ISRCTN66528622 https://doi.org/10.1186/ISRCTN66528622

# How training and reduction of antispastic medication affects adults with severe cerebral palsy

**Submission date**
23/06/2020

**Recruitment status**
No longer recruiting

**Registration date**
24/06/2020

**Overall study status**
Completed

**Last Edited**
20/07/2021

**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
Cerebral palsy (CP) is caused by an injury to the immature brain that disturbs typical development. People with CP often have reduced muscle strength and difficulties in learning motor (movement) activities. This may impact their ability to perform activities such as standing, walking, running and participation in everyday life. Traditional treatment consists of physiotherapy and efforts to normalize movements. People with CP are often treated with antispastic treatment, but this medication may cause inactivity because of side effects such as drowsiness, muscle weakness and impaired motor learning. There is very little research regarding physical interventions in adults with CP, especially the severy affected. This study therefore aims to investigate if adults who are severely affected by CP are able to improve their motor function through tailored training supported by a reduction in their antispastic medication.

Who can participate?
Adults aged over 18 with CP

What does the study involve?
Participants are assigned to three different groups. The first group receives a 3-month physical intervention (3-5 times per week over 12 weeks) and discontinued antispastic medication (oral bachlofen or dantrolene). The second group receives an intervention including standard care and discontinued antispastic medication. The third group functions as a control group including standard care and no changes to medication. Participants' functional ability is measured at the start of the study, immediately after the 4-week drug discontinuation, immediately after the 12-week active intervention, and at follow-up 1 month after finishing the intervention.

What are the possible benefits and risks of participating?
Participants in the intervention group may benefit from better physical function and health. No risks are expected, except for occasionally muscle soreness. Participants whose antispastic medication is reduced may experience fewer side effects. Reduction of medication is evaluated individually and an experienced physician will oversee the process. Information obtained from

this study may benefit future rehabilitation approaches and individualized training methods for adults with severe brain damage.

Where is the study run from?
Jonstrupvang Bebyggelsen (Denmark)

When is the study starting and how long is it expected to run for?
September 2018 to September 2022

Who is funding the study?
The Elsass Foundation (Denmark)

Who is the main contact?
Helle Hüche Larsen
hhl@elsassfonden.dk

# Contact information

### Type(s)
Scientific

### Contact name
Miss Helle Hüche Larsen

### Contact details
Panum Institute 33.3
Blegdamsvej 3
Copenhagen
Denmark
2200
+45 (0)26573438
hhl@elsassfonden.dk

### Type(s)
Public

### Contact name
Miss Helle Hüche Larsen

### Contact details
Panum Institute 33.3
Blegdamsvej 3
Copenhagen
Denmark
2200
+45 (0)26573438
hhl@elsassfonden.dk

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
1A

# Study information

### Scientific Title
Effect of motor learning-based activities combined with discontinuation of antispastic medication on functional ability in adults with severe cerebral palsy

### Study objectives
Gross motor function in adults with severe cerebral palsy can be optimized by daily motor-learning based activities combined with discontinuation in antispastic medication.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 07/09/2018, Center For Sundhed (Regionsgården, Kongens Vænge 2, 3400 Hillerød; +45 (0)38666395; vek@regionh.dk), ref: H-18029151

### Study design
Open-label non-randomized pragmatic clinical pilot study with a two-group design

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Gross motor function in cerebral palsy

### Interventions
Adults with severe CP (Gross Motor Function Classification Scale III-V) are recruited through convenience sampling and assigned to three different groups:
1. The first group receives a 3-month physical intervention including activities based on motor learning principles and discontinued antispastic medication (oral bachlofen or dantrolene)
2. The second group receives an intervention including standard care and discontinued antispastic medication
3. The third group functions as a control group including standard care and no changes to medication

The physical intervention is planned based on science-based neurorehabilitation and motor learning principles and adjusted individually to each participant. The dose will be 3-5 times per week in 12 weeks.

Participants will be reduced in bachlofen or dantrolene dose by 25% per week during a 4-week period. In this period participants are closely followed by an experienced physician.

Participants will be enrolled through convenience sampling and are distinguished by their willingness to participate and therefore not randomly assigned to groups.

### Intervention Type
Mixed

### Primary outcome(s)
Functional ability measured by Gross Motor Function Measure (GMFM-88) at baseline; immediately following 4-week drug discontinuation and prior to starting the 12-week active intervention; immediately following the intervention; and at follow-up 1 month after finishing the intervention

### Key secondary outcome(s))
Neurological screening including Modified Ashworth's Scale (MAS), Range of Motion (ROM), tendon reflex testing and 0-5 strength scale at baseline; immediately following 4-week drug discontinuation and prior to starting the 12-week active intervention; immediately following the intervention; and at follow-up 1 month after finishing the intervention

### Completion date
01/09/2022

## Eligibility

### Key inclusion criteria
1. Diagnosed with cerebral palsy
2. GMFCS level between III-V
3. >18 years of age

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

**Total final enrolment**
16

**Key exclusion criteria**
Does not meet inclusion criteria

**Date of first enrolment**
12/09/2018

**Date of final enrolment**
08/03/2020

# Locations

**Countries of recruitment**
Denmark

**Study participating centre**
**Jonstrupvang Bebyggelsen**
Chr. Hauchs Alle 11
Værløse
Denmark
3500

# Sponsor information

**Organisation**
University of Copenhagen

**ROR**
https://ror.org/035b05819

# Funder(s)

**Funder type**
Charity

**Funder Name**
Elsass Fonden

**Alternative Name(s)**
Elsass Foundation

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
Denmark

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Helle Hüche Larsen (hhl@elsassfonden.dk). Participants gave written informed consent to the study, which was approved by the local ethics committee of Copenhagen region and performed in accordance with the Helsinki Declaration. All personal data are anonymized. Files containing personal data are stored on a separate hard drive and stored securely according to the guidelines provided by The Danish Data Protection Agency. Raw data will be available in anonymized form on request for statistical or scientific purposes of significant meaning according to the guidelines provided by The Danish Data Protection Agency.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 30/04/2021 | 20/07/2021 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |