Arm training for boys with Duchenne muscular dystrophy.

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An assisted three-dimensional training of both arms could maintain arm functions in boys with Duchenne muscular dystrophy.

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

Samenvatting

ID

NL-OMON27200

Bron
Nationaal Trial Register

Verkorte titel
Arm training Duchenne

Aandoening

Duchenne muscular dystrophy
Training
Arm
Virtual reality computer game
Dynamic arm support

Ondersteuning

Primaire sponsor: Perfomer: Radboud University Nijmegen Medical Centre, department of rehabilitation
Overige ondersteuning: Duchenne Parent Project

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Motor Function Measure.

Toelichting onderzoek

Achtergrond van het onderzoek

Boys with Duchenne Muscular Dystrophy (DMD) lose their independency for several activities of daily life (ADL) soon after the onset of wheelchair-dependency due to muscle weakness of the upper extremity. Nowadays, there are promising modern arm-supports becoming available that re-enable patients with proximal arm weakness to functional use their arms by providing external mechanical compensation for muscle weakness of upper arm and shoulder. However, to make optimal use of these modern arm-supports patients should maintain joint mobility and muscle elasticity. Results from previous pilot studies indicate that assisted functional arm-training can delay the secondary functional deterioration caused by disuse. A three-dimensional (3D) training of both arms, starting at an early age, to maintain arm function could even be more useful but this has not been investigated yet.

Objective:

To determine whether 3D arm training with arm-support is effective in delaying the loss of arm functions in daily activities from an early age onwards in boys with DMD.

Study design:

Explorative Randomized Controlled Trial (RCT).

Study population:

20-30 ambulant or wheelchair-dependent boys with DMD with a functional status of Brooke 2 to 4 (i.e. some difficulties with raising the arms above the head, to difficulties with bringing a glass to the mouth).

Intervention:

Boys in the intervention group will receive an assisted 3D arm training for 24 weeks. They will train both arms during 15-min sessions for 5 days per week at home. Training will consist of a virtual reality game that stimulates the boys to use their arms in three directions while using an arm-support. The control group will receive the same intervention after their waiting list period.

Main study parameters/endpoints:

The primary outcome will be the Motor Function Measure (MFM).

Secondary outcomes will be: The Abilhand, the patient-related outcome measure questionnaire (PROM) joint range of motion (ROM), muscle echo intensity (EI), lab-based structured 3D movement analysis combined with surface electromyography (sEMG), accelerometry, a quality of life questionnaire, the Assisted Six-Minute Cycling Test (A6MCT) and the Performance for the Upper Limb for DMD (PUL).

Doel van het onderzoek

An assisted three-dimensional training of both arms could maintain arm functions in boys with Duchenne muscular dystrophy.

Onderzoeksopzet

Assessments of both the intervention and control group will be conducted during the screening period (screening 1), the baseline
period (T0: 2 weeks after screening 1), training (intervention group)/control (control group) period (T1: after 12 weeks training/waiting list, T2: after 24 weeks training/waiting list), and follow-up (intervention group)/training (control group) (T3:after 12 weeks follow-up/training, T4: after 24 weeks follow-up/training). The primary endpoint is T2 (after 24 weeks of training/waiting).

Onderzoeksproduct en/of interventie

The intervention group will receive a three-dimensional (3D) arm training for 24 weeks. Participants will train both arms during 15-min sessions for 5 days per week at home or at (special) school. Training will consist of a virtual reality game that stimulates the participants to use their arms in three directions while using an arm-support (Sling, Focal Meditech B.V.).

The control group will be on a waiting list.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A DNA-established diagnosis of DMD;

2. Ambulant or wheelchair-dependent and:

A. Able to raise arms (at least one arm) above head only by flexing the elbow (shortening the circumference of the movement) or using accessory muscles during 10 repetitions, or;

B. Unable to raise hands above head, but can raise an 8-oz glass of water to the mouth, or;

C. Able to raise both hands to the mouth, but cannot raise an 8-oz glass of water to the mouth.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. <7 years old;

2. Able to raise both arms 10 times above head without flexing the elbow or without using accessory muscles;

3. Presence of other disabling diseases influencing mobility;

4. A clinical symptomatic cardiomyopathy;

5. Unable to bring the hands to the mouth;

6. Participation in another intervention trial that aims to delay physical deterioration: in particular patients that already participate in an Antisense oligonucleotide (AON)-induced exon skipping study, which may alter the course of the disease.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37157
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3687
NTR-old	NTR3857
CCMO	NL41708.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37157

Resultaten

Samenvatting resultaten
N/A