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Physical activity and exercise pathway for patients with congenital heart disease

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
12/03/2021

Overall study status
Completed

Last Edited
04/04/2023

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
Congenital heart disease (CHD) is a general term for a range of birth defects that affect the normal way the heart works. The term "congenital" means the condition is present from birth. Increased physical activity has been shown to result in improved physical fitness, quality of life and self confidence with reduced anxiety in adults with congenital heart disease.
While clinicians recognise the importance of promoting physical activity to children with CHD, 'how' it is best promoted and delivered to the young patients is not known. Most guidelines for patients with CHD are focused on restriction of competitive sports and are also devised for adults. However, competitive sport is only one part of being physically active, with physical activity being defined as 'any increase in movement, which results in energy expenditure greater than rest' and therefore can include activities such as walking, dancing, jogging, swimming.
The study aims to evaluate a 6 month physical activity promotion programme and assess improvements in physical and mental health. We plan to introduce a formalised structure ("exercise prescription") to promote the use of physical activity for young patients with CHD.

Who can participate?
Young patients (12 - 18 years) with CHD.

What does the study involve?
Participants entered into the study will be randomly allocated to an individualised exercise prescription or to normal care. The study will require extra visits by participants to the hospital for cardiovascular, physical activity and mental health assessments (Questionnaires). Results from the initial baseline assessment along with individual participant discussion will inform the type and intensity of physical activity and exercise prescribed for the 6 month period. Participants will have a choice of activities that are safe, appropriate and feasible for them to undertake, unsupervised at home. Repeat assessments will take place at the hospital at 3 months and 6 months to assess change. Support will be provided to all participants throughout the study and any issues with the physical activity and exercise prescribed will be reviewed throughout. Patient interviews will be used to assess the value and acceptability of the individualised plan with the aim of developing a simple, exercise prescription strategy.

What are the possible benefits and risks of participating?
This project will translate the scientific benefits of exercise into a workable programme that suits patients, resulting in increased physical activity and improvements in overall health and well-being. Currently there is no one programme or system to promote and advise patients about physical activity and exercise. There is also an educational component for participants which details reasons for exercising, motivations and barriers to exercise habits. Participants will also benefit through the knowledge that they are helping to better inform those involved in managing congenital heart disease and exercise prescription.
With any physical activity intervention there is a burden of time and commitment for the participant but we hope to minimise this by tailoring the intervention to fit the lifestyle of each person. Exercise is an important aspect of clinical care and patients are readily encouraged to participate. Performing any exercise can pose a cardiovascular risk to some individuals and also carries some risk of injury and muscle strain. This will be minimised in two ways. Firstly by conducting a baseline assessment of suitability to participate and secondly by teaching the participants the importance of sufficient warm-up and cool down periods prior to and following exercise. Clearance to participate will be given by a consultant paediatric cardiologist and participants will be given familiarisation time with equipment and procedures. During the exercise assessments (CPET) at baseline and 6 months, participants may feel tired and their legs may feel heavy. Some slight discomfort may also be felt in the legs 24-48 hours following exercise cessation. Such sensations are normal following exercise and are typically temporary. All participants will be given adequate recovery periods and will be monitored by an experienced team.

Where is the study run from?
Bristol Royal Hospital for Children (BRHC), University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) (UK)

When is the study starting and how long is it expected to run for?
May 2020 to April 2023

Who is funding the study?
Heart Research UK

Who is the main contact?
Professor Graham Stuart, graham.stuart@nhs.net

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
252807

Protocol serial number
CPMS 44962, IRAS 252807

Study information

Scientific Title
An evaluation of a physical activity and exercise promotion pathway for young patients with congenital heart disease

Study objectives
A 6 month physical activity and exercise promotion pathway improves cardiovascular, physical and mental health outcomes in young patients with congenital heart disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/05/2020, South West - Central Bristol REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8360; centralbristol.rec@hra.nhs.uk), ref: 20/SW/0021

Study design

Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Congenital heart disease

Interventions
The study protocol is organised into three phases.
Phase I comprises baseline assessments of physical activity, physical examination to rule out contradictions and physiological and psychological tests and is completed by all participants. Phase II is focused on the physical activity intervention for those in the intervention group, but will include some measurements that will also be collected on the control group. Phase III comprises a repeat of the baseline tests and allows analyses both of the effects of time Phase I, II and III but also against a control group. All these tests described in Phase 1 will be reassessed identically in Phase III by all participants.

