# No Use is Disuse: what can we gain upon functionality with exercise in boys with Duchenne Muscular Dystrophy (DMD)?

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The primary objective of this project is to contribute to the knowledge of the optimal medical care of DMD patients with regard to the optimal level of physical activity by examining the effects of training primarily upon muscle endurance and/or the...

| Ethical review        | Approved WMO     |  |
|-----------------------|------------------|--|
| Status                | Pending          |  |
| Health condition type | Muscle disorders |  |
| Study type            | Interventional   |  |

# Summary

### ID

NL-OMON32290

**Source** ToetsingOnline

Brief title NUD study

### Condition

• Muscle disorders

**Synonym** Duchenne Muscular Dystrophy (DMD), muscular dystrophy

# Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Duchenne Parent Project

### Intervention

Keyword: Disuse, Duchenne Muscular Dystrophy, Functionality, Training

### **Outcome measures**

#### **Primary outcome**

Primary outcomes for study 1 will be muscle endurance and functional abilities

of the lower and upper extremities, as assessed with bicycle ergometry and the

Motor Function Measure (MFM). The primary outcome for study 2 will be

functional abilities of the upper extremity (reaching, lifting, manipulating),

as assessed with the Action Research Arm Test (ARAT).

#### Secondary outcome

Secondary outcomes for both studies will be at the level of body functions and

structures (e.g. muscle tissue), activities (e.g. activities in daily life) and

participation (e.g. health related quality of life).

# **Study description**

#### **Background summary**

"Use it or lose it" is a well known saying and is to some extent also applicable to boys with Duchenne Muscular Dystrophy (DMD). Boys with DMD have reduced muscle mass, muscle strength, muscle endurance and, therefore, loss of functionality. The increasing effort to perform certain activities, fear of falling and the need of personal aids (like an electric wheelchair) may limit leg and arm functions as a result of disuse. An important aim in the management of DMD is to preserve functional abilities as long as possible, since there is still no curative (pharmaco)therapy. It is hypothesized that, in the case of disuse, training may help to gain functional abilities or preserve them.

#### Study objective

The primary objective of this project is to contribute to the knowledge of the optimal medical care of DMD patients with regard to the optimal level of

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physical activity by examining the effects of training primarily upon muscle endurance and/or the functional abilities of boys in different stages in the course of DMD.

### Study design

The NUD study will consist of two studies: study 1 \*Dynamic leg and arm exercise training for ambulant or recently wheelchair confined boys with DMD\* and study 2 \*Functional training with arm support for boys with DMD who have been wheelchair confined for several years\*. Study 1 will be an explorative (randomized controlled) trial with multiple baseline measurements. Boys will be randomly assigned to either the intervention group or the control group (waiting list). Repeated measurements will be done during the first two months, followed by a six months training intervention period. The control group will get the same intervention after the waiting period. Study 2 will be a repeated measures design, starting with a two months period for baseline measurements, followed by a six months period in which a training intervention is given.

#### Intervention

The intervention of study 1 will consist of a low-to-moderate intensity dynamic exercise training. Boys will train their legs and arms with active-passive cycling equipment. The intervention of study 2 will be a functional training of the non-dominant arm and hand with arm support.

#### Study burden and risks

Burden associated with participation will be limited, since measurements are non-invasive. Most measurements will be done at home and training intensity and frequency will be relatively low. This low training intensity will also strongly reduce the risk of muscle damage. In addition, it is expected that the interventions are beneficial and may help to gain functional abilities or preserve them for a longer period. If the results are positive, the principles of this training may be applicable to other neuromuscular disorders.

# Contacts

#### Public Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4 6525 GG Nijmegen NL Scientific

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Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4 6525 GG Nijmegen NL

# **Trial sites**

# Listed location countries

Netherlands

# **Eligibility criteria**

#### Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

### **Inclusion criteria**

Study 1 'Dynamic leg and arm exercise training for ambulant or recently wheelchair confined boys with DMD':

- Boys with a DNA established diagnosis of Duchenne Muscular Dystrophy

- Boys who are at the end of their ambulation phase and experience difficulty in at least one of the following activities: walking at normal speed, climbing stairs at normal speed, raising from the floor

- Boys who are recently wheelchair confined (1-2 years after stop walking) and are able to stand (un)supported (eventually help needed), are able to touch the top of their head with both hands without assistance ;Study 2 'Functional training with arm support for boys with DMD who have been wheelchair confined for several years'

- Boys with a DNA established diagnosis of Duchenne Muscular Dystrophy

- Boys who are a few years wheelchair confined (2-5 years after stop walking)

- Boys who have problems with lifting their arms and reaching, and are unable to touch the top of their head, are able to use their hands for daily activities and experience difficulties in lifting their arms and reaching

# **Exclusion criteria**

Study 1'Dynamic leg and arm exercise training for ambulant or recently wheelchair confined boys with DMD':

- Other disabling diseases influencing mobility
- Boys with a clinical symptomatic cardiomyopathy

- Boys who are wheelchair confined and/or: are unable to stand and/or are unable to touch the top of their head with both hands

- Boys <=5 years old ;Study 2 'Functional training with arm support for boys with DMD who have been wheelchair confined for several years'

- Other disabling diseases influencing mobility
- Boys who are able to stand
- Boys who are unable to use their hands
- Boys >20 years old
- Boys who already use an arm support

# Study design

### Design

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

### Recruitment

| NL                        |             |
|---------------------------|-------------|
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-10-2008  |
| Enrollment:               | 40          |
| Туре:                     | Anticipated |

# **Ethics review**

#### Approved WMO

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| Application type:  |
|--------------------|
| Review commission: |

# **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
 NL21842.091.08