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Powered mobility training for young children with disability

Submission date
17/12/2015

Recruitment status
No longer recruiting

Registration date
18/12/2015

Overall study status
Completed

Last Edited
18/12/2015

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a condition which affects movement, posture and coordination. It is caused by an injury to the parts of the brain responsible for controlling muscles, usually before or very soon after birth. Children who are suffering from CP struggle to control movement which can affect their mobility (ability to walk) and stop them from taking part in certain activities at home and at school. Many studies have shown that helping children to regain their mobility using electric wheelchairs (powered mobility) can be extremely beneficial for their development, independence and self-esteem. Although many older children can access powered mobility training (sessions where they learn how to use their electric wheelchair), programs for very young children are currently lacking. The aim of this study is to test the effectiveness of powered mobility training in very young children with CP.

Who can participate?
Children aged between 2 and 4 who have been diagnosed with CP within the last 6 months and are able to sit up and control their head movements without support.

What does the study involve?
At the start of the study, the children's functioning abilities (mobility and independence) are tested using a number of assessments. Questionnaires are also filled in by parents in order to measure the children's quality of life and social interaction with other children. The participants then continue for 4 months without any powered mobility training (control phase). After four months, the initial assessments are repeated. The children then receive weekly powered mobility training sessions lasting for 45-60 minutes over a period of four months, teaching them how to use electric wheelchairs. After 4 months, the children are assessed again to evaluate the effectiveness of the powered mobility training. The measurements are also taken at 12 and 16 months to look at the long term effects of taking part in the mobility training.

What are the possible benefits and risks of participating?
The children taking part in the study can directly benefit, as the powered mobility training will help with their mobility. There are no notable risks of taking part in this study.

Where is the study run from?
Eastern Swiss Children's Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
November 2015 to February 2017

Who is funding the study?
1. Foundation for occupational therapy Zurich (Switzerland)
2. Cerebral Foundation (Switzerland)
3. Ebnet Foundation (Switzerland)
4. Foundation for Western culture (Switzerland)

Who is the main contact?
Dr Brigitte Elisabeth Gantschnig

Study website
https://www.zhaw.ch/de/forschung/personen-publikationen-projekte/detailansicht-projekt/projekt/2464/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2015-004581-28

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EKSG 15/087

Study information

Scientific Title
Powered mobility training in young children with cerebral palsy: A single-case study

Acronym
Powered mobility for children

Study objectives
The aim of this study is to evaluate the effectiveness of early powered mobility training in children with cerebral palsy between the ages of 2 and 4 years.

The specific research question is: How effective is early powered mobility training in children with cerebral palsy on:
1. Moving distance
2. Learning to use a powered wheelchair
3. Quality of ADL task performance
4. Quality of social interaction
5. Quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the Canton St. Gall, Switzerland, 02/07/2015, ref: EKSG 15/087

Study design
Single-centre single-case study using time series A-B-A-B-design

Primary study design
Interventional

Secondary study design
Single case study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Cerebral palsy

Interventions
A time series design (A-B-A-B-design) with repeated measures is used for this single case study. Thus, the participants act as their own controls.

After baseline evaluation (i.e. the first measure at time 1 [t1]), participants start with phase A (control phase). Participants receive no powered mobility training during this control phase that lasts 4 months. Then, another evaluation is implemented (i.e. the second measure at time 2 [t2]), followed by an intervention phase B. During the phase B participants receive powered mobility training. The powered mobility training is implemented in weekly session, 45 to 60 minutes each, over 4 months. It is based on Nilsson's work about the Driving to Learn method and the works of Durkin and Nilsson involving outcome assessment and facilitating strategies of learning powered mobility use. We use their work as an intervention protocol that supports occupational therapists with general (e.g. provide participants with activities with the right challenge) and specific (e.g. use specific langue in different learning phases) facilitating strategies as they implement powered mobility training.

Intervention Type
Device

Primary outcome measure
Mobility is assessed using the driving distance (meters/session) at baseline, 4, 8, 12 and 16 months.

Secondary outcome measures
1. Quality of ADL task performance is determined using the Assessment of Motor and Process Skills (AMPS), is a standardised observational assessment at baseline, 4, 8, 12 and 16 months
2. Level of mastery and independence in specific ADL tasks is measured using the Pediatric Evaluation of Disability Inventory (PEDI) completed by parents at baseline, 4, 8, 12 and 16 months
3. Quality of social interaction in children with CP is measured using the Evaluation of Social Interaction (ESI), a standardised observational assessment, at baseline, 4, 8, 12 and 16 months
4. Children's process of learning powered mobility use is measured using the Assessment of Learning Powered mobility use (ALP), an observational assessment, at baseline, 4, 8, 12 and 16 months

Overall study start date
01/11/2015

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Aged between 2 and 4 years
2. diagnosed within the last 6 months with infantile cerebral palsy according to ICD-10 G80 criteria
3. GMFCS level II to IV
4. MACS Level II to IV

5. Able to sit in the seat with physical support
6. Able to control their head and no risk of hurting themselves
7. Good general health condition

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Those who are not able to sit without support
2. Those who cannot control their head position
3. Those who have a instable health status
4. Those whose parents did not agree to participate in the study

Date of first enrolment
01/11/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
Eastern Swiss Children's Hospital
Centre of Neurology
Development and Rehabilitation – KER-centre
St. Gall
Switzerland
9006

Sponsor information

Organisation
ZHAW Zurich University of Applied Sciences

Sponsor details
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Sponsor type
University/education

Website
https://www.zhaw.ch/de/gesundheit/

ROR
https://ror.org/05pmsvm27

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for occupational therapy Zurich (Stiftung für Ergotherapie Zürich)

Funder Name
Cerebral Foundation (Stiftung Cerebral)

Funder Name
Ebnet Foundation (Ebnet Stiftung)

Funder Name

Foundation for Western culture (Stiftung für Abendländische Kultur)

Results and Publications

Publication and dissemination plan
Planned publication of study results in at least one international journal, with other publication in national journals and at national and international congresses. The results will also be shared with stakeholders, such as parents of children with CP, neuropaediatricians, physical therapists, other rehabilitation professionals, and the CP foundation in Switzerland.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date