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# Effectiveness of a multidisciplinary team care programme in comparison with usual care for patients with scleroderma

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02/04/2010

**Recruitment status**
No longer recruiting

**Registration date**
15/04/2010

**Overall study status**
Completed

**Last Edited**
08/08/2011

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Miss Anne Schouffoer

**Contact details**
postbus 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5263598
A.A.Schouffoer@LUMC.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
P06.102

# Study information

## Scientific Title
A randomised comparison of a multidisciplinary team care program with usual care in patients with systemic sclerosis

## Study objectives
Systemic sclerosis (SSc or scleroderma) is a chronic, disabling, disfiguring and painful multisystem connective tissue disease, associated with significant morbidity and mortality. The incidence is estimated to range between 0.6-19 per million per year. Dysfunction of the skin, musculoskeletal system, kidneys, lungs, heart, and gastrointestinal tract as well as painful symptoms, including digital ulcers, Raynauds phenomenon, joint contractures and gastro-oesophagal reflux may seriously interfere with all aspects of an individuals life, with physical, mental and social functioning, as well as overall quality of life being seriously impaired. Although in many other rheumatic conditions the effectiveness of a multidisciplinary approach (including exercise therapy and patient education) has been established, in systemic sclerosis research in this area is virtually absent. Among patients, there is a strong need for a multidisciplinary treatment programme, however more knowledge regarding its outcomes is needed. In case of proven effectiveness, the programme should be offered to as many patients as possible, however if the intervention is not effective, it should not be recommended.

Research question: Is a group-based, multidisciplinary treatment programme more effective than usual care in patients with systemic sclerosis?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Local medical ethics committee (Commisie Medische Ethiek [CME]), Leiden University Medical Centre approved on the 18th of July 2006 (ref: P06.102) (contact: cme@lumc.nl, Mr W.Kool)

## Study design
Randomised single blind controlled parallel group clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Systemic sclerosis, scleroderma, rehabilitation

## Interventions
1. Intervention Groups:
The multidisciplinary team care programme is conducted 2 times a week for 12 consecutive weeks. Patients are treated in groups of 4-6 patients. All patients are treated by a multidisciplinary team comprising a rheumatologist, nurses, physical therapists, occupational therapists and social workers. Additional health professionals are called in to deliver services according to the individual participant's health status. The programme offers a patient-centred approach: After an assessment by all team members, individual goal setting on the level of body functions and structures, daily activities and societal participation is done, in co-operation with the patient. Individual treatment goals are evaluated during weekly multidisciplinary team conferences. The programme consists of individual as well as group interventions:
1.1. Optimisation of individual medical treatment based on a standardized assessment of all specific medical aspects of the condition (including pulmonary function, ECG with rhythm strip and cardiac echo); If needed, additional assessments (laboratory tests, function tests and imaging) as well as interventions or consultations by other medical specialists are arranged.
1.2. Exercise therapy, both on an individual basis as well as group therapy. The group exercise programme is aimed at improving joint range of motion, muscle strength, aerobic fitness, and the performance of daily activities. This programme, with a duration of 1.25 hours is conducted two times a week. It has three parts: bicycle training (20 minutes), exercise circuit (20 minutes) and sport or game (20 minutes). Each session is preceded by a warm-up and followed by a cool-down. During the bicycle training, the heart rate is kept at a minimum of 60% of the predicted maximal heart rate (220-age; chest heart rate frequency meter), whereas the rate of perceived exertion (Borg scale; 7-20) is kept between 12-16. The exercise circuit consists of 8-10 different exercises intended to improve muscle strength and endurance, joint mobility and activities of daily living. The sport or game section consists of activities such as badminton or volleyball. The program is supervised by 2 physical therapists on alternate days. In addition to the group exercise programme, individual exercises (with emphasis on hand function improvement and mouth opening exercises) and group hydrotherapy are offered once a week.
1.3. A group educational program, comprising a number of fixed topics (i.e. information on the disease; medication; skills for coping with pain, disfigurement and disability; skin care; oral hygiene; food and diet) as well as specific items required by participants. Patients receive standardized written information materials (leaflets, books, references to websites). Additional information is provided on an individual basis by all health professionals involved.
1.4. Occupational therapy, on an individual basis, comprising e.g. the teaching of joint and skin protection and energy conservation strategies and the use of aids and appliances and other relevant products such as stockings and gloves.
1.5. Guidance by a social worker, on an individual basis tailored to the individuals needs (e.g. housing, household assistance, finances, leisure activities or work).

2. Control Group:
Patients in the control group will receive usual care as initiated by their attending rheumatologist. Attending rheumatologists will have free choice with respect to diagnostic and therapeutic interventions, except for referrals to group exercise or group education programmes or multidisciplinary team care programmes. After all patients have finished the follow-up assessments, patients randomized to the control condition will be offered to participate in the multidisciplinary team care programme.

