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Feasibility study of rehabilitation for cardiac patients aided by an artificial intelligence web-based programme: a randomised controlled trial (RECAP trial)—a study protocol

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ABSTRACT

Introduction Cardiac rehabilitation (CR) delivered by rehabilitation specialists in a healthcare setting is effective in improving functional capacity and reducing readmission rates after cardiac surgery. It is also associated with a reduction in cardiac mortality and recurrent myocardial infarction. This trial assesses the feasibility of a home-based CR programme delivered using a mobile application (app).

Methods The Rehabilitation through Exercise prescription for Cardiac patients using an Artificial intelligence web-based Programme (RECAP) randomised controlled feasibility trial is a single-centre prospective study, in which patients will be allocated on a 1:1 ratio to a home-based CR programme delivered using a mobile app with accelerometers or standard hospital-based rehabilitation classes. The home-based CR programme will employ artificial intelligence to prescribe exercise goals to the participants on a weekly basis. The trial will recruit 70 patients in total. The primary objectives are to evaluate participant recruitment and dropout rates, assess the feasibility of randomisation, determine acceptability to participants and staff, assess the rates of potential outcome measures and determine hospital resource allocation to inform the design of a larger randomised controlled trial for clinical efficacy and health economic evaluation. Secondary objectives include evaluation of health-related quality of life and 6 minute walk distance.

Ethics and dissemination RECAP trial received a favourable outcome from the Berkshire research ethics committee in September 2022 (IRAS 315483).
Trial results will be made available through publication in peer-reviewed journals and presented at relevant scientific meetings.

Trial registration number ISRCTN97352737.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Rehabilitation through Exercise prescription for Cardiac patients using an Artificial intelligence-web based Programme is the first randomised control trial to use artificial intelligence (AI) to automate exercise prescription in a home-based cardiac rehabilitation programme in the National Health Service.
⇒ Real-life cardiac patients' data were used to inform the AI algorithm.
⇒ Views of healthcare professionals were taken into account before the intervention was tested in patients.
⇒ A limitation of this study is that it will be only conducted in a single geographical area, which may affect its generalisability.

Cardiac rehabilitation (CR) programmes improve functional capacity and reduce readmission rates after cardiac surgery.[2 3] They can also benefit the participants in the long term, as postoperatively, patients with higher physical activity levels experience fewer subsequent cardiovascular events and lower mortality at 10 years.[3 4] A study on CR participants concluded that physical activity also resulted in low total cholesterol.[5] A meta-analysis of the effects of exercise-based CR in patients with acute coronary syndrome found that CR was associated with a reduction in cardiac mortality and recurrence of myocardial infarction.[6]

The European Society of Cardiology guidelines for stable cardiovascular disease strongly recommend secondary prevention, including participating in comprehensive CR.[7] However, despite the numerous benefits of CR, uptake is low.[8] In the EUROASPIRE IV survey, only 51% of the patients were advised to attend a CR programme, and out of them 81% attended, representing 41% of

INTRODUCTION

Cardiovascular disease is the leading cause of death worldwide and affects around 7.6 million people in the United Kingdom (UK). Coronary heart disease (CHD) is the most common form of cardiovascular disease.[1]

the study population.[9] Participation may be improved by inviting a greater proportion of patients to attend a CR programme, and potentially through providing rehabilitation remotely.

Hospital-based CR is currently recommended for all patients following cardiac surgery, percutaneous coronary intervention, myocardial infarction; and for those with angina or heart failure. National Institute for Health and Care Excellence guidelines recommend that patients should be provided with a range of options within a rehabilitation programme.[10] These patients should be offered a CR preassessment clinic appointment following discharge. The long-term plan of the National Health Service (NHS) England focuses on providing digitally-enabled primary and outpatient secondary care, with the aim of reducing face-to-face outpatient visits by up to one-third over the next 5 years by redesigning services.[11] In 2019, 16% of CR participants were enrolled onto a home-based CR programme, whereas in 2020, with the impact of COVID-19, this rose to 76%.[12] Patients may prefer home-based CR due to convenience and a hesitancy to attend a hospital due to a perceived risk of infection.[8]

