ISRCTN27986270 https://doi.org/10.1186/ISRCTN27986270

Biophysical & psychosocial wellbeing in teenagers with congenital heart disease

Submission date 27/01/2013	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 06/02/2013	**Overall study status** Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 12/09/2013	**Condition category** Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims
In Northern Ireland lots of new babies are born every year with heart problems and most of these children are growing up to reach adulthood. As they become teenagers many of them are taking responsibility for their condition for the first time and realising what it might mean for their future. Everyone knows that regular exercise and a healthy lifestyle can have good effects but few people get the recommended amount of activity each week. We believe that young people with heart problems are a group who could benefit from regular exercise. We would like to see how physical and mental health compares between young people with major and minor heart problems. We would like to see if by a supportive program we can encourage good life style choices and increase the amount of exercise this group gets. We would 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 better understanding of how young people and their families view their heart problems evidence that regular exercise can have good effects for young people with congenital heart disease.

Who can participate?
Patients with Congenital Heart Disease aged 12-20 years who attended the Department of Paediatric Cardiology at Royal Belfast Hospital For Sick Children (RBHSC) are invited to take part.

What does the study involve?
Participants will be randomly divided into 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 RBHSC for assessment. This will involve taking measurements such as height, weight and BMI (body mass index). Participants will be given a treadmill 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 will 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 6 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 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 at RBHSC, Belfast, Northern Ireland (UK).

When is the study starting and how long is it expected to run for?
The study took place between August 2008 and August 2010.

Who is funding the study?
The study is funded by a Royal Belfast Hospital for Sick Children Research Fellowship.

Who is the main contact?
Dr Margaret Louise Morrison
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Contact information

Type(s)
Scientific

Contact name
Dr Frank Casey

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Additional identifiers

Protocol serial number
RGHT000534

Study information

Scientific Title
Biophysical & psychosocial wellbeing in teenagers with congenital heart disease: A structured programme of assessment and intervention

Study objectives
The hypothesis behind this study is twofold. Firstly that physical and psychosocial health is reduced in adolescents 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)
The Office for Research Ethics Committee of Northern Ireland (ORECNI), 27th June 2008, REC reference number 08/NIR02/44

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
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 six month period.

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 a standard treadmill protocol 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
11/08/2010

Eligibility

Key inclusion criteria
The potential participant group included all young people aged 12-20 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
12 years

Upper age limit
20 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
11/08/2008

Date of final enrolment
11/08/2010

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
Hospital/treatment centre

Funder Name
Royal Belfast Hospital for Sick Children (RBHSC) (UK) - research fellowship

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?
Results article	results	01/08/2013		Yes	No