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# 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

**Protocol serial number**
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

## Study type(s)
Treatment

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

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
4 years

### Upper age limit
12 years

### Sex
All

### 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
United Kingdom

England

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

## Sponsor information

### Organisation
Sussex Community NHS Trust (UK)

### ROR
https://ror.org/04e4sh030

## Funder(s)

### Funder type
Charity

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

# 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 | 01/05/2015 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |