

# Biophysical & psychosocial wellbeing in children with congenital heart disease

<b>Submission date</b> 09/09/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/03/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

scallaghan@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  
180-184 Falls Road  
Belfast  
United Kingdom  
BT12 6BE

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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 submitted 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

### **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**

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 measure**

Increase in physical activity from that measured at baseline using exercise bike testing 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**

01/02/2014

**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

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

10 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**

01/02/2014

**Date of final enrolment**

01/02/2016

**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

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frank.casey@belfasttrust.hscni.net

**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

<https://ror.org/02tdmfk69>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

To be confirmed

## **Results and Publications**

**Publication and dissemination plan**

29/03/2018: Baseline results presented at Irish Cardiac Society Annual Scientific Meeting & AGM 2016 ([http://heart.bmj.com/content/102/Suppl\\_9/A29.2](http://heart.bmj.com/content/102/Suppl_9/A29.2) )

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration