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Biophysical & psychosocial wellbeing in children with congenital heart disease

Submission date
09/09/2013

Recruitment status
No longer recruiting

Registration date
25/10/2013

Overall study status
Completed

Last Edited
29/03/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
In Northern Ireland lots of babies are born every year with heart problems and following advances in treatment, most of these children are growing up to reach adulthood. Everyone knows that regular exercise and a healthy lifestyle can have benefits but few people get the recommended amount of regular activity each week. We believe that children with heart problems are a group who could benefit from regular exercise. In this study we would like to find out how physical and mental health compares between children with major and minor heart problems. We would like to see if by a motivational program we can encourage them and their families to increase their level of daily activity and make healthier lifestyle choices. We would also like to see if we can show positive benefits on both physical and mental health by increased activity. If this study is successful it will provide a better understanding of how children and their families view their heart problems and provide evidence that regular exercise can have benefits for children with congenital heart disease.

Who can participate?
Patients with congenital heart disease, aged 5-10 years, who attended the participating hospital are invited to take part.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will be called the intervention group and the other the control group. Both groups will be asked to attend the Department of Paediatric Cardiology at the Royal Belfast Hospital For Sick Children (RBHSC) for assessment. This will involve taking measurements such as height, weight and BMI (body mass index). Participants will be given an exercise bike test. They will be asked to complete a diary of their diet and some questionnaires about how they view their heart condition. These tests will be arranged by the research doctor and a specialist in psychology. They will also be available to answer any questions about the study. Participants will be asked to return to the Department of Paediatric Cardiology at RBHSC to collect an activity monitor to wear as part of the assessment. This is like a pedometer and measures the amount of activity done. They will be asked to wear this for one week. Those participants in the intervention group only will then be asked to attend the Department of Paediatric Cardiology at RBHSC for an education session. During this session they will be given advice about healthy diet and lifestyle. They will also be given some

information to take home. At this stage the participants will be seen by the research doctor who will suggest some exercises that would be safe and suitable for them to do. These will have been discussed with their heart specialist. The intervention group will then have 4 months to put the new lifestyle changes and exercise programme into practice. During this time the research doctor will keep in close contact to see how things are going and be available to answer any concerns. The control group will have their usual level of care. Both the intervention and control groups will be asked to return to the Department of Paediatric Cardiology at RBHSC at the end of the study for final assessment. This will be similar to the assessment performed at the start.

What are the possible benefits and risks of participating?
This study aims to promote a healthy lifestyle and increase the general activity levels of the participants. This will be done in a safe way, using an exercise programme designed for the participants condition and with advice from their heart specialist. We expect participants to experience benefits in terms of improved exercise tolerance, mood and self esteem.

Where is the study run from?
Department of Paediatric Cardiology, Royal Belfast Hospital For Sick Children (RBHSC), Belfast, Northern Ireland (UK).

When is the study starting and how long is it expected to run for?
It is hoped the study will commence in February 2014 and run for 2 years.

Who is funding the study?
Funding is to be confirmed.

Who is the main contact?
Dr Sinead Callaghan
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Contact information

Type(s)
Scientific

Contact name
Dr Frank Casey

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BT12 6BE

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Biophysical and psychosocial wellbeing in children with congenital heart disease: a structured programme of assessment and intervention

Study objectives
There are two hypotheses forming the basis of the study. Firstly, is that physical and psychosocial health is reduced in children with major congenital heart disease compared to those with a minor diagnosis and secondly that a structured intervention programme could improve physical and psychosocial well-being.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submittied to The Office for Research Ethics Committee of Northern Ireland (ORECNI) by October 2013

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Congenital Heart Disease

Interventions
1. Participants in the intervention group will attend a motivational style activity day to discuss attitudes to exercise. They will be given a structured exercise plan to practise at home over a four month period.
2. The control group received their usual level of care from the tertiary centre.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Increase in physical activity from that measured at baseline using exercise bike testing and during free-living activity using accelerometer technology.

Key secondary outcome(s))
Improvements in self-esteem, self-efficacy and general mental health functioning as a consequence of increased activity. These were assessed using standardised questionnaires.

Completion date
01/02/2016

Eligibility

Key inclusion criteria
The potential participant group included all children aged 5-10 years with a primary diagnosis of congenital heart disease currently attending the Department of Paediatric Cardiology in Belfast for follow-up.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
10 years

Sex
All

Key exclusion criteria
1. Patients with a syndromic diagnosis (such as Down's)
2. Major learning difficulty or other serious co-morbidity that would render it difficult for them to follow the instructions required for participation were excluded from the project
3. Individuals with diagnoses for whom participation in exercise would be considered dangerous, e.g. hypertrophic obstructive cardiomyopathy

Date of first enrolment
01/02/2014

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Department of Paediatric Cardiology
Belfast
United Kingdom
BT12 6BE

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Not defined

Funder Name
To be confirmed

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes