Power Move: a randomized controlled pilot study on a computerized motor intervention program to improve motor function in very preterm children at 5 years of age

Published: 23-12-2016
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To investigate whether a computerized, motor intervention program, titled *Timocco* yields significant and clinically reliable improvements in motor function in very preterm children at five years corrected age (CA).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50580

Source
ToetsingOnline

Brief title
Power Move

Condition

- Other condition

Synonym
Motor problems

Health condition

ontwikkelingsstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Rotary Gooi en Vechtstreken 60.000;-

Intervention

Keyword: e-health, intervention, motor function, very preterm

Outcome measures

Primary outcome

Total score on the MABC-II-NL.

Secondary outcome

Secondary study parameters include visual-motor performance, attentional

functioning, school performance, and behavior of the child.

Visual-motor performance

- Balance board for balance skills

- Caterpillar Tracing task

- Beery Visual-Motor Integration test for visual-motor integration skills

Attentional functioning

- Stop signal task for inhibitory control, processing speed and variability in

speed

- Nutley visual working memory task for visual working memory

School performance

- Dutch Pupil Monitoring system scores

Behavior questionnaires parents

- Child Behavior Checklist (CBCL)

- Behavior Rating Inventory of Executive Function - preschool

- Early Language Scales

Behavior questionnaires teachers

- Teacher Report Form (TRF)

Study description

Background summary

At early school age, motor problems occur frequently in children born very preterm Existing effective interventions, such as physical therapy, yield short term benefits only and require parents and child to visit health care institutions. Home-based, child-friendly computer training to remediate motor problems in this population may be more easily accessible and longer lasting, however, is efficacy is unknown.

Study objective

To investigate whether a computerized, motor intervention program, titled *Timocco* yields significant and clinically reliable improvements in motor function in very preterm children at five years corrected age (CA).

Study design

Randomized waitlist-controlled intervention study.

Intervention

Timocco® home-based computerized motor training program (www.Timocco.com).

Study burden and risks

Children whose parents provided informed consent will be assessed three times: at FU (visit outpatient clinic for follow-up assessment at five years CA), at home before start of the first trainingsession and at T1 (within one week after the last training session). Both assessments include administration of tests motor function, visual-motor function, attentional functioning, and behavior. For the latter, parents and teachers will be asked to complete a questionnaire. The Timocco home-based motor training program will entail a 12 week period with three training sessions (±30 minutes each) per week. During a session, children have to move a colourful gaming ball in order to successfully accomplish game levels of various attractive games that are displayed on a computer screen. The study examines an intervention that we hope yields positive effects for children and parents. There is no risk related to participation and all study and Timocco related activities are non-invasive. The risk of participation is negligible.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Intervention and waitlist group: a standard score of <8 (<-1.0 SD) on the total scale or one of the subscales of the M-ABC-II-NL

Reference group 1 (children born premature without motor problems): children <32wk and/or <1500 grams, at 5 years CA with a standard score *8 on all the scales of the Movement Assessment Battery for Children-II-NL (MABC-II-NL)

Reference group 2 (children born at term): children born at term (>37wk) and with a birth weight of >2500 grams at the age of 5

Exclusion criteria

- severe vision problems
- diagnosis cerebral paresis, GMFCS II or higher
- IQ-score <70

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	22-02-2017
Enrollment:	232
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL58428.018.16
Other	Trial NL7568