Lifebalance; an important outcome for fatigue management in neuromuscular diseases

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Primary objective: To evaluate effectiveness, directly after intervention, of an individual face to face Managing Fatigue program on participation for people with NMD, including FSHD or MM compared to a control group receiving usual care.Secondary...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON48997

Source
ToetsingOnline

Brief title
LiBaS: LifeBalance Study

Condition

- Neuromuscular disorders

Synonym
Facioscapulohumeral dystrophy (FSHD) and Mitochondrial myopathy (MM)

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Spier Fonds

Intervention

Keyword: Fatigue management, Lifebalance, Neuromuscular diseases, Rehabilitation

Outcome measures

Primary outcome

The primary outcome will be participation in activities measured with the Canadian Occupational Performance Measure, COPM (performance and satisfaction scales).

Secondary outcome

Secondary outcomes will be activity balance and life balance (Activity Calculator, AC, Activity Card Sort-Dutch version, ACS-NL(18-65)) and life balance (Occupational Balance Questionnaire, Dutch version, OBQ-NL); fatigue (Checklist Individual Strength-subscale fatigue, CIS-fatigue); participation (Utrecht Scale for Evaluation of Rehabilitation-Participation, USER-P); health status (General Health Questionnaire, GHQ); quality of life (Short Form-36, SF-36); and self-efficacy regarding implementation of energy conservation strategies (Self-Efficacy in Performance of Energy Conservation Strategies Assessment, SEPECSA).

Study description

Background summary

About 60% of persons with neuromuscular diseases (NMD) experiences chronic fatigue. Fatigue management programs, like the occupational therapy program *Managing Fatigue* support persons to plan, pace and prioritize activities and to find a balance in activities in daily life. A group intervention on managing fatigue has been developed and tested in different populations including multiple sclerosis. However, not everyone has access to such a group program.

Recent studies on a one-to-one fatigue management courses have shown mixed results, but have merely been tested among people with MS. There are no studies available for individual *Managing fatigue* programs for people with neuromuscular diseases (NMD) such as facioscapulohumeral dystrophy (FSHD) or mitochondrial myopathy (MM).

Study objective

Primary objective: To evaluate effectiveness, directly after intervention, of an individual face to face Managing Fatigue program on participation for people with NMD, including FSHD or MM compared to a control group receiving usual care.
Secondary objectives:
To evaluate effectiveness, directly after intervention, of an individual face to face Managing Fatigue program on participation, fatigue, life balance and quality of life for people with FSHD or MM compared to a control group receiving usual care.
To evaluate the effectiveness, at six and twelve months after baseline of an individual face to face Managing Fatigue program on participation, fatigue, life balance and quality of life for people with NMD, including FSHD or MM compared to a control group receiving usual care.

Study design

Study design A randomised clinical trial (RCT) will be conducted comparing the personalized, individual face-to-face program Managing Fatigue (next to usual care) with a control group receiving usual care excluding occupational therapy.

Intervention

The individualized one-to-one face-to-face program, MF, consists of education, practice, evaluation and implementation of energy conservation strategies in daily life. Following education, persons are invited to gain experience with the strategies and discuss the successes and barriers experienced. Whereas this intervention was originally developed as a group intervention, in the Life Balance Study (Libas) this intervention will be delivered as a individual face to face intervention, delivered by occupational therapists in primary care.

Study burden and risks

Burden and risks for the participants Participants in the intervention group (n=30) will receive 6-10 sessions of the Managing Fatigue program. This program will be delivered individually face-to-face by an occupational therapist in the patients* own environment. The intervention includes education, practice and homework assignments. The thirty participants in the control group will receive care as usual, but no occupational therapy during the time of the study. All

participants will complete the outcome measures at four measurement moments: at baseline (before the intervention), and at three, six and twelve months after baseline (post intervention). The measurements will take place at the participants* home by interview (estimated time for each interview 2 hours) and by mailed questionnaires (digital or paper, estimated time is 45 minutes per measurement moment). There are no medical risks involved.

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

- age 18 years or older;
- diagnose: FacioScapuloHumerale Dystrofie (FSHD) or Mitochondrial Myopathy (MM);
- sufficient command of Dutch language, to be able to fill in questionnaires;

- Checklist Individual Strength- fatigue (CIS-Fatigue) * 35, indicating severe fatigue

Exclusion criteria

- depression or other major psychiatric disorders
- severe cardiorespiratory and/or onclological disease limiting life expectance or independency in daily life

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	05-09-2019
Application type:	First submission
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	NL61389.091.19