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’

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28071

Bron
Nationaal Trial Register

Verkorte titel
POWER MOVE

Aandoening

motor problems after very preterm birth

Ondersteuning

Primaire sponsor: Rotary Gooi en Vechtstreken
Overige ondersteuning: Rotary Gooi en Vechtstreken

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total score on the M-ABC-II-NL

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

T0, T1

Onderzoeksproduct en/of interventie

Timocco® home-based computerized motor training program.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	07-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
none yet