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# Rehabilitation through exercise prescription for cardiac patients using an artificial intelligence-based programme - RECAP

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| **Submission date**<br>22/09/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>17/11/2022 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>02/12/2022 | **Condition category**<br>Other | [_] Individual participant data<br>[_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Increasing physical activity after a heart attack or a heart operation can help improve fitness levels and help patients return to normal activities more quickly. Traditionally this has been done in hospitals in the form of rehabilitation classes. Most hospitals offer these classes to patients. The sessions are conducted by a health care professional with specific training, and patients attend the hospital every week to take part. However, some patients may not be able to attend sessions due to practical reasons, such as the availability of transport. Patients may also be fearful of exposure to infections by going into hospitals or any other community spaces.

Following the Covid-19 pandemic, it is clear that new ways of working that reduce the need for patients to go to the hospital are urgently needed. The NHS long-term plan for the NHS has committed to moving services into the community wherever possible. It would be ideal if rehabilitation could be moved from the hospital to the home. However, there are challenges to being able to do this successfully, including communicating effectively with patients, monitoring what they are doing, and adapting the rehabilitation program to respond to their needs in a timely way. This study will work out if new technologies can be used to help deliver safe and effective rehabilitation at home.

Who can participate?
Patients eligible for cardiac rehabilitation

What does the study involve?
A home-based rehabilitation system will be tested that uses devices that patients can wear on their wrists. The devices, known as accelerometers, will help to monitor patients' activity levels as they go about their day. It captures information such as their step count and how many calories they use. This information will be used to set goals for each patient based on their own activity levels. At first, a healthcare professional will set these goals. Later, the goals will be set automatically using a computer system.

Patients will have access to a mobile phone application on which they will receive their weekly target goals. Once they achieve these, the application will automatically mark it as complete. We will also develop a web portal to allow the rehabilitation team to remotely monitor patients' activity levels, and a computer system to prescribe exercises to each patient.

A feasibility trial will compare traditional classes with the home-based exercise system to see the impact of the home-based rehabilitation programme compared to the hospital-based setting. Researchers will look at whether there is an improvement in patients' fitness levels by comparing how far they can walk in six minutes before and after the programme. The home-based program will be tested to see it if increases the proportion of eligible patients who complete the rehabilitation program. Several other elements will be tested to confirm this is feasible, and if the results are positive, the information will be used to plan a larger trial to confirm the findings.

What are the possible benefits and risks of participating?
We know that cardiac rehabilitation offers various benefits to patients. Previous studies looking at home-based rehabilitation programmes have found that they are effective in increasing the physical activity of patients. However, we do not know if a fully automated rehabilitation programme will result in better patient recovery but that is what we expect this trial to tell us. In a hospital-based exercise class, patients would be guided by a physiotherapist. However, patients in the intervention arm wouldn't have any face-to-face sessions. This may mean, that if they were to experience any problems during their home exercise sessions, they may not have access to help immediately. We will minimise the risk of any problems occurring as a result of exercise, by ensuring that the exercises that are prescribed for the patients are realistic. Healthcare professionals will have the option of changing the exercises after they have been prescribed using the web portal. We will also monitor the patient's progress through the programme using this portal. If we are concerned about any patient, we will call them to find out how they are doing. Having to wear the accelerometers 24 hours a day could be uncomfortable for some patients. We have minimised the burden by ensuring the accelerometer straps are comfortable on the skin. They can also be loosened if necessary. In extreme cases, we will let the patients know that if it gets too uncomfortable, it may be taken off.

Breach of data held online is another possibility. We have minimised the risk of this by adding security keys and extra security rules to the online database. This means anyone who is not registered on the mobile app will not be able to access the data. Even those who are registered will only be able to access the data that are relevant to them. Furthermore, we have ensured that no personally identifiable data is stored online.

Where is the study run from?
James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2022 to March 2024

Who is funding the study?
South Tees Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Mr Pasan Witharana (UK)
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# Contact information

### Type(s)
Principal Investigator

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
315483

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRAS 315483, CPMS 53664

# Study information

### Scientific Title
Rehabilitation through Exercise prescription for Cardiac patients using an Artificial Intelligence-based Programme - RECAP

### Acronym
RECAP

### Study objectives
This study hypothesises that new technologies can be used to help deliver safe and effective rehabilitation to patients recuperating after a heart attack or a heart operation at home.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 05/09/2022, Health Research Authority (3rd Floor, Barlow House, 4 Minshull, Manchester, M1 3DZ, UK; +44 (0)207 104 8178; e. benita.hallewell-goodwin@hra.nhs.uk), ref: 22/SC/0262

## Study design
Interventional randomized controlled study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Service users requiring cardiac rehabilitation

## Interventions
This study will be done in two phases. The first phase, a single-arm study of 20 patients, will aim to determine if an in-house home rehabilitation app we have developed could successfully be used along with physical activity monitors to deliver a home rehabilitation programme. The second phase will be a feasibility study, a pilot randomised control trial of 70 patients (35 per arm). As with phase II, the exercise programme in phase I will be for 8 weeks and patients will undergo all the same assessments in both phases.
The cardiac rehabilitation team offers all patients who have had heart surgery, a heart attack or heart failure a rehabilitation preassessment clinic appointment as standard. This will be within 6 weeks of discharge depending on their diagnosis. We will aim to post the study participant information sheet before they attend this appointment or give it to them before their discharge from the hospital. During this appointment, after routine assessments have been performed, the rehabilitation team will talk to the patient about the study and answer any questions they may have. If they are happy to take part, the research team will obtain informed consent at this point.
At the pre-assessment clinic, the rehabilitation team will get a medical history from the patient and assess their vital signs including the heart rate, blood pressure and oxygen saturation levels. They will also test their 6-minute walk distance. This is the distance walked in 6 minutes. These assessments are routinely done as part of the preassessment clinic. In addition to this, if the patient has consented to the study, we will also ask them to complete questionnaires, which would assess their quality of life, mood, and independence in activities of daily living (using EQ-5D-5L, SF36, Rockwood Scale, HADS and Barthel index questionnaires).
In phase II, they will then be randomised to either the hospital-based (control) or home-based rehabilitation programme (intervention). Patients in the control group will attend the standard

