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The effect of gait training in adults with cerebral palsy on ankle joint stiffness and kinematics

Submission date
08/04/2015

Recruitment status
No longer recruiting

Registration date
22/04/2015

Overall study status
Completed

Last Edited
29/05/2020

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 the general term to describe a number of conditions that affect muscle control, movement and co-ordination. It can happen of the brain develops abnormally or is damaged before, during or shortly after birth. People with cerebral palsy (CP) often develop contractors in their lower limbs (that is, muscles shortening leading to loss of range of movement), especially in the ankle joints. This often contributes significantly to their disability. Treatment has often been focused on passive stretching even though no evidence of any clinical benefit has been found. However, intensive gait training has been shown to reduce muscle stiffness in children with CP. Here, we are going to investigate whether intensive gait training can reduce ankle stiffness in adults CP sufferers as well.

Who can participate?
Adults (age 18-60) with CP and increased ankle stiffness.

What does the study involve?
The study involves two tests days (one before and one after the intervention, or treatment) that includes assessing each participants degree of ankle stiffness with the use of dynamometers and EMG, neurological examination, a functional gait test including 3D kinematic evaluation and ultrasound of the muscles in the lower limbs (legs and ankles). The participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given gait training on a treadmill for 30 minutes every day for 6 weeks. This is in addition to their normal activities. Those in group 2 (control group) go about their usual activities.

What are the possible benefits and risks of participating?
The participants may possibly improve their walking abilities and general fitness level due to the intervention. There are no risk involved in participation of this study.

Where is the study run from?
Helene Elsass Center and University of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
January 2014 to February 2015.

Who is funding the study?
Ludvig and Sara Elsass Foundation (Denmark)

Who is the main contact?
Dr Jakob Lorentzen
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Randomized controlled clinical trial of the effect of gait training in adults with cerebral palsy on ankle joint stiffness and kinematics

Study objectives
We wanted to evaluate the effect of intensive daily gait treadmill training on passive and active ankle stiffness and gait ability.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics committee of Copenhagen, Denmark (Videnskabsetisk komite, Region hovedstaden), ref: H-2-2014-028

Study design
Randomized controlled clinical training study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
32 adults with CP (GMFCS 1, n=10; 2, n=7; 3, n=15) aged 38.1 years +/-12 (SD) years old were recruited for the study. The participants were randomly allocated to either a training group (n=16) where gait training on a treadmill was performed daily for 30 min for six weeks in addition to their usual activities or a control group (n=16) that performed their usual activities.

Intervention Type
Behavioural

Primary outcome(s)
1. Evaluation of muscle stiffness and gait ability was made twice on all participants before and after the six week of training or control period
2. Measurement of passive and reflex stiffness in the ankle joint plantar flexors was made by a dynamometer which applied stretches below and above the stretch reflex threshold
3. Gait kinematics was recorded by 3D video analysis during treadmill walking with a velocity chosen by the participant at the first evaluation
4. Foot pressure was measured by force sensitive foot soles during treadmill and over ground walking

Key secondary outcome(s))
Balance - tested by Romberg 30 seconds, eyes open test.

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Adults, both genders
2. Aged 18-60 years
3. with CP and increased ankle stiffness and reduced ankle ROM (range of motion)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
32

Key exclusion criteria
Severe cognitive and physical disability that made training impossible

Date of first enrolment
01/03/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Helene Elsass Center
Holmegaardsvej 28
Charlottenlund
Denmark
2920

Study participating centre
University of Copenhagen, Institute of Sports and Nutrition
Nørre Alle
Copenhagen
Denmark
2200

Sponsor information

Organisation
Institute of Sports and Nutrition

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Research organisation

Funder Name
Ludvig and Sara Elsass Foundation (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes