

Martial arts training for boys with Duchenne Muscular Dystrophy * a feasibility study.

Published: 11-03-2019

Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON45883

Source

ToetsingOnline

Brief title

Martial arts training for boys with DMD.

Condition

- Muscle disorders

Synonym

DMD, Duchenne Muscular Dystroph

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Duchenne Parents Project (patiëntenorganisatie)

Intervention

Keyword: Feasibility, Martial arts, Physical abilities, Psychosocial abilities

Outcome measures

Primary outcome

The primary outcome of our study is the feasibility of the exercise program, which we consider achieved as the mean adherence rate > 70% of the trainings sessions and no injuries or adverse effects occur.

Secondary outcome

Secondary outcome measures are: self-perception measured with the CBSK, strength measured with the hand-held dynamometer, passive range of motion measured with a goniometer, psychosocial questionnaires, quality of life questionnaire and functional scales.

Study description

Background summary

Duchenne muscular dystrophy (DMD) is a progressive X-linked disorder characterized by progressive muscle wasting and weakness, resulting in loss of functional abilities. Functional deterioration leads to loss of independence and a reduced quality of life. Previous studies have indicated that physical training programs delay functional deterioration. Nevertheless, the level of inactivity increases as boys and men with DMD get older. This results in reduced participation on both physical and social level. Therefore, a training program aimed at optimally using one's capacity, slowing down physical deterioration and improving psychosocial wellbeing, may have great benefits for boys and men with DMD. We think that a physical and psychosocial training program, based on martial arts, can have positive effects for boys and men with DMD.

Study objective

The primary objective of this study is to evaluate the safety and feasibility

of 3 months martial arts based training program for DMD patients. The secondary objective is to gain a first impression on the program's ability to optimally use one's capacity, slow down physical deterioration and improve psychosocial wellbeing, and to evaluate participant experiences and compliance, in order to see if there is a base to conduct the training on a broader scale.

Study design

Explorative feasibility study

Intervention

a 3 month martial arts based training program for DMD patients.

Study burden and risks

The risks associated with participation are negligible. The burden of participation is low, as the intervention consists of a 1.5 hour weekly training session, which is comparable to regular sport participation. Expected benefits are improved physical and psychosocial health.

Contacts

Public

Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6500 HB
NL

Scientific

Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

- DNA established diagnosis of DMD
- Able to touch the top of the head with both hands

Exclusion criteria

- Participants younger than 4 years
- Other disabling diseases influencing physical or psychosocial function
- Not being able to follow instructions or moderate to severe cognitive limitations (IQ<70)

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-08-2019

Enrollment: 12

Type: Actual

Ethics review

Approved WMO

Date: 11-03-2019

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL67757.091.18