IMproving FItness in NEuromuscular diseases

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Primary objective:(1) To evaluate the efficacy of a personally tailored physical activity program on the physical fitness of individuals with slowly progressive NMD, compared to usual care. Secondary objectives:(2) To evaluate the efficacy of a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON50618

Source
ToetsingOnline

Brief title
I'M FINE

Condition

- Neuromuscular disorders

Synonym
Neuromuscular diseases, NMD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: Exercise therapy, Neuromuscular diseases, Physical activity, Physical fitness

Outcome measures

Primary outcome

(1) Physical fitness

The primary endpoint will be the change in peak oxygen uptake directly after intervention.

Secondary outcome

(2) Daily activity

Measured through heart rate monitoring during 7 consecutive days, to establish the total time spent in low, moderate and vigorous intensity activities.
Activity monitors will be used to determine the total step count during the 7 day period and subjects will also be asked to keep an activity diary.

(3) Health-related quality of life

Assessed using the Dutch version of the Short Form 36-item Health Survey (SF36). The physical health component scores and mental health component scores will be calculated, using age-correlated means and standard deviations of a healthy Dutch population.

(4) Perceived physical functioning

Administered with the ACTIVLIM questionnaire. ACTIVLIM is a questionnaire on self-reported activity limitations that was validated using the Rasch model.
The questionnaire consists of 22 daily activities of which the perceived

difficulty in performing the activity is scored.

(5) Muscle strength

The maximal voluntary torque (MVT) of the upper extremities elbow flexors and shoulder abductors), or lower extremities (hip flexors, knee extensors and plantar flexors) will be determined, depending on the selected exercise mode for training. Subjects will perform three maximal-effort contractions at an angular velocity of 60°/sec on a fixed dynamometer (Biodex System 4, New York, USA. The highest value of peak torque (Nm) will be used for the analyses.

Creatine kinase will be determined from the blood sample.

(6) Markers of metabolic syndrome

Blood lipids and fasting glucose, assessed from blood samples and blood pressure.

(7) Self-efficacy

Self-efficacy will be assessed with the following question *How confident are you that you will be physically active in the following situations*, including feeling tired, bad mood, do not have the time, on vacation, and, want to be active outside, but bad weather, rated on a 5-point Likert scale (1=absolutely no confidence, 5=completely confident).

(8) Physical capacity

Assessed with the 6-min walk test (6MWT), or 6-min push test (6MPT) in case of

wheelchair-bound participants.

Study description

Background summary

There is strong evidence that physical activity has positive effects on physical and mental health, quality of life, and prevention of health problems in the general non-disabled population, and that physical inactivity is associated with a range of chronic diseases and early deaths. People with neuromuscular diseases (NMD) engage less in physical activity than non-disabled people, and generally represent a sedentary and deconditioned segment of the population. Although an increasing number of studies in slowly progressive NMD has demonstrated positive (short-term) effects of aerobic exercise on physical fitness, overall evidence is inconclusive due to several negative studies. It remains unclear what the optimal training approach is, and how to support successful transition from supervised exercise to home or community exercise to preserve an active lifestyle in the long term. Therefore, we developed the theory-based, personally tailored physical activity program I*M FINE (IMproving FItness in NEuromuscular diseases), combining aerobic training and a coaching program, for slowly progressive NMD, specifically focusing on post-polio and post-polio syndrome (PPS) and Charcot-Marie-Tooth disease (CMT).

Study objective

Primary objective:
(1) To evaluate the efficacy of a personally tailored physical activity program on the physical fitness of individuals with slowly progressive NMD, compared to usual care.

Secondary objectives:
(2) To evaluate the efficacy of a personally tailored physical activity program on daily activity, quality of life, physical functioning, muscle strength, markers of metabolic syndrome and self-efficacy in individuals with slowly progressive NMD, compared to usual care.
(3) To study underlying mechanisms of improving physical fitness and daily activity in individuals with slowly progressive NMD.

Study design

A multicenter, assessor-blinded, randomized controlled trial.

Intervention

Participants will be randomized (ratio 1:1) to the intervention group, receiving a 6-month personalized physical activity program according to the I*M FINE strategy, or a control group, receiving usual care.

Study burden and risks

All patients will be asked to visit the Academic Medical Center at 4 times over the study period of 18 months to collect a blood sample, participate in a physical examination and to fill out questionnaires. The duration of these examinations will be approximately 2 hours . Additionally, patients will be asked to wear a heart rate monitor for 7 consecutive days at the 4 different time measurements. There are no costs related to the interventions for the patients. To check for contra-indications for physical activity, a physician will thoroughly examine the participants according to the guidelines by the American College of Sports Medicine (ACSM) and a rest ECG will be reviewed by a cardiologist. All participating centers are well experienced in providing exercise therapy in patients with different neuromuscular diseases. Therefore, the occurrence of medical events is considered minimal. Considering the positive effects of exercise therapy known from preliminary research it can be concluded that the benefits outweigh the burden and minimal risk associated with this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) Prior paralytic poliomyelitis (confirmed by signs of residual weakness and atrophy of muscles on neuromuscular examination, and with EMG) or diagnosis of PPS (according to the March of Dimes criteria), CMT (confirmed by DNA testing or polyneuropathy compatible with CMT and positive family history), or other slowly progressive NMD (with no effective drug therapy).
(2) Presence of a question for help indicative of impaired physical fitness or physical inactivity.
(3) Minimum age of 18 years.

Exclusion criteria

(1) Contraindication for being physically active (according to the guidelines by the American College of Sports Medicine).
(2) Unable to follow verbal or written instructions.
(3) Insufficient mastery of the Dutch language.
(4) Engaged in an exercise program for a period longer than 4 weeks during the last 6 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-09-2018
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62104.018.17