Phase 1 Baseline Pre-Assessments
Baseline Assessment: A measurement of all the participant's physical activity using a wrist worn accelerometer will be taken first to establish a baseline. The participants will receive the monitors, questionnaires and a log sheet to record any times of monitor removal, on the first day of the study and will be asked to wear it for seven consecutive days.
Monitors will be returned via self-addressed postage to the research fellow.
Implementation of Physical Activity Pathway
a) Participant History, Physical Examination and Assessment of 5 Baseline Parameters by a Consultant: The consultant will perform a detailed physical assessment including details of surgical history and on-going symptoms, especially related to hemodynamic and electrophysiological complications. A resting ECG and echocardiograph will be completed according to European Society for Cardiology (ESC) guidelines including assessment of left ventricular function, pulmonary artery pressure, aorta, any arrhythmias and arterial saturation at rest. This assessment takesapproxi mately 45 minutes.
b) Cardiopulmonary Exercise Testing (CPET) by Cardiac Technician and Clinical Support Team: The continuous incremental cycle exercise test to voluntary exhaustion determines aerobic fitness and is designed to quantify the maximal volume of oxygen that can be transported, consumed and utilised and is a strong predictor of morbidity and mortality and takes approximately 6-15 minutes to complete.
This session will take approximately 45 minutes to complete. As per usual care at Bristol, a CHD toolkit (a set of information booklets and internet information from the charity Heart Research UK about physical activity, sport and recreation for young people with congenital heart disease and their parents) is presented to all participants to take away and read, with questions to be answered one week later. This stage is designed to be completed in one week, preferably a) and b) on the same day if possible.

Randomisation
After completion of the baseline tests all participants will be randomised either to ‘usual care’ (entitled control group from herein) or the ‘Exercise Prescription’ intervention group. Randomisation will be 1:1, stratified for New York Heart Association (NYHA) class I, II or III.

Stratification will include NYHA status to allow for any differences in local treatment practices, including those related to usual prescription of exercise. Randomisation will be computer generated, entered into an online database by a researcher independent of this study. Given the nature of the intervention, group allocation will not be blinded.
At this point the participants will be randomised to either the training group or the control. For the training group, the following will then be determined:
c) Decision of Type and Relative Intensity of Physical Activity by Clinical Support Team: Research fellow meets up with the patient. Results from the CPET are used according to the decision matrix of Budts et al. based on the fitness level of the patient, desaturation during of CPET using non-invasive pulse oximetry and assessment of ventricular function, pulmonary artery pressure, aortic size (using non-invasive echocardiography) and the presence of abnormalities of heart rhythm on ECG and knowledge of the underlying cardiac condition. The types and relative intensity of activities are discussed with the patient, particularly ruling out any activities that might be unsuitable.
d) Individualised Recommendation of Physical Activity Programme for Patient: A one month written plan will be prescribed according to the goals of the patient and will be specific regarding engagement in competitive sport, recreational exercise participation or simple increase in physical activity. The plan will utilise both the acronyms F.I.T (frequency, intensity and time) and S.M.A.R.T (specific, measurable, achievable, relevant and timely) to ensure the prescription fits the needs of the patient. Further detailed information and knowledge enhancement will be highlighted through the use of the Heart Research UK web based resources. Peer support will be provided by the research fellow by use of weekly text messaging or telephone contact.
This stage is designed to be delivered in one session lasting approximately one hour and should be completed one to two weeks after the CPET.

Phase 2 Intervention Activity Plan (the plan comprises one, three and six monthly checks)
a) Review of Physical Activity Prescription: After one month, a second meeting with the research fellow will take place to review progress, and where necessary, to amend by decreasing or increasing objectives and plan for the next two months. Barriers and facilitators to the completion of the programme will be recorded. Overall, a three month plan is proposed to be the minimum amount of time for behaviours to be changed and become more habitual. Peer support will be continued by the research fellow by use of weekly text messaging or telephone calls.
b) Assessments of Physical Activity, ECG/Echocardiographic and Blood Pressure Measurements at month 3: After three months, measurements of physical activity, ECG/echocardiographic and blood pressure functions are reassessed as described above to quantify the magnitude of change. Please note CPET has not been selected to be retested to reduce the burden of time on the patient and to be able to fit these 3 month measurements into one clinical visit. Peer support will be continued by the research fellow by use of weekly text messaging or telephone calls.
c) Continuation of agreed plan up to month 6: All goals are then reassessed with the research fellow for the physical activity prescription and a new three month plan is agreed and competed. Peer support will be continued by the research fellow by use of weekly text messaging or telephone calls as described above.

Phase 3 Post-Assessments as per Phase I
a) Assessments of All Measurements to Evaluate Six Month Physical Activity Pathway Promotion: As described above all measurements in PHASE 1 a and b will be reassessed to determine the rate and magnitude of change after a six month physical activity prescription programme.

b) One month after the completion of the 6 month physical activity prescription programme, the research fellow will telephone all the patients to assess ongoing participation in physical activity and obtain any other feedback.

Control Group Pathway
a) Participants in the control group will after Phase 1 continue as per usual care with their physical activity routines.
b) The participants in the control group will be reassessed at month 3 as described above (phase 2 b), as well as at month 6. This will allow us to assess changes due to usual care and compare it to the intervention at different time points.
c) Participants in the control group will also be interviewed one month after the completion of the study to assess their on-going participation in physical activity

At the conclusion of the study the control group will be offered all the training programme information and materials. The measurements from the participant include:
1. Physical activity measurement: Physical activity will be measured objectively by physical activity monitors and subjectively by validated questionnaires (Seven day physical activity recall). The GENEActiv monitor is a triaxial device and worn on the non-dominant wrist but has the advantageous of permitting the extraction of the raw data, enabling more sophisticated analysis to be performed. This device is becoming the most popular choice in clinical settings. The participants will receive the monitor, questionnaire and a log sheet to record any times of monitor removal, on the first day of the study and will be asked to wear them for seven consecutive days. Participants will be included in the data analysis if they wore the monitors for at least 600 minutes per day.
2. Clinical examination/ECG/ resting echocardiography: A full cardiovascular examination, 12 lead electrocardiograph and resting echocardiogram will be conducted by the research fellow and checked by Dr Graham Stuart and Dr Guido Pieles.
3. Cardiopulmonary Exercise Test (CPET): Formal ‘gold standard’ measurement of aerobic fitness and exercise capacity using a cycle ergometer conducted under the supervision of the research fellow and cardiac technician. This test allows measurement of key variables including peak VO2, gaseous exchange threshold, saturation of blood gases, detection of arrhythmias during exercise, modified Borg scale and blood pressure responses.
4. Quality of Life and Psychological Profile Assessment: Quality of life [HRQoL] and psychological Profile [PP] will be assessed through the Physical Self Perception Profile [PSPP], the Perceived Importance Profile [PIP].
5. Feasibility and Acceptability: The feasibility of the pathway to promote physical activity and exercise will be assessed by the number of activity sessions recorded during the 3 month intervention period. Acceptability will be assessed via semi-structured interviews. The interview schedule is designed to gain a deeper understanding of participants likes, dislikes, concerns and challenges around physical activity and exercise, and explore their views on the nature of the programme, the delivery providers, individual and group workouts, and anything that could be included in the programme to promote sustained motivation for and adherence to physical activity. Each participant will be interviewed at the end of the 3 and 6 month period. Participants will receive an additional telephone call 1 month after completion of the 6 month programme to assess ongoing usage of activity and any further feedback

Intervention Type
Behavioural

Primary outcome(s)

Cardiovascular/aerobic fitness as measured by a cardiopulmonary exercise test (CPET) at baseline and post exercise intervention (6 months)

Key secondary outcome(s))
Measured at baseline, 3 months and 6 months. Quality of life questionnaires will be completed by participants at baseline and end of the intervention (6 months):
1. Physical activity measured in counts per minute
2. Blood pressure in millimetres of mercury
3. Exercise duration time measured in minutes and seconds
4. Heart rate measured in beats per minute
5. Rating of perceived exertion measured by RPE scale

6. Qualitative data from semi-structured interviews at 3 months and after 6 months will be analysed to assess the feasibility and acceptability of the exercise intervention

Completion date
18/04/2023

Eligibility

Key inclusion criteria
1. 12 - 18 years of age
2. Asymptomatic CHD patients, or
3. NYHA class 2, or
4. Palliated or uncorrected CHD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Total final enrolment
28

Key exclusion criteria

1. If exercise poses a risk to the patient in the form of induction of arrhythmias/chest pain
2. Surgery within last six months or anticipated within the subsequent 1 year
3. Unable to walk for more than 5 minutes
4. Any other illness which exercise is a contraindication
5. Unable to cycle
6. Pregnancy

Date of first enrolment
04/01/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol and Weston NHS Foundation Trust
Marlborough Street
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Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK; Grant Codes: TR2429

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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