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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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

Sponsor details
Panum Institute 33.3
Blegdamsvej 3
Copenhagen

Denmark
2200
+45 (0)26573438
hellel1@hotmail.com

Sponsor type
University/education

Website
http://www.ku.dk/english/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2021

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