Power Move: a randomized waitlist-controlled study on a computerized motor intervention program to improve motor function in very preterm children at five years of age’

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28071

Source
Nationaal Trial Register

Brief title
POWER MOVE

Health condition

motor problems after very preterm birth

Sponsors and support

Primary sponsor: Rotary Gooi en Vechtstreken
Source(s) of monetary or material Support: Rotary Gooi en Vechtstreken

Intervention

Outcome measures

Primary outcome

Total score on the M-ABC-II-NL

Secondary outcome

Secondary study parameters include visual-motor performance, executive and attentional functioning, language skills, school performance, and behavior of the child

Study description

Background summary

Rationale: 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 at least as effective.
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.
Study population: Children <320wk and/or <15000 grams, at 5 years CA with a standard score <8 (i.e. <1.0 SD) on the total scale or one of the subscales of the Movement Assessment Battery for Children-II-NL (MABC-II-NL).
Participating Centers: Academic Medical Centre Amsterdam, The Netherlands; VU University Medical Centre Amsterdam and University Medical Center Groningen
Intervention (if applicable): Timocco® home-based computerized motor training program.
Main study parameters/endpoints: Total score on the M-ABC-II-NL.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Children whose parents provided informed consent will be assessed three times: at follow-up (FU) at the outpatient clinic for follow-up assessment at five years CA, at home before start of the first training session (T1) and within one week after the last training session (T2). Both assessments include administration of tests for 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 colorful gaming ball in order to successfully accomplish game levels of various attractive games that are displayed on a computer screen. As a parent is required to support the child during the playful training session, this program is family-integrated.
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.

Study objective

Motor training with Timocco Training Program significantly improves motor function assessed by the M-ABC.

Study design

T0, T1

Intervention

Timocco® home-based computerized motor training program.

Contacts

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Eligibility criteria

Inclusion criteria

- a standard score of <8 (i.e.,<1.0 SD) on the total scale or one of the subscales of the M-ABC-II-NL (a standard score of <8 on the M-ABC-II-NL indicates difficulties with handwriting, aiming and catching, and poor balance skills. Children with severe motor impairments such as CP are not assessed with the M-ABC-II).

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	84
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	07-03-2019
Application type:	First submission

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
NTR-new	NL7568
Other	TIMOCCO Tel: 1-330-968-2879 526 South Main St. Suite 709A Akron, OH 44311 : METC 2016_259

Study results

Summary results
none yet