Exploring the effects of a combined exercise programme on pain and fatigue outcomes in patients with systemic sclerosis: A large multi-centre randomised controlled trial

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To assess the effect of a previously-established, supervised 12-week combined (aerobic and resistance training) exercise programme on pain and fatigue as compared to no exercise.

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

Summary

ID

NL-OMON53458

Source
ToetsingOnline

Brief title
Exercise in systemic sclerosis

Condition

- Autoimmune disorders

Synonym
scleroderma, systemic sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Sheffield Hallam University
Source(s) of monetary or material Support: FOREUM

Intervention

Keyword: exercise, pain, Raynaud's phenomenon, systemic sclerosis

Outcome measures

Primary outcome

Pain is measured with the visual analogue scale (VAS) included in Scleroderma Health Assessment Questionnaire (SHAQ; VAS-SHAQ) and fatigue with the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F).

Secondary outcome

Mood will be assessed with the Centre for Epidemiologic Studies-Depression Scale (CES-D). In addition, a microvascular assessment by means of nailfold capillaroscopy (NC) is done, aerobic capacity is measured by a Peak Oxygen Uptake test on an arm crank ergometer and hand and arm strength are assessed by a hand held dynamometer and the biceps curl test, respectively. Added questionnaire in LUMC 22/03/2023: Illness Perceptions Questionnaire-Revised (IPQ-R).

Study description

Background summary

Raynaud*s phenomenon and digital ulceration are two of the most common disease manifestations leading to digital and/or toe pain in systemic sclerosis (SSc). In addition to pain, fatigue has been identified as a key stressor and the most prevalent and debilitating symptom of SSc. Both, affect significantly quality of life (QoL) domains. Pharmacological therapeutic strategies have not been

proved sufficiently effective in the management of SSc-induced pain and fatigue. Evidently the effectiveness of non-pharmacological interventions (e.g. exercise, cognitive behavioural therapy) is limited, although for some of them (i.e. exercise) evidence is promising. As yet, the effects of a feasible, long-term, tailored exercise program on pain and fatigue in people with SSc have not been explored.

Study objective

To assess the effect of a previously-established, supervised 12-week combined (aerobic and resistance training) exercise programme on pain and fatigue as compared to no exercise.

Study design

Multi-centre, randomized controlled clinical trial.

Intervention

A 12-week exercise programme (aerobic and resistance training) twice per week (5 minutes warm up, 30-minutes' high intensity interval training on an arm crank ergometer combined with resistance training (RT) lasting for a total of 15 min, 5 min cool-down period). Each session will be delivered as a one-to-one supervised session by a qualified health care professional (e.g., clinical exercise physiologist/physical therapist with experience in SSc).

Study burden and risks

All participants in this trial will be screened for any contra-indication for exercise therapy by the researchers in close collaboration with the treating rheumatologist before inclusion The screening is done according to a protocol that was used in a previous RCT on multidisciplinary team care including exercise therapy that was executed in the LUMC (P16.259). After randomization, patients in the control arm will be treated as usual by their rheumatologist, whereas participants from the experimental arm will receive a 12-week exercise therapy program. The burden of the participants will be minimized to the time necessary for completing the assessments (3 visits, baseline, 3 and 6 months, 1.5 - 2 hours per visit), and for those in the experimental arm 24 treatment sessions of 60 minutes over 12 weeks.

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

1) A diagnosis of Systemic Sclerosis according to the 2013 ACR/EULAR criteria experiencing Raynaud's phenomenon;
2) Age over 18 years old; and
3) ability to perform the prescribed exercise regime.
4) be able and willing to give written informed consent prior to entry in the study.

Exclusion criteria

1) Advanced pulmonary involvement (e.g., pulmonary arterial hypertension);
2) New York Heart Association class 3 or 4;
3) Active disease/exacerbations such as active digital ulcers;
4) A recent change in patient*s medical treatment (either type or dose of drug targeting vascular function), following a period of three months the interested patients will be able to take part; and
5) Active disease-related exacerbations (e.g., active digital ulcers).

6) Current pregnancy.

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:	Completed
Start date (anticipated):	06-02-2023
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	06-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05234671
CCMO	NL79999.058.22