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Cardiac rehabilitation for children and young people

Submission date	**Recruitment status**	[X] Prospectively registered
02/03/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/05/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Heart problems are amongst the most common physical illnesses in children and young people (CYP). They can be present from birth or develop as CYP get older and are linked to increased physical and psychological difficulties. Approximately 1 in 3 CYP with heart problems have anxiety and/or depression so it is also important to support their mental health. One way to do this is to develop and test the acceptability and feasibility of a trial of cardiac rehabilitation (CR) consisting of exercise with mental health support for CYP. The aim of this study is to develop and test the feasibility and acceptability of a trial of a cardiac rehabilitation programme for CYP.

Who can participate?

CYP aged 11-16 years old who have been diagnosed with one of the following heart conditions: congenital heart disease (all subtypes), cardiomyopathy, cardiac arrhythmia, heart failure, post-cerebrovascular event or post-heart valve repair/replacement.

What does the study involve?

Participants will be randomised into one of two groups: CR or treatment as usual. CR will be delivered across 6 sessions lasting 90 minutes. All participants will complete questionnaires at baseline, 12 weeks (end of treatment), and 24 weeks (follow-up). A qualitative study will explore CYP and their parents' experiences of CR and trial participation.

What are the possible benefits and risks of participating?

The information gathered as part of this study will help inform future care within cardiac services for CYP with heart problems, and will provide details to develop further research on physical and mental health interventions for CYP with heart problems. While the risks in taking part are minimal it is possible that engagement in the exercise and physical activity component of the intervention may cause anxiety for patients and/or caregivers of patients with a heart condition. However, it will be highlighted to patients and their caregivers that the exercise sessions have been reviewed by a physiotherapist with experience working with patients with heart conditions and a child cardiologist who has deemed the exercise safe for CYP to engage in. It is also acknowledged that answering questionnaires and/or talking about difficulties can cause distress for patients. However, the mental health component of the intervention is designed to aid the management of negative thoughts and feelings more effectively, and participants will be

made aware that they can withdraw at any time without any detrimental effect on their healthcare.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2022 to August 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK) Research for Patient Benefit

Who is the main contact?
Dr Lora Capobianco, lora.capobianco@gmmh.nhs.uk

Study website
https://www.adept-ru.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319134

ClinicalTrials.gov number
NCT05968521

Secondary identifying numbers
CPMS 54520, IRAS 319134

Study information

Scientific Title
Cardiac rehabilitation for young people: a single-blind randomised acceptability and feasibility study of an integrated physical and mental health approach

Acronym
CardioActive

Study objectives

The study aim is to develop and test the feasibility and acceptability of a trial of a cardiac rehabilitation programme for children and young people

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/02/2023, Greater Manchester East Research Ethics Committee (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 22/NW/0367
2. Approved 23/01/2023, North West Greater Manchester East Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 2NT, UK; +44 (0)20 71048061; gmeast.rec@hra.nhs.uk), ref: 22/NW/0367

Study design
Single-blind randomized acceptability and feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular and mental health in children and young people

Interventions
Cardiac rehabilitation (CR) will consist of six sessions delivered weekly, with each session lasting between 60-90 minutes. CR consists of a structured group-based exercise programme and accompanying educational, lifestyle and mental health sessions. Cardiac rehabilitation will be delivered by a combination of cardiac nurses, physicians, or physiotherapists. Sessions will be delivered face-to-face in a hospital gym. Staff do not need to have a background in mental health in order to deliver the training. Staff delivering the intervention will receive two full-day workshops followed by a pilot delivery of the CR programme to a group of volunteer patients. A further workshop will be arranged subsequently to review any successes and challenges in the pilot delivery. Staff will receive ongoing supervision throughout the trial in the delivery of the intervention.

