ISRCTN37572029 https://doi.org/10.1186/ISRCTN37572029

The Introduction of Petra Running-bikes: A Pilot Study

Submission date	Recruitment status	[ ] Prospectively registered
17/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/01/2017	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
15075

Study information

Scientific Title
The introduction of Petra running-bikes to encourage and facilitate weight-bearing exercise for children with cerebral palsy who are unable to walk independently: a pilot study

Study objectives
Cerebral palsy (CP) is an umbrella term used for disabilities resulting from damage to the brain in the early stages of development and causing motor (movement) difficulties. Poor physical mobility results in reduced weight-bearing activity and since weight-bearing activity is essential for normal bone development, these children are more likely to develop osteoporosis (bone thinning). The benefit of weightbearing exercise for typically developing children is well documented, in terms of improvements observed in muscle strength, bone health and functional ability. This pilot study will introduce a novel mobility device, Petra running-bikes,to a group of children with CP who are unable to walk independently to investigate whether it is a feasible and enjoyable mode of weightbearing exercise facilitating their participation in physical activity. Running-bikes have a unique design with postural supports enabling non-ambulant children to weight-bear in a supported position. As opposed to a pedalling system the user sits on the saddle and propels themselves forward by contact with his/her feet on the ground.

A minimum of twelve children with CP, aged 4-12 years, will be recruited to the study to trial the running-bikes for twelve weeks (one school term). Each child will be provided with a running-bike appropriately sized and individually adapted according to their requirements. The children will use the running-bikes within their specialist schools three times a week.

At the end of the trial the physiotherapists and children will be interviewed to find out their views and experiences of using the running-bike. Any changes in bone status, motor function (mobility), quality of life and ability to use therunning-bike will be investigated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/0577; First MREC approval date 06/06/2013

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant 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 minimum of 12 children aged 4-12 years will be recruited for this pilot study. This will provide sufficient data to answer the research question "can non-ambulant children with cerebral palsy use and enjoy runningbikes?"

This will provide a range of ages and levels of disability to allow a wide spread of children and is considered appropriate for a pilot study.

Intervention: Each participant will be issued with a running bike to use at school for 12 weeks (three times a week) during their physiotherapy or PE session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Ability to use the running bike; Timepoint(s): This will be assessed and scored on 3 occassions (baseline, week 6 and week 12).

Secondary outcome measures
1. Bone health; Timepoint(s): Bone status will be assessed using an ultrasound bone densitometer at baseline and week 12
2. Focus group feedback from participants; Timepoint(s): Week 13
3. Gross Motor Function; Timepoint(s): Standing ability will be assessed at baseline and week 12
4. Quality of life; Timepoint(s): QoL will be assessed at baseline and week 12.

Overall study start date
19/08/2013

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Children with CP aged 4 to 12 years
2. Children with CP who are unable to walk independently (Gross Motor Function Classification levels III, IV or V)
3. Ability to follow instructions to use the running-bikes
4. Target Gender: Male & Female

Participant type(s)

Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
1. Children under the age of 4, or over the age of 12 years.
2. Children with CP who are able to walk (Gross Motor Function Classification Levels I or II)
3. Children who have undergone orthopaedic surgery to the spine or lower limbs within the last six months (due to the risk of fracture).
4. Children with a history of leg fractures (who may be vulnerable to further fracture).
5. Children with cognitive or behavioural impairment (preventing simple instructions on how to manoevre the running-bike).
6. Children with serious visual impairment (safety issues regarding using the runningbike).

Date of first enrolment
19/08/2013

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Speech and Language Therapy Department
Near Lewes
United Kingdom
BN8 4JN

Sponsor information

Organisation
Sussex Community NHS Trust (UK)

Sponsor details
Research and Development
Freshfield Annex
Brighton General Hospital Elm Grove
Brighton
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04e4sh030

Funder(s)

Funder type
Charity

Funder Name
Sparks Charity (UK) Grant Codes: 11CHY01

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	01/05/2015		Yes	No

HRA research summary	28/06/2023	No	No