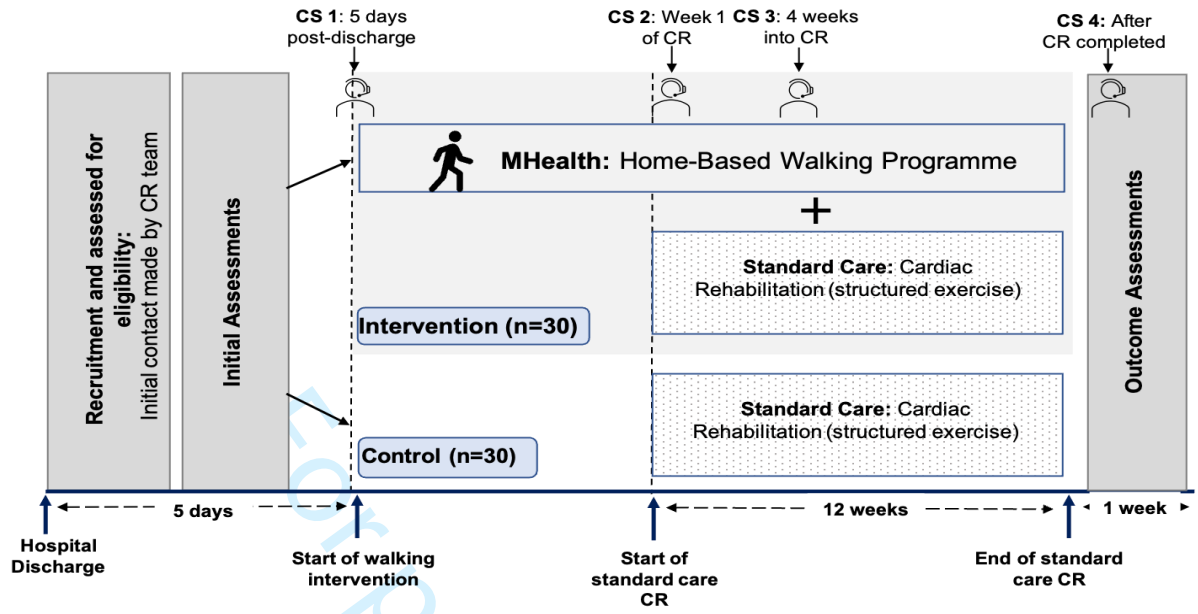

Figure 2: Schematic of the experimental design. Abbreviations: CR; cardiac rehabilitation, n; number, CS; counselling session.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Page 2-3
	2b	All items from the World Health Organization Trial Registration Data Set Page 2-3
Protocol version	3	Date and version identifier Included
Funding	4	Sources and types of financial, material, and other support Page 25
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Page 1, 28
	5b	Name and contact information for the trial sponsor Page 2-3,27
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Page 28
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) Page 25-26
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Page 3-5
	6b	Explanation for choice of comparators Page 3-10
Objectives	7	Specific objectives or hypotheses Page 5-10

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Page 6
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained Page 6-7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) Page 7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered Page 16-20
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) Page 16-20
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Page 9-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 1 & 2)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Page 24
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size Page 24
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions Page 6-8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned Page 6-8, 16-20
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions Page 6-8, 16-20
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how Page 6-8, 16-20
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial Page 16-20
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol Page 10-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols n/a
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Page 23-24
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol Page 9-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) n/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Page 23-26
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Page 23-26
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct Page 23-26
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Page 23-26

Ethics and dissemination Page 2-3, 26-27 where applicable

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Page 26-27
	31b	Authorship eligibility guidelines and any intended use of professional writers Page 26-27
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Page 26-27
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates included
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.