Personalized RehabilitatiOn in severly Fatigued patients with Idiopathic inflammatory myopaThies: a pilot randomized controlled trial

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To answer the following questions; (1) What is the estimated effect size of personalized rehabilitation therapy for improving daily functioning in severely fatigued myositis patients, compared to usual care? (2) What are the societal costs of...

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

Summary

ID

NL-OMON56514

Source
ToetsingOnline

Brief title
PRO-FIT

Condition

- Autoimmune disorders
- Muscle disorders

Synonym
inflammatory myopathy, myositis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cognitive behavioural therapy, exercise therapy, fatigue, idiopathic inflammatory myopathies

Outcome measures

Primary outcome

The primary endpoint will be the change in daily functioning from baseline to

directly post-intervention, as assessed by the performance score of the

Canadian Occupational Performance Measure (COPM).

Secondary outcome

-Daily functioning - satisfaction

Assessed with the satisfaction score of the Canadian Occupational Performance

Measure (COPM).

-Fatigue

Assessed with the Checklist Individual Strength (CIS), subscale fatigue.

-Physical fitness

For physical fitness we will determine the maximal oxygen uptake as assessed

through cardiopulmonary exercise testing.

-Daily activity

Measured through synchronous heart rate monitoring and accelerometry during 7

consecutive days, to establish the total time spent in low, moderate and

vigorous intensity activities. Subjects will also be asked to keep an activity

diary.

-Disability

Assessed with the Health Assessment Questionnaire.

-Quality of life

Assessed with the EQ-5D-5L questionnaire.

-Anxiety and depression

Assessed with the Hospital Anxiety and Depression Scale (HADS)

-Societal costs

We assess costs from a societal perspective meaning that we include all costs regardless of who pays for them. Societal costs include: healthcare costs (e.g., hospital admissions, medication use, general practitioner visits); patient and family costs (e.g. informal care); and lost productivity costs (absenteeism from paid and unpaid work, presenteeism related to paid work). Costs of the personalized rehabilitation therapy will be estimated using a bottom-up micro-costing approach in which each component of the therapy will be estimated and valued in Euros.

Study description

Background summary

Myositis is the most prevalent acquired muscle disorder in adults and affects 100.000 people in Europe. Despite an initial favorable effect of immunosuppressive treatment most people suffer from long-standing disability. Severe fatigue is highly prevalent (70-90%) during this chronic phase, leading to decreased daily functioning, participation and quality of life. Disease related costs are 3 to 5 times higher than in the general population, with a significant contribution attributable to indirect costs. This warrants development of interventions to improve function and return-to-work. Cognitive behavioral therapy (CBT) and Exercise Therapy (ET) are promising rehabilitation interventions that have shown to be effective in muscular dystrophies.

Personalized rehabilitation therapy, including remotely delivered CBT, ET, or both is likely to be (cost)effective compared to usual care in the chronic phase of myositis. A pilot study is first needed to estimate the effect size of the intervention.

Study objective

To answer the following questions; (1) What is the estimated effect size of personalized rehabilitation therapy for improving daily functioning in severely fatigued myositis patients, compared to usual care? (2) What are the societal costs of personalized rehabilitation therapy compared to usual care amongst severely fatigued myositis patients?

Study design

A multicenter, assessor-blinded, pilot randomized controlled trial.

Intervention

Participants will be randomized (ratio 1:1) to the intervention group, receiving 6-months personalized rehabilitation therapy including either CBT or ET, or both, or a control group, receiving usual care.

Study burden and risks

All participants will be asked to visit the Amsterdam UMC, location AMC at 3 times over the study period of 6 months. The first visit is the screening visit with an estimated duration of 1 hour, to: fill out the CIS-Fatigue questionnaire and to participate in a physical examination (including resting ECG). The second (T0, baseline) and third visit (T1, directly post-intervention) are the assessment visits with an estimated duration on 2 hours each, for: assessment of the COPM, filling out the other study questionnaires, and conduction of the maximal exercise test. The total duration of all procedures is estimated at 5 hours (excluding travel time). Additionally, all patients will be asked to wear a heart rate monitor and accelerometer for 7 consecutive days following the 2 assessment visits (T0 and T1). For participants allocated to the intervention group there is an additional time investment (see intervention section). There will be pre-cautions to minimize potential risks related to the intervention, including a screening procedure to ensure safety of physical exercise and clear instructions on when to stop exercising. The participating centers are well experienced in providing ET and CBT in people with IIM. Therefore, the occurrence of medical events is anticipated to be minimal. Considering the positive effects of ET and CBT known from preliminary research it can be concluded that the benefits outweigh the burden and minimal risk associated

with this study.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >=18 and <68 years
• Idiopathic inflammatory myopathy according to EULAR/ACR criteria, except inclusion body myositis
• Disease duration >=12 months from diagnosis
• Severe fatigue as assessed by a score of >=35 on the subscale fatigue of the Checklist Individual Strength (CIS-Fatigue)

Exclusion criteria

• Unstable disease/evidence of disease activity as assessed by increase in dosage of immunosuppressant/modulating therapy/therapies < 3 months
• Co-morbidity interfering with the intervention or influencing outcomes, e.g. severe anaemia, abnormalities in thyroid function, or contraindications for being physically active according to the guidelines by the American College of Sports Medicine
• Unable to complete study questionnaires or interventions
• Participation in another trial interfering with the intervention or influencing outcomes

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-07-2024
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	07-02-2024
Application type:	First submission
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	NL84987.018.23