Forced use therapy in the piratsgroup to improve upper limb activities in children with Cerebral Palsy:
An approach in a meaningful setting with play-based occupational therapy

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The development of an attractive child centred intervention based on the forced use perspective, to study the effects regarding the following question:Is a period of 6 weeks Forced Use of the more affected upper limb (I) for children with Cerebral...

Ethical review	Approved WMO
Status	Pending
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON29890

Source
ToetsingOnline

Brief title
Forced use therapy in the piratsgroup

Condition

- Encephalopathies

Synonym
cerebral palsy, encephalopathie infantilis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: subsidie bij fondsen wordt mogelijk aangevraagd

Intervention

Keyword: cerebral palsy, forced use, occupational therapy, upper limb activities

Outcome measures

Primary outcome

Measurement 1: AHA

AHA, Assisting Hand Assessment , has been developed for children aged 18 months to 6 years with a unilateral disorder at the hand/ arm due to Cerebral Palsy or Obstetric Plexus Brachial leasion.

Measurement 2: VOAA

Observation of the use of the affected arm and hand during bimanual activities. The Video Observation Aarts & Aarts will be used to measure duration and frequency.

Secondary outcome

Measurement 3: Melbourne

The *Melbourne Assessment of unilateral upper limb function for children with neurological impairment*

Measurement 4: PDMS-2 and/ or Movement ABC

The *Peabody Developmental Motor Scales* is not developed for children with cerebral palsy but is included in this study to measure change in fine motor skills.

Measurement 5: COPM and GAS

COPM is an instrument to list the experienced problems in daily living by means of an open interview. Subsequently goals are described in steps by means of Goal Attainment Scaling (GAS) to make the results measurable.

Measurement 6: ABILHAND- Kids

The ABILHAND-kids is a questionnaire to measure manual ability.Parents are asked to fill in the questionnaire.

Measurement 7: measurement of muscle tone

Muscle tone of elbow and wrist are determined by means of the Tardieu-method and the SPAT (Spasticity test)

Measurement 8: muscle strength

Muscle strength is measured with the Hand-Held-Dynamometer (for arm strength), and pinch meter (strength between thumb and index finger for pincer grasp and thumb and lateral side index finger for lateral grasp. Also grip strength will be measured

Measurement 9: Mobility ROM

Active and passive ROM (Range of Motion) of wrist (with fisted hand and also with extended fingers), elbow and Thumb are determined by means of a goniometer.

Measurement 10: Box and Bocks

To measure change in manual ability of the affected arm and hand during the weeks of intervention and to adjust the therapy program in which repetitive exercises are important, the box and block test will be administered weekly. The child is asked to replace as much as possible blocks from one box to the other within 1 minute. Reliability and validity of the Box and Block test has been examined and are satisfactory (Mathiowetz, 1985)

Study description

Background summary

Title of the study:
Effect study: forced use therapy based on play combined with intensive occupational therapy in the so called pirate group to improve the skills of arm/ hand in children with cerebral palsy and asymmetric upper limbs

Background of the study
Interventions aimed at arm/hand skills with children with a spastic pareses are expected to influence positioning and manipulation in order to improve manual skills. Therapy , based on the perspective of *forced use of the affected upper limb* is known under different names, namely:
Forced Use (FU)
Constraint Induced Movement Therapy (CI or CIMT)
Modified Constraint Induced Movement Therapy (MCIT)
Point of similarity is that, by wearing a sling, glove or ortheses on the únaffected arm, one is forced to use the affected upper limb. The intensity is varying from two to eight hours a day during two to eight weeks.

Study objective

The development of an attractive child centred intervention based on the forced use perspective, to study the effects regarding the following question:

Is a period of 6 weeks Forced Use of the more affected upper limb (I) for children with Cerebral Palsy and asymmetric upper extremities, combined with two weeks bimanual play activities in the so called Pirate group (for 3 hours on 3 afternoons a week) providing the opportunity to increase (O) the spontaneous use qualitatively and quantitatively more than a standard group therapy with the same duration and frequency but without using *forced use* (C).