A systematic review and meta-analysis looking at home-based cardiac telerehabilitation (HBCTR) versus usual care concluded that HBCTR was associated with an increase in functional capacity, physical activity and a reduction in depression when compared with usual care.[13] This study included patients over the age of 18 years, with a diagnosis of CHD, acute coronary syndrome or patients who had undergone coronary artery bypass graft surgery. However, one issue with HBCTR is that adherence may be low due to reduced contact with the rehabilitation team.[14] There is also no way of keeping track of the physical activity levels of patients and modifying the programme to either increase or reduce intensity. Even when changes are possible, there is significant interclinician variation in exercise prescriptions for patients with cardiovascular disease.[15]

One solution is to use a mobile application (app) to make the programme interactive to both patient and the rehabilitation team. This can be further tailored using artificial intelligence (AI) to alter exercise prescriptions and set exercise goals automatically. A systematic review of behaviour change techniques in cardiovascular disease using smartphone apps found that one of the techniques that resulted in a larger increase in physical activity was goal setting.[16]

An AI-based programme may be used to offer CR to patients following acute coronary syndrome and cardiac surgery. AI is increasingly used in various fields in medicine. A systematic review of using AI in CR concluded that AI holds a lot of potential in the early detection of cardiac events and home-based monitoring of patients.[17] However, none of the included studies used AI to facilitate the exercise prescription itself in the setting of rehabilitation. This trial will assess the feasibility of a home-based CR programme delivered via a mobile app using machine learning, a subfield of AI, to facilitate exercise prescription.[18] We have presented the trial protocol according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines.

Objectives

The primary objective is to determine the feasibility of a large, definitive randomised controlled trial (RCT) to determine the clinical and cost-effectiveness of a tailored home base rehabilitation programme facilitated by an AI-enabled app. Therefore, we will collect data to inform the feasibility and determine the key outcomes for a larger RCT, which will include participant recruitment and dropout rates; the feasibility of randomisation, acceptability to participants and staff and hospital resource allocation.

Secondary objectives are to collect data to inform a better machine learning algorithm capable of prescribing realistic exercise goals, assess the impact of the intervention on patients' physical fitness using the 6 min walk test (6MWT), health-related quality of life using the EQ-5D-5L scale and Short Form 36 Health Survey Questionnaire (SF-36) questionnaire (V.1.0); explore health motivators of behaviours using the data collected from the app, and qualitative interviews and to evaluate the usability of the app using the System Usability Scale (SUS) Questionnaire and mHealth App Usability Questionnaire (MAUQ).

METHODS
Study design and setting

The Rehabilitation through Exercise prescription for Cardiac patients using an Artificial intelligence web-based Programme (RECAP) trial is a single-centre prospective feasibility RCT. Participants will be randomly allocated 1:1 to the home-based app-assisted rehabilitation (intervention) programme or the standard hospital-based rehabilitation classes (control). The study will be conducted at a single NHS centre: The James Cook University Hospital (South Tees Hospitals NHS Foundation Trust), Middlesbrough, United Kingdom.

Randomisation and blinding, sequence generation and concealment mechanism

Randomisation to the two groups will be undertaken using the web-based Castor service (https://www.castoredc.com). Randomisation will be in the ratio 1:1 to the two groups with stratification. Stratification will be based on the initial treatment, a participant has had: surgical (eg, coronary artery bypass graft surgery) versus non-surgical (eg, percutaneous coronary intervention). Due to the nature of the intervention, it will not be possible to blind participants to the allocation.

Patient recruitment

Wherever possible, participant information sheets (PIS, online supplemental appendix A) and a letter of invitation will be sent to potentially eligible patients by the clinical team prior to their preassessment CR clinic

Table 1 Timing of preassessment clinic appointment

Diagnosis	Timing of preassessment clinic appointment following discharge
Cardiac surgery	5–6 weeks
Percutaneous coronary intervention (PCI)	1–2 weeks
Myocardial infarction	1–2 weeks
Angina	As soon as possible following diagnosis

appointment (table 1), which may be by email. We aim to recruit 70 patients, with 35 allocated to the intervention arm and 35 to the control arm. Where patients do not receive the PIS or letter of invitation prior to their clinic appointment, the CR or research team may discuss the trial with the patient and provide the PIS and invitation letter during the clinic appointment.

Participants who meet the eligibility criteria and decide to take part will be asked to provide written informed consent (online supplemental appendix B). The person who obtains the consent will be a suitably qualified and experienced member of the research team and have been authorised to do so by the chief/principal investigator.

