IMproving FItness in NEuromuscular diseases

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It is hypothesized that this personally tailored physical activity program (I’M FINE intervention) will be more effective in improving physical fitness and enhance daily activity in individuals with slowly progressive neuromuscular diseases (NMD)…

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

Samenvatting

ID

NL-OMON20538

Bron
NTR

Verkorte titel
I’M FINE

Aandoening

Coaching, Motivational Interviewing, Aerobic exercise, Exercise therapy, Quality of life, Polio, Postpoliomyelitis syndrome, Charcot-Marie-Tooth, Neuromuscular diseases

Ondersteuning

Primaire sponsor: Amsterdam UMC, University of Amsterdam, Department of Rehabilitation, Amsterdam Movement Sciences, the Netherlands.
Overige ondersteuning: Prinses Beatrix Spierfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Physical fitness (peak oxygen uptake)

Toelichting onderzoek

Achtergrond van het onderzoek

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, 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).

Objectives:

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.

2. To evaluate the efficacy of a personally tailored physical activity program on daily activity, quality of life, perceived physical functioning, muscle function, 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.

Study population: Adult patients with prior poliomyelitis or PPS (n=30), CMT (n=30), or other slowly progressive NMD (n=30) with a question for help indicative of impaired physical fitness or physical inactivity, recruited from 5 different university hospitals and rehabilitation centers.

Intervention: The 90 patients will be randomized to the group receiving a 6-month personalized physical activity program or the group receiving usual care.

At baseline, post-intervention, and at 6- and 12-months follow-up peak oxygen uptake (CPET) and other secondary outcomes (e.g. daily activity, quality of life, metabolic syndrome markers) will be assessed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. To check for contra-indications for physical activity, a physician will thoroughly examine the participants. 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.

Doel van het onderzoek

It is hypothesized that this personally tailored physical activity program (I’M FINE intervention) will be more effective in improving physical fitness and enhance daily activity in individuals with slowly progressive neuromuscular diseases (NMD) compared to usual care.

Onderzoeksopzet

At baseline upon entry to the study (T0), directly following the 6-months intervention period (T1) and at 6 months (T2) and 12 months post-intervention (T3).

Onderzoeksproduct en/of interventie

- The intervention consists of a 6-month personalized physical activity program according to the I’M FINE strategy. This consists of a gradually increasing polarized home-based aerobic exercise program, with two low-intensity and one high-intensity session per week and a coaching program of 8-12 individual coaching sessions to identify and focus on individual beliefs and aims to promote a physically active lifestyle.

- The control group will receive usual care only.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Prior paralytic poliomyelitis (confirmed by signs of residual weakness and atrophy of muscles on neuromuscular examination, and with EMG) or diagnosis PPS (according to the March of Dimes criteria), Charcot-Marie-Tooth (confirmed by DNA testing or polyneuropathy compatible with CMT and positive family history), or other slowly progressive NMD (with no effective drug therapy).

- Presence of a question for help indicative of impaired physical fitness or physical inactivity.

- Minimum age of 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Contraindication for being physically active.

- Unable to follow verbal or written instructions.

- Insufficient mastery of the Dutch language.

- Engaged in an exercise program for a period longer than 4 weeks during the last 6 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-09-2018
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-11-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7344

Register	ID
NTR-old	NTR7609
Ander register	: Prinses Beatrix Spierfonds

Resultaten

Samenvatting resultaten
N/A