Life Balance Study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29479

Source
NTR

Brief title
LiBaS

Health condition

Neuromuscular diseases
Spierziekten

Fascio Scapulo Humeral Dystrophy FSHD
Fascioscapulohumerale dystrofie FSHD

Mitochondrial Myopathy MM
Mitochondriële myopathie MM

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Outcome measures

Primary outcome

Self-perceived participation measured with the COPM (Canadian Occupational Performance

Measure)

Secondary outcome

- Activity balance (Activity Calculator, AC; Activity Card Sort-NL(18-65), ACS_NL(18-65) and life balance (Occupational Balance Questionnaire, OBQ

- fatigue (Checklist Individual Strength-fatigue, CIS-fatigue);

- participation (Utrecht Scale for Evaluation of Rehabilitation-Participation, USER-P);

- health status (General Health Questionnaire, GHQ);

- quality of life (Short Form Health Survey-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

The Lifebalance study is a randomised clinical trial and evaluates the effectiveness of a personalized, individual face-to-face program ’Managing Fatigue’ to improve participation (Canadian Occupational Performance Measure / COPM) in people with FSHD and MM who experience chronic fatigue in daily life.

Study objective

A personalized, individual face-to-face program ’Managing Fatigue’ is effective to improve participation in people with FSHD or MM who experience chronic fatigue.

Study design

T0: baseline, before intervention

T1: 3 months after start of intervention

T2: 6 months after start of intervention

T3: 12 months after start of intervention

Intervention

Intervention group

Participants in the intervention group will receive a personalized individual face-to-face program ’Managing Fatigue’ (Packer, Brink et al. 1995). The Program ‘Managing Fatigue’ consists of education, practice, evaluation and implementation of energy conservation strategies in daily life. As occupational therapy is a client centred therapy, the intervention will be tailored to the clients’ individual goals and needs.

Control group

Patients in the control group will not receive any occupational therapy or other therapy treating fatigue problems until their last measurement (12 months after baseline). The control group will receive care as usual.

Contacts

Public
Radboudumc
Leenders J.M.P.
Nijmegen
The Netherlands
+31 24 3668185
Scientific
Radboudumc
Leenders J.M.P.
Nijmegen
The Netherlands
+31 24 3668185

Eligibility criteria

Inclusion criteria

- Diagnosed with FSHD or MM,

- age ≥ 18 years,

- severe fatigue, confirmed by the CIS-Fatigue ≥ 35,

- sufficient mastery of the Dutch language to participate in conversation with the therapist, and

- informed consent (written)

- able to identify, using the COPM, at least three problems in occupational performance that they wish to improve.

Exclusion criteria

- patients with co-morbidity with symptoms that include severe fatigue;

- co-morbidity that interferes with actively taking part in the intervention sessions (e.g. severe psychiatric diagnoses or people with limited life expectancy);

- current involvement in other intervention studies where improvement of fatigue is a possible outcome;

- having received occupational therapy that focused on fatigue management, in the previous twelve months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	48
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL7026
NTR-old	NTR7231
CCMO	NL2018-4152

Study results

Summary results
Not published yet