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Effectiveness and feasibility of intensive short-term graded exercise programmes

Submission date	Recruitment status	[_] Prospectively registered
18/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2013	Nervous System Diseases	

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
Lewes
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BN8 4JN

Sponsor information

Organisation
Sussex NHS Research Consortium (UK)

Sponsor details
Research & Development Department
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Lyndhurst Road
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England
United Kingdom
BN11 2DH

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?
Results article	results	01/02/2013		Yes	No