

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/04/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 if the brain develops abnormally or is damaged before, during or shortly after birth. People with cerebral palsy (CP) often develop contractures 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

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home

**Study type(s)**

Treatment

**Participant information sheet**

This material is only available in Danish

**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  $\pm$  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 measure**

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

**Secondary outcome measures**

Balance - tested by Romberg 30 seconds, eyes open test.

**Overall study start date**

01/01/2014

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Both

**Target number of participants**

32 adults with CP (GMFCS 1, n=10; 2, n=7; 3, n=15) aged 38.1 years  $\pm$  12 (SD) years old were recruited for the study.

**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

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/035b05819>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Ludvig and Sara Elsass Foundation (Denmark)

# Results and Publications

## Publication and dissemination plan

Two or three research papers. One paper that describes the changes in ankle stiffness in the intervention group and control group and one paper that describes the changes in gaitability including kinematic measures.

2015 abstract in: [https://doi.org/10.1111/dmcn.39\\_12886](https://doi.org/10.1111/dmcn.39_12886) (added 29/05/2020)

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available