Intervention Type
Other

Primary outcome measure

Current primary outcome measures as of 06/07/2023:
The following primary outcome measures will be assessed from baseline to end of follow-up:
1. Feasibility will be assessed using referral rates (baseline), recruitment and retention rates (baseline, 12 weeks, 24 weeks), participant attendance at CR, and willingness to be randomized to treatment
2. Acceptability of the intervention will be assessed in qualitative focus groups and semi-structured interviews with children and young people, caregivers, and healthcare professionals

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Previous primary outcome measures:
The following primary outcome measures were assessed at baseline, and 12 and 24 weeks
1. Psychological wellbeing measured using the Strength and Difficulties Questionnaire (SDQ)
2. Quality of life measured using the Paediatric Quality of Life (PedsQol)

Secondary outcome measures

Current secondary outcome measures as of 06/07/2023:
1. Psychological wellbeing measured using the Strength and Difficulties Questionnaire (SDQ) at baseline, and 12 and 24 weeks
2. Quality of life measured using the Paediatric Quality of Life (PedsQol) at baseline, and 12 and 24 weeks
3. Aerobic capacity and endurance measured using the six-minute walk test (6MWT) at baseline, and 12 and 24 weeks
4. Physical activity levels measured using an accelerometer (Actigraph) at baseline, and 12 and 24 weeks
5. Metacognitive beliefs measured using the Metacognition Questionnaire-Adolescent (MCQ-A) at baseline, and 12 and 24 weeks
6. Quality of life measured using the Child Health Utility (CHU-9D) at baseline, and 12 and 24 weeks
7. Children’s use of primary, secondary, or community-based health and social care measured using a health and social service use questionnaire at baseline, and 12 and 24 weeks

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Previous secondary outcome measures:
1. Aerobic capacity and endurance measured using the six-minute walk test (6MWT) at baseline, and 12 and 24 weeks
2. Physical activity levels measured using an accelerometer (Actigraph) at baseline, and 12 and 24 weeks
3. Metacognitive beliefs measured using the Metacognition Questionnaire-Adolescent (MCQ-A) at baseline, and 12 and 24 weeks
4. Quality of life measured using the Child Health Utility (CHU-9D) at baseline, and 12 and 24 weeks
5. Children’s use of primary, secondary, or community-based health and social care measured using a health and social service use questionnaire at baseline, and 12 and 24 weeks
6. Feasibility measured using referral rates at baseline, recruitment and retention rates at baseline, and 12 and 24 weeks, participant attendance at cardiac rehabilitation at 12 and 24 weeks and willingness to be randomized to treatment at baseline

Overall study start date

01/09/2022

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Aged between 11-16 years
2. Fluent in English
3. Consent given to participate
4. Diagnosed with at least one of the following:
4.1. Congenital heart disease (all subtypes)
4.2. Cardiomyopathy
4.3. Cardiac arrhythmia
4.4. Heart failure
4.5. Post-cerebrovascular event
4.6. Post-heart valve repair/replacement

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 100 (120 including the qualitative component); UK Sample Size: 100

Key exclusion criteria
Current exclusion criteria as of 06/07/2023:
1. Significant risk or safeguarding concerns (i.e. suicidal ideation)
2. Head injury/organic impairment
3. Significant communication and/or social difficulties

Note: Those with a formal diagnosis or under assessment for any above exclusion criteria will be excluded.

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Previous exclusion criteria as of 26/05/2023:
1. Significant risk or safeguarding concerns (i.e., suicidal ideation)
2. Head injury/organic impairment
3. Learning disability causing communication difficulties

Note: Those with a formal diagnosis or under assessment for any above exclusion criteria will be excluded.

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Previous exclusion criteria:
1. Significant risk or safeguarding concerns (i.e., suicidal ideation)
2. Head injury/organic impairment
3. Autism Spectrum Disorder

Note: Those with a formal diagnosis or under assessment for any above exclusion criteria will be excluded.

Date of first enrolment
01/03/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United Kingdom

Study participating centre
Manchester Childrens Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

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Harrop House
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M265 3BL
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Sponsor type
Hospital/treatment centre

Website
https://www.gmmh.nhs.uk//

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/08/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lora Capobianco, lora.capobianco@gmmh.nhs.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol article		24/02/2024	26/02/2024	Yes	No