Energetic, a self-managment group program aimed at reconditioning and participation in persons with an muscle disease; a randomized controle trial.

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To evaluate the effectiveness and cost-effectiveness of Energetic. Secondary objectives include evaluation of barriers and facilitators for implementation of Energetic in other settings.

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

Summary

ID

NL-OMON41003

Source
ToetsingOnline

Brief title
The Energetic study

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
Muscle disease, neuromuscular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW;revalidatiefonds;Lectoraat Neurorevalidatie

Intervention

Keyword: Effectiveness, Muscle disease, Participation, Reconditioning

Outcome measures

Primary outcome

Social participation is evaluated with the Canadian Occupational Performance Measure (COPM) as primary outcome measure.

Secondary outcome

The Activity Card Sort (ACS), 6 minute walking test (6MWT) and Checklist Individual Strength subscale fatigue (CIS-Fatigue) and General Self- Efficacy Scale (GSE) are secondary measures Also a health diary (health care costs and sick leave) is kept by all participants in the study.

Efficiency is studied from a societal perspective calculating costs and quality adjusted life years.

Study description

Background summary

Fatigue is present in at least 60% of the patients with a muscle disease and can be the most disabling symptom. In combination with other impairments, this often results in low levels of physical activity and decreased social participation, leading to large societal costs. Energetic is a self-management group program aimed at improving social participation and physical endurance. Our hypothesis is that Energetic results in , improved participation and physical endurance and quality of life without increasing health care costs

compared to usual care.

Study objective

To evaluate the effectiveness and cost-effectiveness of Energetic. Secondary objectives include evaluation of barriers and facilitators for implementation of Energetic in other settings.

Study design

Randomized controlled multicenter trial comparing persons participating in Energetic with a control group receiving usual care. Eligible persons are allocated at random to the intervention or control group (waiting list). Outcome measures are recorded before randomisation, at the end of the program (after 16 weeks), at 3 and 12 months follow-up.

Intervention

The Energetic program lasts 16 weeks: the first 9 weeks sessions twice a week and the last 7 weeks once a week. The program includes four modules: 1) tailored aerobic exercise training; 2) education about aerobic exercise; 3) self-management training in applying energy conservation strategies; and 4) implementation and relapse prevention in daily life. In this program, next of kin will also be involved. At three months follow-up a recall session is organized.
During the first year 5 groups (5 persons each) will follow Energetic, 2 at the Radboud University Medical Centre and (after education) 2 groups at rehabilitation centre Groot Klimmendaal and one group in a community health centre. In the second year follow-up measurements will take place and results will be analyzed and presented.

Study burden and risks

The burden includes the frequent visits for the intervention (twice a week for 9 weeks and once a week for another seven weeks). By then persons are encouraged to continue training in their own environment. Participants are also expected to do home exercises. As their cardiopulmonary condition is stable there are no risks associated with participation in Energetic.

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

-Adults between 18 and 65 years of age
- Having one of the following muscle diseases: FascioScapuloHumeral Dystrophy (FSHD), Inclusion Body Myositis (IBM), or Mitochondrial Myopathy (MM) (n=30) or other neuromuscular diseases (n=20)
- Being severely fatigued (CIS-fatigue > 35);
-Being cardiopulmonary stable and capable of aerobic training (as determined using a Submaximal cycling exercise test with ECG (electrocardiography) and advice from a consultant cardiologist and pulmonologist);
- Being motivated, committed to the program and *ready to change* which is discussed with the patient during the screening by a rehabilitation physician and an occupational therapist; using motivational interviewing tools (advantages /disadvantages matrix; a visual analogue scale, VAS, to rate the importance of participation in de program and a VAS to rate the confidence the
patient has that participation in the program is feasible for them)
- Being able to formulate at least 2 individual participation goals during the interview with the occupational therapist.

Exclusion criteria

- Active depression or other psychiatric disorder as indicated by a consultant psychologist or by the medical history.
- Pregnancy,
- Limited life expectancy (< 5 years) due to known co-morbidity.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-08-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	18-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-03-2015
Application type:	Amendment
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	NL47624.091.14