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Comparing static standing and dynamic supported standing in children and young people with cerebral palsy who are not able to walk independently

Submission date
06/12/2018

Recruitment status
No longer recruiting

Registration date
07/12/2018

Overall study status
Completed

Last Edited
04/01/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol
Background and study aims
Non-ambulatory (not able to walk) children and young people with cerebral palsy (CP) are not physically active and have a lot of sedentary time which has significant health risks. The standard care for those children in Sweden includes static (non-mobile) standing training (StS) in standing frames for 45-90 minutes daily. This helps with bone strength, breathing and digestive function. Innowalk is a frame that can hold a person upright and support their weight while moving their legs as if walking. Parents of non-ambulatory children with CP performing dynamic standing (DyS) in an upright weight-bearing position with the motorised medical device Innowalk report effects not seen during StS. In a pilot study with 7 children the responses of one bout of 30 minutes StS and 30 minutes DyS were compared. The results from the pilot study showed that the study design was feasible and that there were differences in the physical responses to the two standing regimes. This study aims to investigate to see whether there are differences in the response to 4 months of StS and DyS in metabolic response, breathing, pain, gastrointestinal function, quality of life, physical activity, temperature in the feet, spasticity (muscle stiffness) and Passive Range of Motion in the hands and feet among non-ambulatory children and young people with CP.

Who can participate?
Non-ambulatory children and young people with CP aged 2-17, living in the Skane Region, Sweden

What does the study involve?
Each child performs 4 months of static standing and 4 months of dynamic standing in a home-setting, including a wash-out period of 2 weeks between the exercise periods. Assessments and measurements are made at 4 occasions, at the beginning and end of each exercise period.

What are the possible benefits and risks of participating?
Benefits include the knowledge gained about different types of standing. The study

assessments and measurements were performed in a home setting to make the children/young people more comfortable and to minimise the possible inconveniences from the measurements. The parents could end their participation in the study at any time.

Where is the study run from?
Lund University (Sweden)

When is study starting and how long is it expected to run for?
September 2016 to May 2018

Who is funding the study?
1. Stiftelsen för Rörelsehindrade i Skane, Sweden (Foundation for people with physical disabilities in the Skane Region, Sweden)
2. The Promobilia foundation (Sweden)
3. Swedish National Association for Disabled Children and Young People (Sweden)
4. Linnéa och Josef Carlssons stiftelse, Sweden (Linnéa and Josef Carlssons Foundation, Sweden)

Who is the main contact?
Dr Katarina Lauruschkus
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Study website
N/A

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of 4 months static standing compared to 4 months dynamic supported standing among non-ambulatory children and young people with cerebral palsy

Study objectives
The study hypotheses are that there are differences in the response to 4 months exercise of Static Standing and Dynamic Standing in metabolic response, respiration, physical activity, temperature at the feet, quality of life, pain, gastrointestinal function, spasticity and Passive Range Of Motion (PROM) in the hips, knee and ankle joints among non-ambulatory children and young people with cerebral palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board at Lund University, Sweden, 30/03/2017, ref: LU-Dnr 2017/67

Study design
Within-patient controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
The standard care in Sweden for non-ambulatory children and young people with cerebral palsy (CP) includes daily static supported standing. The standing exercise training in standing frames is a static standing (StS) exercise where the child is fixated in the standing frame. No movements in the lower body can be achieved but making standing in an upright position possible. The motorised medical device Innowalk gives an opportunity to experience walking movements in an

upright weight-bearing position, making dynamic standing (DyS) possible. The participants performed 4 months of standing for 30-60 minutes/day in StS and DyS at their home or preschool /school. Measurements were performed and questionnaires filled in at four occasions, at the beginning and end of each exercise period. Assessments of spasticity and passive range of motion (PROM) were performed and thereafter, capillary blood sample was taken and heart rate belt were put on. The child was positioned in either the standing frame or in the Innowalk. If the Innowalk was to be used it was individually adjusted to the child. When the child was in an upright position the airtight mask covering mouth and nose was put on. The indirect caloric assessment in a standing position was performed for 30 minutes. Temperature of the feet was measured every 10th minute during standing. After 30 minutes of standing the child was lifted down on a mat and a capillary blood sample was taken and assessments of spasticity and PROM were performed once more.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome measure
Respiratory gas exchange VO2, VCO2, VE and BF using with an airtight mask covering the mouth and nose while standing for 30 minutes at all four test points (at baseline and after 4 months of StS or DyS)

Secondary outcome measures
1. Metabolic response: capillary blood samples were taken from a fingertip for blood glucose and blood lactate analysis before and after standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS)
2. Heart rate monitored with a Polar belt while standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS) at all four test points (at baseline and after 4 months of StS or DyS)
3. Spasticity in hip flexors and extenders, adductors, hamstrings, knee extenders and gastrocnemius assessed by the Modified Ashworth Scale before and after standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS)
4. Passive Range Of Motion (PROM) in the hips, knee and ankle joints measured by goniometry before and after standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS)
5. Pain was assessed by questionnaire before, during and after standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS)
6. Body temperature assessed using infrared thermometer at both feet at rest before standing, 1 minute before the test started, at 10, 20 and 30 minutes of standing and at rest after standing for 30 minutes in StS or DyS at all four test points (at baseline and after 4 months of StS or DyS)
7. Gastro-intestinal function questionnaires was completed at all four test points (at baseline and after 4 four months of StS respectively DyS).
8. Quality of life was assessed by the CPChild assessment at all four test points (at baseline and after 4 four months of StS respectively DyS).

Overall study start date

01/09/2016

Completion date
17/05/2018

Eligibility

Key inclusion criteria
1. Cerebral palsy, with Gross Motor Function Classification System (GMFCS) level IV and V (non-ambulatory)
2. Aged 2-17 years
3. Living in the Skane Region in Southern Sweden
4. Performing static standing as standard care
5. Body length 80-190 cm

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
24

Total final enrolment
20

Key exclusion criteria
1. Body length less than 80 cm or more than 190 cm
2. Body weight more than 90 kg, due to the restrictions of the device producers
3. Planned orthopaedic surgery in the spine and lower extremities

Date of first enrolment
01/04/2017

Date of final enrolment
01/06/2017

Locations

Countries of recruitment

Sweden

Study participating centre
Health Sciences Center, Lund University
Box 157
Lund
Sweden
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Sponsor information

Organisation
Lund University, Faculty of Medicine

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Sponsor type
University/education

Website
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ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Other

Funder Name
Stiftelsen för Rörelsehindrade i Skane, Sweden (Foundation for people with physical disabilities in the Skane Region, Sweden)

Results and Publications

Publication and dissemination plan
The study protocol will be available on request. 3-6 scientific papers and presentations at conferences are planned.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
Participant level data will be available on request from Dr Katarina Lauruschkus (katarina.lauruschkus@med.lu.se) from December 2018 to November 2028. Consent from the participants' parents as their legal guardians was obtained. All data presented are anonymised, and there is a code list locked in at Lund University.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/03/2020	26/08/2020	Yes	No
Dataset	Raw data of PROM	17/03/2020	04/01/2024	No	No
Dataset	Raw data of spasticity assessments	17/03/2020	04/01/2024	No	No