Cognitive-behavioral therapy and exercise training to treat fatigue in Sjögren*s syndrome, non-Sjögren*s sicca syndrome, rheumatoid arthritis and systemic lupus erythematosus, a randomized controlled trial

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

Summary

ID

NL-OMON41248

Source
ToetsingOnline

Brief title
Management of fatigue in rheumatic diseases

Condition

- Autoimmune disorders

Synonym
non-Sjögren's sicca syndrome, rheumatic diseases consisting of chronic fatigue, rheumatoid arthritis and systemic lupus erythematosus, Sjögren's syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Samenwerking Universiteit Utrecht en Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Dutch Arthritis Association (Reumafonds)

Intervention

Keyword: Cognitive-behavioral therapy, Exercise training, Fatigue, Rheumatic diseases

Outcome measures

Primary outcome

Fatigue

Secondary outcome

Physical functioning, mental wellbeing, subjective and objective dryness of the

eyes and mouth, physical activity, sleep,

Study description

Background summary

Invalidating fatigue is a prevalent and debilitating symptom of syndromes in which key symptoms are dryness of the eyes (keratoconjunctivitis sicca) and mouth (xerostomia). Examples are Sjögren's syndrome and non-Sjögren*s sicca syndrome, but also rheumatic diseases such as rheumatoid arthritis and systemic lupus erythematosus. Although fatigue is indisputably an adverse consequence of the diseases, to target fatigue cognitive-behavioural therapy combined with exercise training is most promising. In other diseases and syndromes, this combined therapy has been shown successful, but such interventions have as yet not been evaluated in rheumatic diseases. In this study, a psychological intervention aimed at the reduction of fatigue will be tested.

Study objective

The aim of the study is to examine in 144 patients with primary Sjögren*s syndrome, non-Sjögren sicca syndrome, rheumatoid arthritis and systemic lupus

erythematosus, whether a intervention consisting of cognitive-behavioural therapy combined with exercise training will improve fatigue. Three groups of 48 patients each (primary Sjögren's syndrome, non-Sjögren sicca syndrome, rheumatoid arthritis and systemic lupus erythematosus) will participate: a treatment group, a waiting-list control group, and a non-treatment group. We expect that the intervention will improve fatigue.

Study design

An open randomised controlled trial with three repeated (pre- and post intervention and six months follow-up) assessments in a treatment group and a waiting-list control group matched on age and gender. For comparison purposes, all assessments will also be taken in a non-treatment group with no intention to treat, but otherwise similar to the groups with an intention to treat, to examine differences in the course of fatigue, disease activity and psychological factors.

Intervention

Patients in the treatment group receive a structured outpatient treatment program in a group setting of 6-8 participants. Treatment consists of 16 twice-weekly sessions and one booster session three months after treatment completion, with every regular session starting with two hours of cognitive behavioral therapy, followed by two hours of exercise training. The patient*s partner (or other significant relation) will be invited by the patient to attend the third, ninth and fifteenth session. The treatment focuses on diminishing the daily perceived cognitive, behavioral, emotional and social consequences of fatigue and accompanying symptoms. Every session, guided by a cognitive behavioral therapist, starts with discussion of the assignments that were trained at home, then the specific topic of the session will be introduced and practiced with the other participants, and finally the homework for the next session will be explained. The cognitive behavioral therapy will focus on realistic goal setting, a balanced daily activity program, cognitive restructuring techniques, and assertive social skills. The exercise training, led by physiotherapists, aims to increase the level of physical fitness and flexibility. Each exercise session consists of relaxation training, aerobic exercises (e.g., cycling, gymnastic exercises), and hydrotherapy or anaerobic exercises (e.g., strength and flexibility exercises, functional walking training). During the exercise training, patients learn to gradually and systematically increase their daily exercises.

Study burden and risks

The study will not involve risks for the participants, but a significant time investment is asked from the participants, who will come twice a week to the therapeutic center for an intervention of 4 hours each. During the blood

examination at baseline, there is a slight risk of excessive bleeding, fainting or feeling light-headed, hematoma, or an infection. The completion of questionnaires at three time points is a small burden. A benefit of participation is the possible reduction of fatigue and improvement of quality of life (wellbeing and functioning).

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

- Patients >= 18 years. Patients with Sjögren's syndrome fulfill the European criteria for classification (Vitali et al., 2002). Patients in whom no other cause for dryness was found and who did not fulfill the European classification criteria of Sjögren syndrome, are classified as non-Sjögren's sicca syndrome. Patients with rheumatoid arthritis fulfill ACR criteria (Amett et al., 1988). Patients with systemic lupus erythematosus fulfill the ACR criteria (Tan et al.,

1982).
- A score >= 14 on the Multidimensional Fatigue Inventory (MFI) in a previous questionnaire study (ID = NL24985.041.08);
- No medication or stable use of regular medication during the intervention;
- Motivated to participate in a cognitive-behavioural therapy combined with exercise training.

Exclusion criteria

- Participation in other (recent) interventions which can possible effect fatigue (i.e. start of using anti-depressants during the last half year, or participating in a pharmacological trial);
- Pregnancy or wish to become pregnant the upcoming year;
- Physical inability to participate in the intervention;
- Severe psychopathology;
- Illiteracy or difficulty to communicate in Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2013
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2011
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-03-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC NedMec

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	NL34073.041.10