The efficacy of cognitive behavior therapy and aerobic exercise training for decreasing experienced fatigue in patients with facioscapulohumeral dystrophy.

Published: 28-10-2008
Last updated: 11-05-2024

The primary objective is to study the efficacy of AET and CBT in decreasing experienced fatigue in patients with FSHD. Secondary objectives are (1) to identify generic and disease-specific determinants of effects, (2) to evaluate the effect of CBT…

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

Summary

ID

NL-OMON32128

Source
ToetsingOnline

Brief title
FACTS2NMD

Condition

- Muscle disorders

Synonym
facioscapulohumeral muscular dystrophy, Landouzy Dejerine

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cognitive behavior therapy, experienced fatigue, facioscapulohumeral muscular dystrophy, physical fitness

Outcome measures

Primary outcome

At baseline, after conclusion of the intervention and after 3 and 6 months

follow-up experienced fatigue will be assessed by the subscale fatigue of the

Checklist Individual Strength

Secondary outcome

aerobic exercise tolerance

muscle strength

cardiovascular risk factors

limitations in autonomy and participation

objective and subejctive phyiscal activity in daily life

pain

fall incidence

psychological well being and sleeping pattern

self perceived functional status

coping style

illness cognitions

perceived control or self efficacy

motivation

concentration

social support

experienced fatigue of first relative

caregiver strain

optional:

metabolic profile of muscles, blood and urine

Study description

Background summary

In facioscapulohumeral dystrophy (FSHD) muscle function is impaired and declines over time. Currently there is no effective therapeutic treatment available for FSHD. Loss of muscle strength contributes to experienced fatigue through a lower level of physical activity. Fatigue and physical inactivity determine social dependency and loss of participation. Therefore, to decrease experienced fatigue and improve quality of life, two distinctly different therapeutic approaches can be followed: aerobic exercise training (AET) to maintain functional capacity or a cognitive-behavioral approach (CBT) to stimulate an active life-style yet avoiding excessive physical strain. There is preliminary evidence for the effectiveness of aerobic exercise in FSHD. CBT has been proven effective in chronic fatigue syndrome and post-cancer fatigue. AET and CBT are hypothesized to be both more effective in improving activity level and, with that, decreasing experienced fatigue of FSHD patients compared to the usual care. The maintenance of the beneficial effects of CBT may be longer than those of AET, because the changes in activity level are achieved more intrinsically.

Study objective

The primary objective is to study the efficacy of AET and CBT in decreasing experienced fatigue in patients with FSHD. Secondary objectives are (1) to identify generic and disease-specific determinants of effects, (2) to evaluate the effect of CBT and AET in reducing fall incidence, (3) to obtain insight into patients* expectations of, and experiences with both interventions and compare these with health care professionals* views and experiences.

Study design

a randomized controlled trial.

Intervention

one group will receive AET consisting of 3 days a week aerobic cycling exercise for a period of 16 weeks. Twice a week they will exercise at home and once a week individually guided in group sessions in a rehabilitation centre. The second group will receive a maximum number of 16 sessions of CBT during 16 weeks for treatment of the factors maintaining the fatigue. The third group will receive care as usual, for 16 weeks and will be placed on a waiting list. They will be randomized to one of the training groups after 7 months.

Study burden and risks

There are very little risks associated with participation, as none of the interventions or clinical measurements are invasive. The proposed tehrapies have little to none known side-effects. The safety standards for training are strictly followed.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
6525 GC Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
6525 GC Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) aged 18 years and older
(2) a life-expectancy longer than one year
(3) suffering from severe experienced fatigue (i.e. a score on the CIS-fatigue >= 35)
(4) ability to walk independently (ankle-foot orthoses and canes are accepted)
(5) being able to exercise on a bicycle ergometer
(6) being able to complete the intervention

Exclusion criteria

(1) cognitive impairment
(2) insufficient mastery of the Dutch language
(3) disabling co-morbidity interfering with the intervention programs or influencing outcome parameters
(4) pregnancy
(5) use of psychotropic drugs (except simple sleeping medication)
(6) severe cardiopulmonary disease (chest pain, arrhythmia, pacemaker, cardiac surgery, severe dyspnoea d* effort, emphysema)
(7) epileptic seizures
(8) poorly regulated diabetes mellitus or hypertension
(9) clinical depression, as diagnosed with Beck Depression Inventory for primary care (BDI-PC) (Arnau et al. 2001) (Beck et al. 1997)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-10-2008
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	NL23082.091.08