## Intervention Type

Other

## Phase
Not Applicable

## Primary outcome measure
1. 6-minute walk test (metre)
Validated in patients with rheumatic, cardiac and lung disease and is extensively used in trials in patients with scleroderma aiming at improvement of exercise tolerance. Assuming a 30% improvement in the intervention group and 0% in the control group, á=0.05 and â =0.20 (power of 0.80), 22 patients per group would be needed to detect this difference (N = 7.85 x 0.15(0.85) x 2 / (0.3)2)
2. The Physical Component Summary scale (Phys-SS) of the Short Form-36 (SF-36)
A generic, multi-dimensional quality of life questionnaire. Phys-SS includes physical functioning, role-physical, bodily pain, vitality and general health. Assuming an standard deviation (SD) of the Phys-SS baseline score of 11, an improvement of 10 points in the intervention and 0 in the control group, ≥ 0.05 and ≤ 0.20, 19 patients per group would be needed.
3. The Scleroderma-Health Assessment Questionnaire (SHAQ)
Assesses difficulty with daily activities (20 items) and interference of scleroderma symptoms with activities (visual analogue scale [VAS] 0-10 cm for Raynaud phenomenon, finger ulcers, lung problems, gastrointestinal problems, general disease related problems, and pain). Assuming a 22% improvement in the intervention group and 0% in the control group, ≥ 0.05 and power of 0.80, 28 patients per group would be needed to detect this difference (N = 7.85 x 0.11(0.78) x 2 / (0.22)2).

Based on an average of these calculations we aimed to enrol 50 patients in the study.

Baseline characteristics assessed at baseline only. All other assessments carried out at baseline, 12 and 24 weeks. Assessments are done by a trained assessor, who is blinded for the treatment condition.

## Secondary outcome measures
1. The Hand Mobility in Scleroderma (HAMIS) test
Consisting of 9 items graded on a scale of 0-3, the final score ranges from 0 (normal function) to 27 (severe immobility). It was found to be a reliable instrument in evaluation of hand function in SSc and longitudinal assessment of hand mobility in early SSc.
2. Grip strength (kg)
Measured with a Jamar dynamometer. After testing twice, the highest score was registered. An average value of the grip strength of the left and right hand was computed.
3.Maximal Mouth Opening (MMO)
Measured with a digital calliper as the maximal interdentally distance. Measurement of the maximal mouth opening was used in several studies evaluating mouth function in SSc.
4. Maximal oxygen uptake (VO2max)
A standard exercise test on an electronically braked cycle ergo meter performed according to the American Thoracic Society /American College of Chest Physicians (ATS/ACCP) Statement on Cardiopulmonary Exercise Testing. At baseline (forehead) pulse oximetry, blood pressure, heart rate and gas exchange were recorded. Pulse oximetry and heart rate were monitored during 1 min of rest, 2 min of unloaded cycling at 60 rpm followed by an increasing load to maximum tolerance, and 3 min of recovery. Each exercise test was supervised by a pulmonary physician. Apart from the VO2 max, maximal rate (Watt), heart rate and ventilation at maximal tolerated work rate were monitored.

5. Checklist Individual Strength-20 (CIS-20)
A Dutch generic 20-item self-report instrument that measures 4 dimensions of fatigue: fatigue, concentration, impaired motivation and impaired activity on a seven-point Likert scale. Higher scores indicate a higher degree of fatigue, more concentration problems, reduced motivation, and less activity. The CIS developed for patients with chronic fatigue syndrome, and has good psychometric properties.

Baseline characteristics assessed at baseline only. All other assessments carried out at baseline, 12 and 24 weeks. Assessments are done by a trained assessor, who is blinded for the treatment condition.

### Overall study start date
01/09/2006

### Completion date
31/12/2008

## Eligibility

### Key inclusion criteria
1. Scleroderma according to the Leroy's criteria
2. Age 18-70 years
3. Able to cycle on a bicycle ergometer
4. Able to engage in a day patient programme 2 times a week over 12 continuous weeks and to reach the hospital at 10.00 a.m.
5. Stable antirheumatic medication over the past 2 months
3. Fluent in Dutch

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
70 Years

### Sex
Both

### Target number of participants
50; 25 intervention, 25 control group

### Key exclusion criteria
1. Current engagement in a multidisciplinary or group exercise therapy program
2. Planned hospitalisation or surgery in the next 6 months
3. Psychiatric disorders including alcohol and drugs abuse

4. Concomitant diseases (other than heart or lung disease) interfering with the performance of daily activities
5. Pregnancy or planned pregnancy in the next 6 months
6. The following concomitant heart or lung disease:
6.1. Instable angina pectoris
6.2. Recent myocardial infarction
6.3. Heart rhythm disturbances with haemodynamic consequences
6.4. Symptomatic stenosis of the aortic valve
6.5. Symptomatic heart failure
6.6. Recent lung embolism or lung infarction
6.7. Acute myocarditis or pericarditis
6.8. Aortic dissection

### Date of first enrolment
01/09/2006

### Date of final enrolment
31/12/2008

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**postbus 9600**
Leiden
Netherlands
2300 RC

## Sponsor information

### Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

### Sponsor details
c/o T.W.J. Huizinga
Head of the department Rheumatology
Reumatologie C1-R
Postbus 9600
Leiden
Netherlands
2300RC
+31 (0)71 5263598
T.W.J.Huizinga@LUMC.nl

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/027bh9e22

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Leiden University Medical Centre (LUMC) (Netherlands)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2011 | | Yes | No |