ISRCTN13188513 https://doi.org/10.1186/ISRCTN13188513

Twenty weeks of home-based interactive training of children with cerebral palsy improves functional abilities

Submission date
20/11/2014

Recruitment status
No longer recruiting

Registration date
04/12/2014

Overall study status
Completed

Last Edited
17/12/2020

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 in a term used to describe a number of neurological conditions that effect movement and co-ordination. It can result in stiff or floppy muscles, muscle weakness, random or uncontrolled movements and balance and co-ordination problems. Treatment can include physiotherapy to strengthen muscles and improve balance and co-ordination. Home-based training (treatment) is becoming more important with increasing demands on public health systems. We investigated whether individually tailored and supervised interactive home-based training delivered through the internet improves functional abilities in children with cerebral palsy.

Who can participate?
Children with cerebral palsy aged between 7 -16.

What does the study involve?
Children are allocated into one of two groups. Those in the interventional group are given access to the home-based training system, which includes training modules to train cognitive, perceptual and motor abilities. The training consists of 30 minutes daily home-based training for 20 weeks. Those children in the control group are not given access to the training system. Each participant's motor skills and functional strength are evaluated before and after the 20 week training period.

What are the possible benefits and risks of participating?
The training is likely to lead to improvements in arm and leg function and general improvement in motor skills.

Where is the study run from?
1. Helene Elsass Center, Charlottenlund (Denmark)
2. Institute of Sport and Nutrition, University of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
January 2009 to January 2011

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Twenty weeks of home-based interactive training of children with cerebral palsy improves functional abilities: an interventional trial

Study objectives
Home-based training is becoming ever more important with increasing demands on the public health systems. We investigated whether individualized and supervised interactive home-based training delivered through the internet improves functional abilities in children with cerebral palsy (CP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Copenhagen, Denmark (Videnskabsetisk komite, Region hovedstaden), 18 /06/2009, ref: H-B-2009-017

Study design
Non-randomized controlled clinical training study

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 below to request a patient information sheet

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

Interventions
34 children with CP were included in this non-randomized controlled clinical training study. 12 children were allocated to a control group in which measurements were performed with 20 weeks interval without any intervening training.

The intervention consisted of training of the children that took place in their own home over a 20 week period. The training program was delivered to the children and ensured that they

trained 30 minutes per day every day during the whole period. The training was delivered through the internet and consisted of a server-based interactive training-system using flash-technology. The system has been developed through collaboration between The Helene Elsass Center, a private software development company (Head-fitted; Århus, Denmark) and the University of Copenhagen. It has now been made commercially available through collaboration between the Helene Elsass center and the Ministry of Research under the name Mitii (Move It To Improve It; Mitii developments, Charlottenlund, Denmark). The training-system is designed to combine cognitive and motor challenges in order to train cognitive, perceptual and motor abilities at the same time. It consists of a number of training modules in which the child has to analyse visual information, solve a cognitive problem (i.e. mathematical question or similar) and respond with a motor act to objects presented on the screen (i.e. bend to pick up needle and blow up balloon with the right answer). The core of the system is that the computer program identifies the movements of the child from video images sampled from a simple web-camera attached to the computer.

Intervention Type
Behavioural

Primary outcome measure
1. Daily activities - tested by AMPS (Assessment of motor and process skills
2. Functional abilities of upper- and lower limbs. Upper limb function was tested by AHA (Assisting Hand Assessment) test. Functional Strength of lower limbs was tested by the Sit-to-stand test and Half kneeling-standing test.

All evaluated before, immediately after training and 12 weeks after training. The training consisted of 30 minutes daily home-based training for 20 weeks delivered through the internet.

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

Overall study start date
01/01/2008

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Children (both girls and boys) with cerebral palsy
2. Age range from 7 to 16

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
34 children with CP (aged 9-16; mean age 10.9+2.4) (GMFCS I-II; MACS I-II) were included in this non-randomized controlled clinical training study. 12 children with CP (aged 7-16 years, mean age: 11.3+/-0.9 years) were allocated to a control group (non intervention)

Total final enrolment
34

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

Date of first enrolment
01/01/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Denmark

Study participating centre
Helene Elsass Center
Holmegaardsvej 28
Charlottenlund
Denmark
2920

Sponsor information

Organisation
Institute of Sports and Nutrition, University of Copenhagen

Sponsor details
University of Copenhagen
Panum Instituttet 33,3, Nørre Alle

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Sponsor type
University/education

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Charity

Funder Name
Ludvig and Sara Elsass Foundation (Denmark)

Results and Publications

Publication and dissemination plan
Two research papers. One paper that describes the pilot phase and one paper that describes the results of the controlled study.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/05/2015	17/12/2020	Yes	No