exercise programme (sessions are once a week for 8 weeks). They will not be expected to visit any more times as part of the study, during this time frame.
Patients randomised to the home-based rehabilitation programme will be guided on how to download the apps on their phones at the preassessment clinic. We will also give them an accelerometer and explain how it works and do a demonstration of the device and the app. They will also be given a charging dock for the accelerometer and asked to charge it every 3 weeks or as indicated by the device. It will have a screen which would display the date/ time as well as the remaining battery life. As a reference guide, they will also receive a booklet explaining the RECAP Trial app. The home-based rehabilitation programme will also be for 8 weeks, and they will not be required to attend the hospital during this time.
Patients will be instructed to wear the accelerometer throughout the day. They will be able to view their activity levels in near real-time using the mobile app, in the form of a table and graphs. Their activity level information will be divided into the following domains: step count, calorie expenditure, moderate to vigorous physical activity minutes, light physical activity minutes, sedentary time in minutes and sleep time in minutes.
They will be given a new set of goals at the end of each week, for the following week. Via the app, they will be able to see their progress in achieving those goals. A progress bar will indicate the percentage of the total goals achieved.
On the 6th day of each week, they will get a pop-up on the app, asking them to rate how they found the current week's goals (based on a scoring scale, the BORG scale). Based on how they rate this, the goals for the following week will be adjusted accordingly. This will give the patient some control over the goals that are prescribed for them.
The goals will be generated automatically using artificial intelligence. This is a sophisticated way of generating goals taking into consideration factors such as the patient's last week's activity levels, their perception of the last set of goals (based on the modified BORG scale), age, height, weight and other factors.
Patients may withdraw from the trial at any point and those who do not want to continue with the home-based rehabilitation programme (the intervention) will be given the option to attend the hospital-based sessions.
At the end of the exercise programme, for both the control and the intervention arm, patients will be asked to visit the hospital to reassess their 6-minute walk test distance and to complete the questionnaires completed at the initial assessment, again.
At the end of the intervention, we will assess patient satisfaction with the technology using three other questionnaires (SUS, MAUQ and PROM-CR). We will further assess the patient experiences with the app using a questionnaire designed for the study.
Patients from both arms, who have consented to the qualitative study will be contacted via phone for a structured interview. This interview will take less than 30 minutes and will ask about their experience with the programme. The interviews will be recorded for transcribing purposes. However, any personally identifiable information will be redacted from the transcriptions.
We will also aim to find out about the experience of staff members in delivering this intervention and taking part in the trial. We will get informed consent from the staff and those who consent will be invited to a focus group to find out about their experience with the programme. They will also be asked to complete questionnaires (SUS) to assess the usability of the staff web portal. We will also determine the hospital resource allocation.

## Intervention Type
Other

## Primary outcome measure

Feasibility of conducting a large-scale randomised controlled trial measured using participant recruitment and dropout rates, acceptability of the intervention and the feasibility of randomisation at 12 weeks

### Secondary outcome measures
1. Aerobic capacity and endurance measured using the 6-minute walk test at baseline and 8 weeks
2. Health-related quality of life measured using EQ-5D-5L questionnaire at baseline and 8 weeks
3. Health-related quality of life measured using SF-36 questionnaire at baseline and 8 weeks
4. Anxiety and depression assessed using HADS questionnaire at baseline and 8 weeks
5. Impact on quality of life measured using PROM-CR questionnaire at 8 weeks
6. Performance in activities of daily living measured using Barthel Index questionnaire at baseline and 8 weeks
7. Adherence to the intervention, including usage of the app measured using app s at 8 weeks

### Overall study start date
11/01/2022

### Completion date
15/03/2024

## Eligibility

### Key inclusion criteria
Patients eligible for cardiac rehabilitation

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
90

### Key exclusion criteria
1. Awaiting urgent surgery
2. Unstable angina
3. Pregnancy
4. Currently enrolled in another interventional clinical trial or experiment
5. Malignant arrhythmias
6. Contraindications to rehabilitation - e.g.
6.1. Severe musculoskeletal conditions affecting exercise ability
6.2. Acute systemic illness or fever
6.3. Acute pericarditis or myocarditis
6.4. Uncontrolled atrial or ventricular arrhythmias

6.5. Uncontrolled sinus tachycardia
6.6. Aortic stenosis associated with pre-syncope/syncope
6.7. Uncompensated Heart failure
6.8. Complete atrioventricular block without a pacemaker
6.9. Recent embolism

### Date of first enrolment
21/11/2022

### Date of final enrolment
15/12/2023

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**South Tees Hospitals NHS Foundation Trust**
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

## Sponsor information

### Organisation
South Tees Hospitals NHS Foundation Trust

### Sponsor details
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+44 (0)1642850850
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### Sponsor type
Hospital/treatment centre

### Website

https://www.southtees.nhs.uk/

**ROR**
https://ror.org/02js17r36

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
South Tees Hospitals NHS Foundation Trust

# Results and Publications

**Publication and dissemination plan**
1. Planned publication in a high-impact peer-reviewed journal
2. Conference presentation

Data will be collated and presented in a way that it is not possible to identify individual participants.

**Intention to publish date**
15/09/2024

**Individual participant data (IPD) sharing plan**
The data sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |