

# Biophysical & psychosocial wellbeing in teenagers with congenital heart disease

<b>Submission date</b> 27/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/09/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 to 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

[louisemorrison@doctors.org.uk](mailto:louisemorrison@doctors.org.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Frank Casey

### Contact details

Department of Paediatric Cardiology  
Royal Belfast Hospital for Sick Children  
180 Falls Road  
Belfast  
United Kingdom  
BT12 6BE

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **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**

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 measure**

Increase in physical activity from that measured at baseline using a standard treadmill protocol and during free-living activity using accelerometer technology.

**Secondary outcome measures**

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

**Overall study start date**

11/08/2008

**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

**Age group**

Child

**Lower age limit**

12 Years

**Upper age limit**

20 Years

**Sex**

Both

**Target number of participants**

180

**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**

Northern Ireland

United Kingdom

**Study participating centre**

**Department of Paediatric Cardiology**

Belfast

United Kingdom

BT12 6BE

## **Sponsor information**

**Organisation**

Belfast Health and Social Care Trust (UK)

**Sponsor details**

Royal Victoria Hospital

274 Grosvenor Rd

Belfast

Northern Ireland

United Kingdom

BT12 6BA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.belfasttrust.hscni.net/index.html>

**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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>	results	01/08/2013		Yes	No