Arm training for boys with Duchenne muscular dystrophy.

No registrations found.

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

Summary

ID

NL-OMON27200

Source
Nationaal Trial Register

Brief title
Arm training Duchenne

Health condition

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

Sponsors and support

Primary sponsor: Perfomer: Radboud University Nijmegen Medical Centre, department of rehabilitation
Source(s) of monetary or material Support: Duchenne Parent Project

Intervention

Outcome measures

Primary outcome

Motor Function Measure.

Secondary outcome

1. Joint range of motion;

2. Hand-held dynamometry;

3. Quantitative muscle ultrasound;

4. Abilhand-kids questionnaire;

5. PROM questionnaire;

6. Kidscreen-52 questionnaire (physical well-being domain);

7. Global health assessment;

8. Performance of Upper Limb module for Duchenne muscular dystrophy;

9. Assisted Six-Minute Cycling Test;

(10. Optional: Three dimensional movement analysis combined with surface electromyography).

Study description

Background summary

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).

Study objective

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

Study design

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37157
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A