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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

Protocol serial number
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)

Primary study design
Interventional

Study design
Multicentre randomised interventional process of care trial

Study type(s)
Diagnostic

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

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Chailey Heritage Clinical Services
Lewes
United Kingdom
BN8 4JN

Sponsor information

Organisation
Sussex NHS Research Consortium (UK)

Funder(s)

Funder type
Government

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

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	01/02/2013		Yes	No