

# Effectiveness and feasibility of intensive short-term graded exercise programmes

<b>Submission date</b> 18/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/08/2013	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
6817

# Study information

## Scientific Title

Effectiveness and feasibility of intensive short-term graded exercise programmes, using either treadmill or static exercise bicycle for non-ambulant children and young people with cerebral palsy in improving functional motor ability and quality of life

## Acronym

STATbiTR

## Study objectives

Effectiveness and feasibility of intensive short-term graded exercise programmes, using either treadmill or static exercise bicycle for non-ambulant children and young people with cerebral palsy in improving functional motor ability and quality of life.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Brighton West Research Ethics Committee approved on the 20th June 2008 (ref: 08/H1111/30)

## Study design

Multicentre randomised interventional process of care trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## 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

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

## Interventions

A mixed methodology comprising the following two sub-studies:

1. Parallel arm randomised controlled trial evaluating programme effectiveness
2. A focus group-based qualitative study evaluating programme acceptability and feasibility

## 1. Parallel arm randomised controlled trial:

Primary outcome measure: Gross Motor Function Measure (GMFM)-88E

Secondary outcome measures: GMFM-88D, GMFM-66, Kidscreen-52 Quality of Life Health Questionnaire for Children and Young People

### Outline of measures:

The GMFM-88D and GMFM-88E measure functional activity in children with CP. It is a standardised measure for use in children between the ages of 5 months and 16 years old. The GMFM-66 is a shorter version of the GMFM-88 and provides facility to convert scores to an interval scale. However, it can be insensitive at low levels and hence both measures will be administered. KIDSCREEN-52 A quality of life questionnaire will be completed by each child before and after the study. This Health-Related Quality of Life Measure is one of the 4 questionnaires, highly evaluated in the Asqme report and has been shown to provide valid results for health status, functional limitations and well-being.

Young people taking part in the focus groups are likely to use alternative and/or augmentative communication and this will require novel approaches to facilitate the groups and the use of pictures and models to aid discussion. The child's Speech & Language Therapist will be consulted regarding his/her form of communication. Advocates who know a child will be used to help children communicate if they wish. Eligible children/young people who consent to participate will be randomised to receive either:

- 1.1. Continuation of individuals standard physiotherapy programme (control arm).
- 1.2. 6 week intensive graded exercise programme using a static bicycle
- 1.3. 6 week intensive graded exercise programme using a treadmill

Assessment of all outcome measures will be taken at baseline, immediately post-intervention, 6 and 12 weeks post-intervention, by a researcher blinded to the study arm allocations. All assessments and interventions will be carried out in physiotherapy departments at participating sites, to minimise costs and inconvenience to participants.

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

1. Gross Motor Function Measure-66, 88D and 88E
2. Kidscreen 27 (quality of life measure)

### Secondary outcome measures

No secondary outcome measures

### Overall study start date

01/10/2008

### Completion date

31/08/2010

## Eligibility

**Key inclusion criteria**

1. Children and young people cerebral palsy at Gross Motor Function Classification System (GMFCS) levels IV and V as this is the population for which exercise to be used
2. Aged 8 to 17 years - 8 years as tall enough to use trike and 17 years as research is taking place largely in schools and this would be upper limit to complete the study
3. Ability to pedal on a static bicycle and take steps on the treadmill when given additional postural support
4. Ability to follow the instructions needed for different aspects of graded exercise

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Planned sample size: 36

**Key exclusion criteria**

1. History of fracture to legs - may be vulnerable to further fracture
2. Cardiovascular disease - risk of heart/respiratory problems

**Date of first enrolment**

01/10/2008

**Date of final enrolment**

31/08/2010

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Chailey Heritage Clinical Services**

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**Sponsor information**

**Organisation**

Sussex NHS Research Consortium (UK)

**Sponsor details**

Research & Development Department  
Worthing Hospital  
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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.sxrc.nhs.uk/>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme

**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	01/02/2013		Yes	No