

# The Introduction of Petra Running-bikes: A Pilot Study

<b>Submission date</b> 17/12/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/01/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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**  
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 the running-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 occasions (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 manoeuvre 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  
United Kingdom  
BN2 3EW

## 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?
<a href="#">Results article</a>	results	01/05/2015		Yes	No

