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Does offering a hybrid cardiac rehabilitation programme increase uptake and adherence compared to in-person programmes?

Submission date
09/05/2023

Recruitment status
No longer recruiting

Registration date
03/07/2023

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Whilst cardiac rehabilitation reduces the risk of death and future heart attacks and improves quality of life, only about half of those invited attended the group-based programmes that were the usual provision before the COVID-19 pandemic. During the pandemic, many cardiac rehabilitation services switched to online or remote real-time delivery and saw an increase in uptake.
Now that in-person services are returning there are continued pressures on services: backlogs of people waiting, hospital gym facilities co-opted for other services, or staff redeployed. The NHS Long Term Plan has a goal of 85% of eligible patients joining cardiac rehabilitation. Delivering a hybrid programme of cardiac rehabilitation that commences with face-to-face delivery and supports patients to move to a remote service at a time that suits them, may enable more people to access rehabilitation and increase uptake.
This study aims to explore the impact of delivering a hybrid programme of cardiac rehabilitation on the staff, patient uptake of cardiac rehabilitation and health outcomes.

Who can participate?
Patients who have been offered a new 'hybrid' way of delivering cardiac rehabilitation that combines in-person classes with remote delivery using Active+me; and rehabilitation staff in centres that are delivering hybrid cardiac rehabilitation using Active+me.

What does the study involve?
A digital technology, called Active+me, which will enable the staff to deliver the hybrid programme and monitor patients safely, is being implemented in several cardiac rehabilitation services across England. Separate focus groups with rehabilitation staff and patients from three services will understand their experience of the new way of delivering rehabilitation. The researchers will use the anonymised data reported to the national cardiac rehabilitation audit to find out whether more people take up rehabilitation and whether the expected improvements in quality of life are seen, compared to pre-pandemic and services only offering face-to-face delivery. A health economic evaluation will explore the costs and consequences of this hybrid form of delivery.

What are the possible benefit and risks of participating?
There are no anticipated risks to taking part in this study. Participants will be offered a £25 voucher to thank them for taking part in a focus group or interview.

Where is the study run from?
The University of Birmingham (UK)

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

Who is funding the study?
1. Innovate UK
2. UK Research and Innovation (UKRI)

Who is the main contact?
Prof. Kate Jolly, c.b.jolly@bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320764

Protocol serial number
IRAS 320764, CPMS 55985

Study information

Scientific Title
Industrial research to generate evidence for submission to NICE, using a novel, real-world trial design for a technology-enabled, hybrid service for cardiac rehabilitation

Study objectives
Hybrid cardiac rehabilitation might increase uptake and adherence to cardiac rehabilitation (CR) compared to all in-person centre-based programmes; the acceptability, barriers and facilitators need to be explored in patients and staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/05/2023, Wales Research Ethics Committee 7 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, UK; +44 (0)2922 941107; Wales.REC7@wales.nhs.uk), ref: 23/WA/0131

Study design
Mixed methods study with a quantitative analysis of routinely collected audit data (work package 1), qualitative interviews/focus groups (work package 2) and health economic model

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiac rehabilitation in people with cardiovascular disease

Interventions
Active+me is a medical-grade platform, which is cloud-based, with an app that patients can access on their smartphone with Bluetooth or connected medical monitors. It has a fully customisable suite of lifestyle education (e.g. weight management) and behaviour change support, live exercise classes, physical activity, health monitoring tools, and medication diaries. The available materials can be locally customised, e.g. educational information in a range of languages, or recordings of exercise classes delivered by CR professionals in minority languages. The platform was designed using behaviour change techniques described by Abraham & Michie. A healthcare professional can decide what resources to provide to patients and when they are provided. This includes which behaviour change techniques to use. Patients are provided with Active+me, at the time of enrolling in CR. An instruction manual and video explaining how to set up and use the devices are provided.

Patients using Active+me can be provided with a physical activity tracker, automated blood pressure monitor with heart rate detection, pulse oximeter, or body mass scales, according to clinical need. All devices are able to be linked using Bluetooth to a smart device through an application downloaded from the Android (Mountain View, California, USA), Kindle Fire (Seattle, Washington, United States), or Apple (Cupertino, California, USA) app stores. Healthcare

professionals can communicate with patients throughout the programme, monitor patient progress towards achieving goals, and patient engagement with CR using data transmitted from their accessory devices to a personal computer terminal. During live remote exercise sessions, patients are able to enter and show privately, their Rated Perceived Exertion values to their instructor, to indicate that they are achieving an appropriate level of exertion.

Separate focus groups with rehabilitation staff and patients from three services will understand their experience of the new way of delivering rehabilitation. The researchers will use the anonymised data reported to the national cardiac rehabilitation audit to find out whether more people take up rehabilitation and whether the expected improvements in quality of life are seen, compared to pre-pandemic and services only offering face-to-face delivery. A health economic evaluation will explore the costs and consequences of this hybrid form of delivery.

Intervention Type
Behavioural

Primary outcome(s)
Uptake of cardiac rehabilitation, defined as attending at least one CR session, either in-person or remotely, recorded on the NACR database within 6 months of referral. A session will be defined in accordance with version 1.2 of the BACPR/NACR definition (June 2020).

Key secondary outcome(s))
1. Adherence to cardiac rehabilitation will be measured as at least 50% of planned cardiac rehabilitation sessions attended and a completion date recorded within approx. 6 months after programme start
2. Health-related quality of life measured by the Dartmouth CO-OP charts measured at programme start and end (approx. 3 months)
3. Anxiety and depression scores measured by the Hospital Anxiety and Depression Scale, the Generalised Anxiety Disorder Assessment (GAD-7) and Patient Health Questionnaire (PHQ-9) at programme start and end (approx. 3 months)
4. Fitness measured by incremental shuttle walk test or 6-minute walk test at programme start and end (approx. 3 months)
5. Smoking cessation measured using self report at programme start and end (approx. 3 months)
6. Self-report of 150 min physical activity/week at programme end (approx. 3 months)

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Work package 1 (NACR data):
Invited to cardiac rehabilitation. If there are sufficient numbers the sample will be limited to people who have acute coronary syndrome. This will make the sample homogeneous in terms of the index condition.

Work package 2 (qualitative):
1. Staff involved in the delivery or management of a cardiac rehabilitation service offering a hybrid programme using

Active_me for the remote part of the programme
2. Patients who were offered and/or engaged with a hybrid cardiac rehab programme using Active+me

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Work package 1 (NACR data):
Does not meet the inclusion criteria

Work package 2 (qualitative):
1. Staff not involved in the delivery or management of a cardiac rehabilitation service offering a hybrid programme using Active_me for the remote part of the programme
2. Patients who were not offered the hybrid cardiac rehab programme using Active+me

Date of first enrolment
01/06/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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			20/09/2023	No	No
Other publications	Qualitative work in three NHS Trusts to explore the patient and staff experience of using a hybrid model of CR	07/03/2025	18/03/2025	Yes	No