Inclusion criteria
▶ Patients' postcardiac surgery or following acute coronary syndrome that have been referred for CR.
▶ Age 18 years and over.
▶ Have access to an Android or iOS mobile device.
▶ Provided informed consent.

Exclusion criteria
▶ Awaiting urgent surgery.
▶ Unstable angina.
▶ Pregnancy.
▶ Currently enrolled in another interventional clinical trial or experiment where the intervention is considered likely to impact the outcomes of RECAP trial.
▶ Malignant arrhythmias.
▶ Contraindications to rehabilitation, including:
  – Severe musculoskeletal conditions affecting exercise ability.
  – Acute systemic illness or fever.
  – Acute pericarditis or myocarditis.
  – Uncontrolled atrial or ventricular arrhythmias.
  – Uncontrolled sinus tachycardia.
  – Aortic stenosis associated with presyncope/syncope.
  – Uncompensated heart failure.
  – Complete atrioventricular block without a pacemaker.
  – Recent embolism.
  – Clinical opinion of the investigator that CR would be inappropriate.

Trial assessments
Participants' baseline visit will coincide with their preassessment CR clinic appointment. The final visit will take place following completion of the CR programme,

8 weeks after the baseline visit. The majority of the trial visits will be at the James Cook University Hospital. For participants' convenience, some visits may be offered at the Friarage Hospital (a hospital of the South Tees Hospitals NHS Foundation Trust) in Northallerton or at a venue near it. During the trial visits, assessments will be conducted by members of the research or CR team.

Baseline visit
The trial assessments will be performed after consent and prior to randomisation. The baseline assessments will consist of a 6MWT,[19] EuroQOL 5-Dimensions (EQ5D5L)[20] and 36-item Short Form survey (SF36) (V.1.0),[21] Hospital Anxiety and Depression Scale (HADS),[22] Barthel Index[23] and clinical frailty scale (CFS) (Rockwood scale).[24] The 6MWT is a valid and reliable submaximal exercise test that is used to assess functional status and endurance.[25] EQ5D5L is a validated five-level health status measure developed by EuroQol designed to assess health-related quality of life.[20 26] The SF36 questionnaire is a 36-item instrument used to assess health-related quality of life with questions in the domains of physical functioning, role limitations due to physical health, pain, general health, vitality, social functioning, role limitations due to emotional problems and mental health.[27] The SF-36 questionnaire is valid and reliable for assessing health-related quality of life in cardiac patients.[28] The HADS score is derived using a validated questionnaire and is widely used within CR to assess cardiac patients' level of anxiety and depression.[29 30] The Barthel index is used for assessment of performance in basic activities of daily living.[31–33] The CFS is a clinical judgement-based frailty tool and is widely used in the assessment of cardiac patients.[24 34]

The participant's medical notes will be used to collect a full medical history and information, including their sex and date of birth. Their height and weight will be measured, and the research team will record clinical observations including blood pressure, heart rate, respiratory rate, temperature and oxygen saturation level.

All participants in the intervention arm will be given an accelerometer (Actigraph CentrePoint Insight Watch Activity Monitor) and assisted to download the app onto their mobile devices, followed by a demonstration. They will be advised to wear it throughout the day. Participants will be asked to keep their mobile device connected to the internet while they are on the home-based CR programme.

Table 2 Trial procedures

Procedures	Visits	
	Baseline visit	Final visit
Talk to the patient about the study and answer any questions	X	
Check eligibility	X	
Obtain written informed consent for participation	X	
Medical history	X	
Demographics	X	
Physical assessment of height, weight and clinical observations including blood pressure	X	X
Assessment of 6 min walk test distance, frailty score (Clinical Frailty Scale)	X	X
EQ-5D-5L, SF-36, Barthel Index and HADS score calculation	X	X
System Usability Scale (SUS) questionnaire and mHealth App Usability Questionnaire (MUAQ)		X
Adverse event evaluation		X

HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form 36 Health Survey Questionnaire.

Final visit

Patients randomised to the home-based CR programme will be asked to complete the SUS and the MAUQ questionnaires at the final visit and complete the questionnaires they completed at the baseline visit. SUS is a 10-item questionnaire designed to measure the usability of a system.[35] The SUS questionnaire consists of five questions with positive statements and five with negative statements asking the user about their experience of the system with a score ranging from 0 to 100. A meta-analysis of SUS benchmarking for digital health apps concluded a score of 68 (SD 12.5) is suitable for assessing the usability of digital health applications.[36] The MAUQ is a validated questionnaire designed to assess mobile health app usability.[37] At the final visit, we will repeat the 6MWT and physical assessments and observations including weight and blood pressure (table 2).

Trial procedures

TRIAL ARMS

Standard care (control arm)

Standard care will be hospital-based CR consisting of a formal exercise programme once a week, for 8 weeks. Each session lasts 2 hours and is conducted by an exercise professional and a rehabilitation nurse in a group of up to 12 participants.

Classes start with a warm-up session to prepare the body and heart for exercise, followed by exercises to improve cardiovascular fitness including strength training using weights. Exercises include walking, squats, shoulder raises, bicep curls and triceps extensions. Patients will be advised to exercise at a moderate intensity. The classes conclude with a cool down session.

In addition to this, patients will also be advised to exercise at home for up to 45 min/day. Their activity levels outside of classes will not be monitored. However, they will be encouraged and reminded to exercise at home during hospital-based classes.

Home-based automated exercise programme (intervention arm)

Patients in this group will follow an 8-week home-based exercise programme. They will be given an exercise booklet (routinely given to patients who decline hospital-based CR as part of standard care), which will outline a series of exercises with varying difficulty, and an accelerometer to take home. They will also be given weekly goals via the app in the domains of step count, calorie count and moderate to vigorous activity minutes.

Patients randomised to this group will follow the home exercise programme. The home-based exercise programme will be guided by exercise videos and a booklet. Patients will be given weekly goals via their mobile app. These exercise targets will be prescribed by the AI algorithm. Before each patient is commenced on the programme, they will undergo an initial fitness assessment at the hospital (standard care). During the initial assessment, they will be seen by a CR nurse and a physiotherapist or an exercise specialist, who will review their medication and advise them on lifestyle factors including diet, smoking and exercise.

Patients will be advised to do up to 45 min of exercise at home daily (unsupervised) during the 8-week period. The CR team will advise them to follow the exercises in the exercise booklet and the videos while aiming to achieve the weekly physical activity targets set by the AI algorithm. They will be advised to exercise to achieve a moderate Borg Score.[38] The Borg scale is a way of measuring perceived physical activity intensity level.

Patients will have access to exercise videos via the mobile app and will be encouraged to follow these to achieve their physical activity targets. These videos will demonstrate the exercises that is done as part of standard care in hospital-based CR classes and will include both aerobic exercises and strength training. The intensity of the exercises in

the videos will increase every 1 to 2 weeks. The videos were developed by the physiotherapy team at the James Cook University Hospital's CR department. There are a total of six exercise videos, each lasting 10–15 min.

The CR team will be able to monitor the patient's progress using the web portal. This will allow them to view the daily step count, calorie expenditure and moderate to vigorous physical activity minutes count of each participant. In addition to that, the CR team will also be able to view the goals that have been set on a week-by-week basis, send custom notifications and set custom goals for each participant. Participants will automatically receive a notification on the third day of each week stating the percentage of total exercise targets they have achieved and on the sixth day of each week reminding them to record their Borg ratings of the exercise sessions via the app.

Participants will also be able to record their mood following each workout via the app. The six basic moods (happy, sad, surprise, anger, fear and disgust) will be available for them to select from.[39] They will also have the option of recording their workouts in a digital diary via the app.

If a participant decides not to continue with the home exercise programme, they will be given the option to attend standard hospital-based rehabilitation classes. This will be documented in their case report form as a crossover. In the development of the app and its AI algorithm, we have involved physiotherapists, nurses, exercise specialists and machine learning and AI experts. The app was tested on 12 healthy volunteers before the start of the clinical trial.

Development of the mobile application

The mobile application used to facilitate the home-based CR programme was developed by the research team at the James Cook University Hospital. The app (figures 1–4, online supplemental appendix C) may be installed on any device running iOS or Android operating systems, including mobile phones or other mobile devices such as iPads. Dart programming language was used to programme the app. Data entered onto the app are held in a secure Google database. Any data stored in this manner will be anonymised.

Artificial intelligence to automate exercise prescriptions

AI is a complex set of computer-based statistical frameworks using data sets to solve problems.[40] Machine learning is a form of AI where statistical algorithms 'learn' by identifying patterns in datasets.[41]

We will use AI to automate exercise prescriptions while accounting for participant demographics such as age and sex, previous physical activity levels and their Borg scale ratings. Participants will be able to input Borg scale ratings via the app after each workout. Machine learning will facilitate the exercise prescription. Exercises will be prescribed in the domains of step count, calorie expenditure and moderate to vigorous physical

activity minutes on a weekly basis. Participants with higher levels of physical activity will be prescribed more challenging exercise targets compared with a participant with low levels of physical activity. The exercise prescriptions will be accessible via the mobile app and will be updated every week. The algorithm will automatically learn to generate more efficient and personalised prescriptions as it gathers more data from the participant over time. Data on physical activity will be collected via the accelerometer.

In the development of the AI prescription system, we tested several machine learning algorithms including linear regression, random forest and XG Boost.[18] Following a comprehensive literature review, we identified a study with a suitable data set that could be used to train and test a model to achieve our objectives: OPTICARE, a RCT involving 731 patients with acute coronary syndrome undergoing CR.[42] We addressed the missing values in the data set using the multiple imputation method, a commonly used approach in machine learning.[43]

One of the challenges with this data set was the limited amount of data that were available. To overcome this problem, a synthetic data set was created based on the original data set using Conditional Tabular Generative Adversarial Network. This approach has been previously used to generate synthetic data based on a smaller sample of real-life data.[44 45] A data set consisting of 5000 rows was generated with this method.

We used 75% of the data to train the models and 25% to test them. XG Boost model was shown to have the best performance in prescribing exercises, and we have subsequently used it in our study. XG boost is a machine learning algorithm that has been widely used in various areas of medicine.[46–48]

More details on the development of the app and the AI algorithm will be available in future publications.

End of intervention

At the end of the rehabilitation programmes (both home-based and in-hospital), the patients will attend the hospital for the assessment of their physical fitness and complete the end-of-intervention questionnaires (table 2). Those patients that consent to take part in the qualitative research (structured interviews) will be contacted by phone to find out about their experience of the programme. This will mark the end of the intervention.

Assessment of compliance

Accelerometer wear time, accelerometer data upload frequency and app usage data will be used to assess compliance with the intervention. Accelerometer data will be uploaded automatically every 24 hours when the participant's phone is connected to the internet. However, at the baseline visit, we will advise all participants to manually upload the data via the app every 2 days to account for any possible faults with the automatic update system.
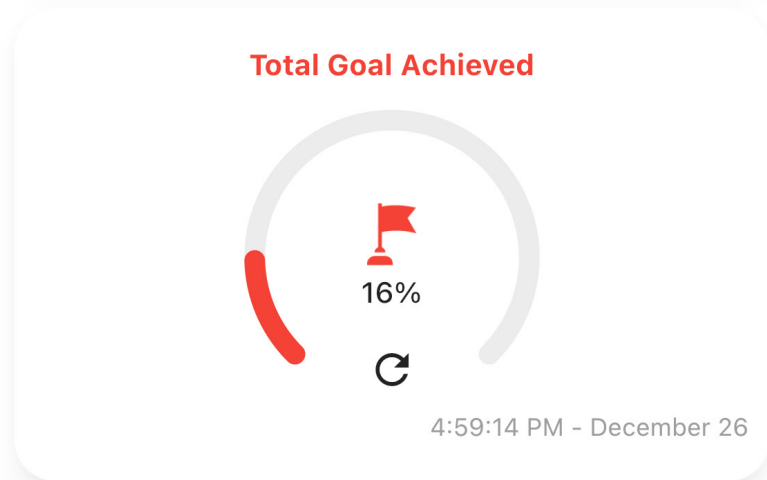
Figure 1 Welcome screen showing percentage of goals achieved.
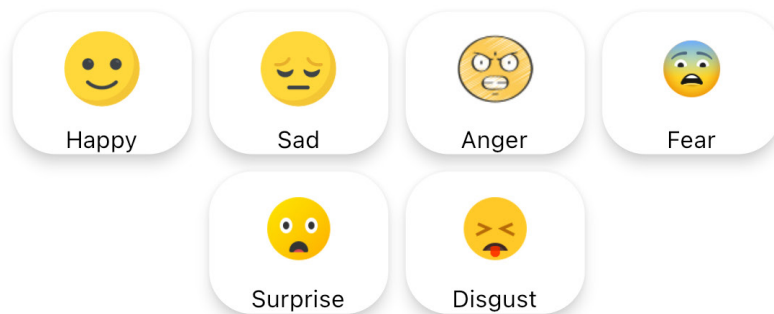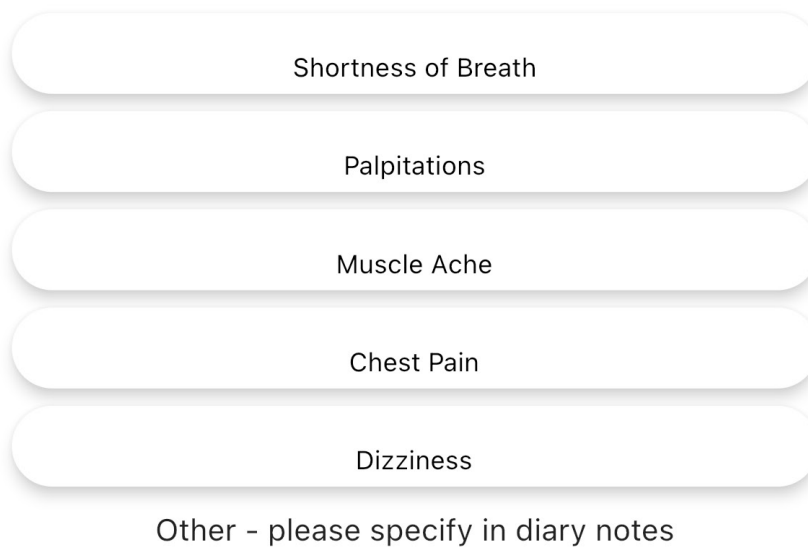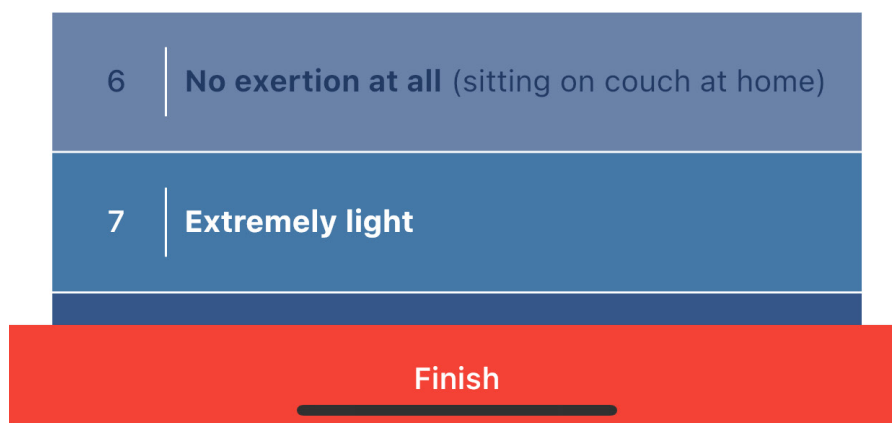
Figure 2 Review screen—user can select how they are feeling.
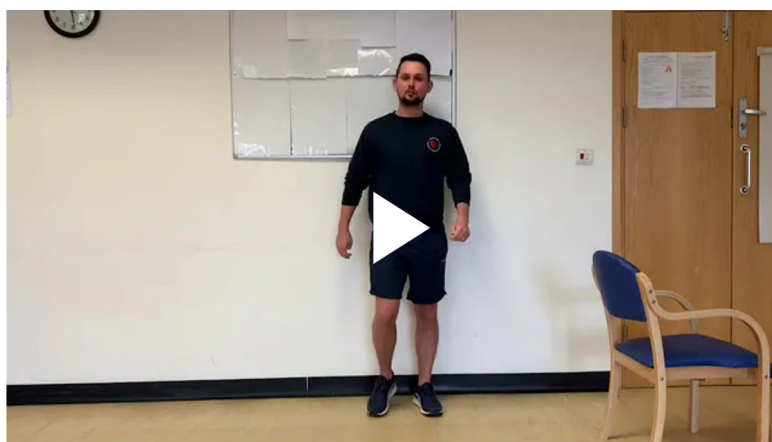
Figure 3 Goals screen of the app.

Figure 4 Summary screen of the app.

Adverse event reporting and harms

Home-based rehabilitation is already in common use.[49] Telerehabilitation can offer a safe solution for patients who are not able to attend the hospital, and there are guidelines on how to optimise the safety and efficacy of virtual rehabilitation programmes.[50] A systematic review of the safety of home-based CR programmes concluded that home-based CR programmes could provide a safe alternative to centre-based CR.[51] These recommendations have been taken into consideration in the development of the home-based CR programme to ensure that it is as safe and effective as possible.

Although exercise is an important component of recovery, there are potential risks. Some patients may experience symptoms such as shortness of breath, light headedness, chest pain, drop in blood pressure or heart rate after exercise, heart rhythm problems and muscular and joint problems. To mitigate the risk, all participants with any contraindication to exercise will be excluded. Patients will be assessed by a healthcare professional at enrolment to ensure that they are suitable to follow an unsupervised home exercise programme.

Any adverse events occurring will be recorded on the electronic case report form. Serious adverse events categorised as related to the trial intervention and unexpected will undergo expedited reporting to the Research Ethics Committee within prescribed timelines.

The study does not have a data monitoring committee. Staff members involved with the study will continuously monitor for any adverse events until the end of the study and take appropriate action.

STATISTICAL ANALYSIS

The number of participants screened, eligible, consenting and randomised will be summarised, with reasons for non-participation given where possible. Baseline data will be summarised by the randomised group. Continuous measures will be summarised using descriptive statistics (mean with standard deviation or median and interquartile range), while categorical data will be reported as frequencies and percentages. The uptake of and adherence to the intervention and follow-up rates will be summarised and presented as percentages. Trial outcomes will be analysed using the intention-to-treat principle, with data analysed according to randomisation, regardless of patients' adherence to intervention, treatment they actually received or deviation from protocol.

As this is a feasibility study, there will be no interim analysis. We will present summary estimates of effects along with their confidence intervals. Continuous outcomes will be presented as unadjusted mean difference and odds ratios for binary outcomes. These will be further adjusted for factors that may influence adherence to the intervention, including age and sex. Analysis will be led by a statistician. There will be no imputation of missing data. The information collected will be used to feed into the suitability and applicability of the chosen outcome measures.

As this is a feasibility study, we have performed no formal sample size calculations. We estimate that 70 participants is practical and will allow us to meet our feasibility objectives. This will allow us to estimate the standard deviation of continuous outcomes, including the 6MWT distance, to inform future trial design.[52]

Data management

Data from medical notes and questionnaires will be collected in a secure electronic data capture system. Anonymous accelerometer raw data files will be securely stored online and transferred securely to the statistics team for analysis. Physical activity data (participants' daily step count, calorie expenditure and moderate to vigorous physical activity minutes count) will be transferred to the online server at least daily to inform exercise prescription by the AI algorithm. Files will be linked to the database by unique participant identifiers only.

Oversight and monitoring

The principal investigator will oversee the day-to-day running of the trial and will have accountability and responsibility for the trial. The trial management group, consisting of the chief investigator, the principal investigator, head of academic cardiovascular unit (ACU) at the James Cook University Hospital, and principal research manager of ACU, will meet once a month to provide oversight of the study.

Criteria for discontinuing or modifying allocated interventions

Each participant has the right to withdraw from the trial at any time. In addition, the investigator may discontinue a participant from the trial if it is considered necessary for any reason, including ineligibility (either arising during the trial or retrospectively having been overlooked at screening), an adverse event, which results in the inability to continue to comply with trial procedures, withdrawn consent or pregnancy.

Participants who have been randomised to the intervention arm will also have the option of attending standard rehabilitation classes if they do not want to continue with the intervention.

Participants who wish to withdraw consent for the trial or whose participation from the trial is discontinued will have pseudonymised data collected and analysed up to the point of that withdrawal. No additional data will be collected from the participant unless they have specifically consented to continue routine clinical outcome data collection, and this is documented in the medical notes.

Clinicians or participants may decide that they should no longer perform certain parts of the trial intervention or assessments, in these cases, participants will continue in the trial and any assessments not completed will be treated as missing data. The reason for withdrawal will be recorded in the CRF. Participants who withdraw once they have been randomised will not be replaced. Participants found to be ineligible after randomisation will be withdrawn with no further data collected after that point.

If the participant is withdrawn due to a related (definitely, probably and possibly related) adverse event, the investigator will arrange for follow-up visits or telephone calls until the adverse event has resolved or stabilised. Adverse events that are not related to the intervention will be followed up to the point of trial completion.

Assessing adherence and strategies to improve adherence to the intervention

Adherence to the intervention will be assessed using the data collected from the mobile applications. Accelerometer wear times and accelerometer data upload frequency (synchronising of accelerometers using the mobile application) will be used to assess adherence to the intervention.

Patients will be contacted via phone if they have not uploaded accelerometer data in 5 days or if issues arise that indicate concern to the clinical team.

Relevant concomitant care permitted or prohibited during the trial

No concomitant care is prohibited during the trial.

Provisions for post-trial care

We do not expect that any further care will arise as a result of participation in this trial and do not anticipate a need for the provision of post-trial care.

Frequency and plans for auditing trial conduct

The Sponsor Research and Development team may perform internal audits of the trial. As such, any part of the RECAP trial may be inspected at any time to ensure that the trial is being conducted according to the principles of the International Council for Harmonisation Good Clinical Practice and General Data Protection Regulation.[53]

Plans for communicating important protocol amendments to relevant parties (eg, trial participants, ethical committees)

Any protocol amendments will be submitted to the research ethics committee and will only be implemented following approval. Any changes will be communicated to staff involved in the trial. Participants will be informed of any protocol amendments that may impact them.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of this study.

ETHICS AND DISSEMINATION PLANS

RECAP Trial received a favourable outcome from the ethics committee (Berkshire Research Ethics Committee) in September 2022 and recruited the first participant in July 2023.

The trial will be published in peer-reviewed journals, reported in accordance with the Consolidated Standards of Reporting Trials guidelines.[54] It will also be presented at national and international conferences. In addition, outcome data will also be disseminated through presentations at NHS hospital trusts and national society meetings.

DISCUSSION

Historically, attendance at a CR programme has been suboptimal: just 50% of those eligible for CR in 2019.[55] There was a significant change in provision as part of the response to the COVID-19 pandemic, whereby provision of a home-based programme increased from 16% to 70% between 2018 and 2021.[56] However, data are limited to guide how to best deliver home-based CR.

This trial has been designed based on the latest available data and to maximise opportunities for participation in CR. A systematic review of prospective cohort studies examined the factors associated with non-participation in CR programmes and found that low socioeconomic status, lower education levels and depression were associated with non-participation and dropout.[57] Furthermore, it showed that the geographical location of the patient may affect participation (although location does not appear to be associated with differences in dropout rates). The use of a mobile phone enabled home-based programme has the potential to reduce geographic inequalities, which is an important consideration given documented disparities in healthcare provision and clinical outcomes across the UK.[58]

We have made efforts to ensure that the intervention is widely accessible. The interface of the app was kept as simple as possible, and participants are able to customise it to some extent to suit their needs—such as changing the size of the text. The app also offers the participants the ability to track their mood and a digital diary if they so wish, where they could reflect on the day and the exercises that they have done. Patient preferences should be considered in designing digital health applications as it could enhance user engagement. Self-monitoring and self-evaluation are key components in the real-world usage of digital CR programmes, as seeing one's own progress could motivate them to adhere to their goals.[59]

This work is novel: we are not aware of any previous studies that have used AI-based mobile apps to deliver home-based CR in the NHS. It is also timely and has the potential to contribute to the policy aspirations set out in the NHS long-term plan to increase the provision of digitally enabled healthcare. Alongside increasing access, there is potential for an automated app-based home exercise programme to reduce the workload for physiotherapists and exercise specialists, and so increase the time they have available for other patients.

TRIAL STATUS

Medicines and Healthcare products Regulatory Agency approval was not required for the app, as it will only be used within a single NHS Trust, and not commercialised.

The RECAP trial recruited its first patient on the 11 July 2023 and is projected to complete recruitment by July 2024.

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