Life Balance: Intervention study

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To evaluate experiences with and fidelity to the individually delivered Managing Fatigue (MF) program of community based occupational therapists and patients with FSHD or MM. Secondary aims:Participants:- To detect which strategies of the MF program...

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

Summary

ID

NL-OMON49896

Source
ToetsingOnline

Brief title
LiBaS-I: Life Balance Study- Intervention

Condition

- Neuromuscular disorders

Synonym
Facioscapulohumeral dystrophy (FSHD) and Mitochondrial myopathy (MM): neuromuscular diseases

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fatigue management, Lifebalance, Neuromuscular diseases, Rehabilitation

Outcome measures

Primary outcome

Outcome measurements:

- Inclusion criteria fatigue: Checklist Individual Strength-subscale fatigue

(CIS-fatigue);

- Goal setting and evaluation: Participation in activities: COPM;

- Self-efficacy regarding implementation of energy conservation strategies:

SEPECSA.

Secondary outcome

n.a.

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 course have promising results, but have merely been tested among people with MS. There are no studies available for individual *Managing fatigue* programs for people with facioscapulohumeral dystrophy (FSHD) or mitochondrial myopathy (MM) experiencing chronic fatigue.

Study objective

To evaluate experiences with and fidelity to the individually delivered Managing Fatigue (MF) program of community based occupational therapists and patients with FSHD or MM.

Secondary aims:

Participants:
- To detect which strategies of the MF program are considered valuable for participants and are being implemented in the participant*s situation.
- To evaluate barriers and facilitators to adhere to the program and to implement the strategies in daily life
- To detect which elements of Managing fatigue are missing in the MF program
- to evaluate experiences with face to face delivery and/or delivery using videocalls
Therapists:
- To evaluate which skills and knowledge therapists need, to be able to deliver the MF program.
- To detect barriers and facilitators to deliver the MF program.
- To evaluate considerations and choices made to deliver the program face-to-face or using videocalls.

Study design

A mixed method study with qualitative and quantitative methods:
- interviews and focus groups to evaluate therapists* and participants* experiences with and fidelity to the MF program;
- log books and questionnaires on delivery and fidelity to the program;
- semi-structured interview using the Canadian Occupational Performance Measure (COPM) to assist in goal setting and evaluation of the intervention and
- a questionnaire called the Self-Efficacy in Performance of Energy Conservation Strategies Assessment. (SEPECSA)

Intervention

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

Study burden and risks

Participants (n=30) will receive 6 to 10 sessions of the Managing Fatigue program. This program will be delivered individually face-to-face or online (videocall) by an occupational therapist in the patient*s own environment. The intervention involves education, practice and homework assignments. Assessments supporting the program (COPM and SEPECSA) will take place at the beginning and ad the end of the intervention (twelve weeks after start of intervention). The measurements are non-invasive and will take place at the participants* home or

by videocall. Evaluation includes participation in interviews (at participant*s home or by videocall). Sixteen participants will be invited to take part in an interview to share their experiences with the intervention. There are no medical risks involved.
The therapists involved will be invited to participate in focusgroups (2 groups of 8 therapists each) to evaluate the delivery and experiences with the MF-program.

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 MitochondrialMyopathy (MM);
- be able to formulte at least 3 goals regarding fatigue management in daily

life
- sufficient command of Dutch language, to be able to fill in questionnaires;
- Checklist Individual Strength- fatigue (ClS-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

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2021
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	NL78368.091.21