Using PICO systematic P stands for patient, I for intervention, C for comparison and O for outcome.

Study design

1. RCT with a qualification period to evaluate the effectiveness of the intervention
2. Cohort study to evaluate the achieved effect on a long-term period
3. exploring analyses to examine sub questions being not the primary question in one of the above mentioned studies

Blinding:
There is blind rating of the tape recorded measurements. The raters are unaware of the fact on which moment in the studyperiod the tape is made.
The measurement scores will be processed and analysed blindly.

Research set-up and planning:
An individual child is participating the research during 24 weeks (first follow-up included). Children in group Fc are participating longer: 32 weeks.

After a final selection áll participants will have the base measurement 1 to 10 (t0).
The children are beginning the so called control period (Co). Before and after this 8 weeks period measurements take place (t0 en t1). Subsequently by randomisation the children will be divided in the experimental group (E) and the control group (C). Dependent on the effect of the interventions children will go on as Fc, Fe, Sc or Se.

Explanation of abbreviations:
Co Control period (standard treatment 2x a week)
R Randomisation
C Control group
E Experimental group
Fe Failures experimental group (see page 10)
Fc Failures control group (see page 10)
Se Success experimental group: progression on AHA = 25% (see page 9 required number of children)
Sc Success control group: progression on AHA = 25% (see page 9 required number of children)

t0 - t6 is time 0 to 6:

t0 to t1 = 8 weeks (control period)
t1 to t2 = 8 weeks (intervention)
t2 to t3 = 8 weeks (intervention for Fc, first follow-up for Fe, Se and Sc)
t3 to t4 = 8 weeks (1st follow-up for Fc after which intervention will follow)
t4 to t5 = 16 weeks (2nd follow-up for Fe, Se and Sc)

t5 to t6 = 16 weeks (2nd follow-up for Fc after which intervention will follow)

Intervention

In the 8 weeks experimental period (E) the children are attending the Pirate group for 3 hours during 3 afternoons a week to be treated according to the Forced use (FU) principles.
After 6 weeks the FU therapy stops.
The following 2 weeks the children will be attending the Pirate group were now bimanual play activities an ADL are presented according to a protocol.
After this period of 8 weeks the Pirate program is completed and next measurement will take place (t3)
After every therapy meeting a registration form will be filled in for every child to record what activities have been done (E/C group.

Protocol Forced use Therapy (first 6 weeks)

A sling will be individually made for every child before the Pirate group starts. A sling is a cloth in which the not affected arm rests in such manner that the arm, hand, fingers and thumb can*t be used. The children are told that they are pirates and their good arm is injured so it has to stay in the *bandage* (sling).

The sling will be put on during the 3hours of the *pirate afternoons* (3 times a week ; Mondays, Tuesdays and Thursdays) and during 6 weeks. They have to stay on the full afternoon.
Parents are provided with suggestions to stimulate the use of the affected arm/ hand at home in bimanual activities. The responsible therapist will use E-learning for these instructions/ suggestions.

The Pirate group activities are recorded in the Pirate Handbook. For two afternoons the emphasis lays on improving strength and mobility, one afternoon on fine motor skills.
To improve mobility the children with Zancolli IIb pattern will have to wear a ortheses at day-time (an individually made cock-up splint consisting of low temperature thermo plastic material (LTTP)(Verreussel, 2004)
The ortheses, if not yet provided, has to be manufactured before the start of the study.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age: 2 years - 8 years
Diagnose: spastic hemiparesis or asymmetrical tetraparesis
The more involved upper limb is used less (performance) as one should expect based on motor possibilities (capacities)

Exclusion criteria

Presence of a handfunctionimpairment on the affected side without perspectives of active handfunction (Zancolli IIB and III)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-10-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13146.091.06