B-FIT! A guideline to individualized exercise in post-polio syndrome

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Primary objective:(1) To evaluate the efficacy of the B-FIT aerobic training program on physical fitness of individuals with PPS in the US and the Netherlands.Secondary objective:(2) To evaluate the patient and healthcare professional satisfaction...

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

Summary

ID

NL-OMON49100

Source
ToetsingOnline

Brief title
B-FIT international

Condition

- Neuromuscular disorders

Synonym
Post-polio syndrome, PPS

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Postpolio Health International (PHI)

Intervention

Keyword: Exercise therapy, Physical activity, Physical fitness, Post-polio syndrome

Outcome measures

Primary outcome

(1) Physical fitness

The primary endpoint will be the difference in peak oxygen uptake before- and directly post-intervention.

Secondary outcome

(2) Patient and healthcare professional satisfaction

An online survey will be developed to evaluate the patient and healthcare professional satisfaction with working according to the B-FIT aerobic training guidelines in the US and the Netherlands. The patient survey includes questions pertaining to the satisfaction with (1) the training program (e.g. feasibility, incorporation into daily life, intensity) and (2) the patient manual (e.g. clearness of instructions). The health care professional survey includes questions pertaining to the satisfaction with (1) the training program (e.g. possibility to use own clinical judgment and preferences), and (2) the therapist manual (e.g. clearness of instructions). Answers are rated on a 5-point Likert scale (1 = very poor, 5 = very good).

(3) 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.

(4) Perceived physical functioning

Perceived physical functioning will be 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) Health-related quality of life

Assessed using the Short Form 36-item Health Survey (SF36). The physical health component scores and mental health component scores will be calculated.

(6) Adherence

Heart rate monitors will be used during training sessions to gain data that will be used to establish the total time that participants train within their prescribed individual heart rate zones.

Study description

Background summary

In individuals with post-polio syndrome (PPS), symptoms of muscle weakness, fatigue and pain may lead to reduced physical activity and a sedentary lifestyle. Physical inactivity causes deconditioning (i.e. reduced physical fitness), which in turn, worsens health and physical functioning and threatens the independence of this ageing population. Successfully breaking this vicious circle of inactivity requires personally tailored physical activity programs

including aerobic exercise to improve physical fitness, but clear guidelines are lacking. Therefore, we recently developed the B-FIT training guidelinethat gives healthcare professionals and patients support in the prescription and evaluation of personalized aerobic training in PPS. B-FIT was successfully applied in a pilot study in rehabilitation centers in the Netherlands, demonstrating its potential for clinical practice. However, a more comprehensive study is required to determine the efficacy of the B-FIT training program to improve physical fitness in PPS and to evaluate the patient and healthcare professional satisfaction with the use of the B-FIT aerobic training guideline on a larger international scale.

Study objective

Primary objective:
(1) To evaluate the efficacy of the B-FIT aerobic training program on physical fitness of individuals with PPS in the US and the Netherlands.

Secondary objective:
(2) To evaluate the patient and healthcare professional satisfaction with the use of the B-FIT aerobic training guideline in individuals with PPS in the US and the Netherlands
(3) To evaluate the efficacy of the B-FIT aerobic training program on daily activity, quality of life and perceived physical functioning of individuals with
PPS in the US and the Netherlands.

Study design

A multicenter, single group, pre-post intervention study

Intervention

Participants will receive a 4-month personalized physical training program according to the B-FIT training guidelines, with two low intensity and one high intensity trianing session a week.

Study burden and risks

The intervention consists of a 4-month home-based training program, with 2 low intensity sessions and 1 high intensity session per week. Study assessments take place at baseline (T-1, T0), directly after intervention (T1) and 3 months after intervention (T2). During assessments, participants perform an exercise tests and fill out questionnaires. The duration of these assessments will be approximately 1.5 hours. Additionally, patients will be asked to wear a heart rate- and step count monitor for 7 consecutive days directly after T0, T1 and T2. To check for contra-indications for exercise, a physician will thoroughly

examine the participants according to the guidelines by the American College of Sports Medicine (ACSM). The study patients are recruited in PPS centers of excellence in the Netherlands and the United States. In the Netherlands, all outcome research and training program- related visits are conducted at the Amsterdam UMC, location AMC. The AMC is 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)

Inclusion criteria

(1) - prior paralytic poliomyelitis (confirmed by signs of residual weakness

and atrophy of muscles on neuromuscular examination, or with EMG) with or without diagnosis of PPS (according to the March of Dimes criteria)
(2) Presence of a question for help indicative of impaired physical fitness
(3) Indication of physical inactivity
(4) Ability to achieve a Borg score of 14 or higher during the incremental exercise test
(5) Minimum age of 18 years

Exclusion criteria

(1) Contraindication for exercise (based on 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-10-2019
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2019
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2020
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	NL69962.018.19