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Static compared to dynamic supported standing for non-ambulatory children with cerebral palsy: a pilot study

Submission date
09/05/2018

Recruitment status
No longer recruiting

Registration date
12/05/2018

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Non-ambulatory (not able to walk) children 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 standing training (StS) in standing frames for 45-90 minutes daily. 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. Therefore, the aim of this study is to see whether there are any differences in the response to one acute bout of StS and DyS in metabolic response, blood pressure, temperature, spasticity and Passive Range of Motion in the extremities among non-ambulatory children with CP.

Who can participate?
Non-ambulatory children with CP aged 2-17

What does the study involve?
Each child performs 30 minutes of static standing and 30 minutes of dynamic standing on two separate occasions at the Health Sciences Lab, Lund University, Sweden, with 5 days in between. Assessments and measurements of metabolic response, blood pressure, temperature, spasticity and passive range of motion in the legs are performed before, during and/or after the standing exercise.

What are the possible benefits and risks of participating?
Benefits include the knowledge gained about different types of standing. The study visits took time from both children and their parents. There might be inconvenience for the children when the metabolic response or the blood pressure are measured. The parents could end their participation in the study at any time.

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

When is the study starting and how long is it expected to run for?
January to September 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Katarina Lauruschkus
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2. Prof. Åsa Tornberg

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
Physiological responses from static and dynamic supported standing among non-ambulatory children with cerebral palsy: a pilot study

Study objectives
The study hypothesis are that there are differences in the response to one acute exercise bout of Static Standing and Dynamic Standing in metabolic response, blood pressure, temperature, spasticity and Passive Range Of Motion (PROM) in the hips, knee and ankle joints among non-ambulatory children with cerebral palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board at Lund University, Sweden, 07/06/2016, ref: LU-Dnr 2016/374

Study design
Clinical controlled study, where the children were their own controls with a cross-over design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

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
Non-ambulatory children with cerebral palsy (CP), who cannot walk or sit without support

Interventions
The standard care in Sweden for non-ambulatory children with CP includes daily static standing. The standing exercise training in standing frames is a static standing (StS) exercise where the child is fixated in an individually casted 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. 30 minutes of standing in StS and DyS were performed

at two separate occasions, at the Health Sciences Lab, Lund University, Sweden, with five days in between. Questionnaires and personal data were collected. Assessments of spasticity and passive range of motion (PROM) were performed and thereafter, capillary blood sample was taken and heart rate belt and blood pressure cuff 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. Blood pressure and. temperature of the arms and legs were 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. Finally the feasibility and evaluation questionnaires were filled in by the parents.

Intervention Type
Device

Primary outcome measure
Metabolic response: capillary blood samples were taken from a fingertip for blood glucose and blood lactate analysis before and after the Static Standing (StS) in the standing frame compared to the Dynamic Standing (DyS) in the Innowalk

Secondary outcome measures
1. Respiratory gas exchange measured with an airtight mask covering the mouth and nose while standing for 30 minutes in StS or DyS
2. Heart rate monitored with a Polar belt while standing for 30 minutes in 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 Sts and DyS
4. Passive Range Of Motion (PROM) in the hips, knee and ankle joints measured by goniometry before and after Sts and DyS
5. Blood pressure assessed at the upper arm (model, country) at rest before standing, 1 minute before the test started, at 10, 20 and 30 minutes of standing and at rest after standing
6. Body temperature assessed using infrared thermometer at both forearms, hands, shanks and feet at rest before standing, 1 minute before the test started, at 10, 20 and 30 minutes of standing and at rest after standing

Overall study start date
15/01/2016

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Children aged 2-17 years
2. Cerebral palsy, GMFCS level IV and V (non-ambulatory)
3. Boys and girls
4. Living in the Skane county, in Southern Sweden

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
The target number was 6-8 children

Key exclusion criteria
1. Children younger than 2 years of age
2. Young people older than 17 years

Date of first enrolment
15/05/2016

Date of final enrolment
15/06/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Lund University
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Sponsor type
University/education

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ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The study protocol will be available on request, 1 scientific paper, presentation at conferences

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
Participant level data will be available on request from Dr Katarina Lauruschkus (katarina.lauruschkus@med.lu.se) from June 2018 to May 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		17/03/2020	02/03/2022	Yes	No