

The effect of physical activity interventions on the course of systemic sclerosis

Submission date 04/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/05/2020	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Systemic sclerosis is characterized by stiffness and contraction of tissues such as the skin, caused by the dominant pathologic feature called fibrosis, which leads to decreased tissue function and to a limitation in the execution of daily activities. The aim of our study was to investigate the impact of a specialized physiotherapy/occupational therapy program focused on the function of the hands and face and quality of life.

Who can participate?

Adults over 18 years, with systemic sclerosis and skin involvement at least of the fingers/hands and the face.

What does the study involve?

Participants will be randomly allocated to receive either treatment as usual or an additional six month program twice a week consisting of supervised physiotherapy (1 hour) and occupational therapy (0.5 hour) focused on the function of hands and face.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Institute of Rheumatology (Czech Republic)

When is the study starting and how long is it expected to run for?

January 2015 to June 2017

Who is funding the study?

Ministry of Health Czech Republic

Who is the main contact?

Dr Michal Tomcik, tomcik@revma.cz

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effectiveness of specialized hand/face physical-occupational therapy in patients with systemic sclerosis

Acronym

RHB-SSc

Study objectives

Our specialized, long-term, tailored, physiotherapy/occupational therapy program focused on hand and face involvement in systemic sclerosis patients improves the function of hands/face, disability, quality of life (compared to controls treated with the standard of care).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/07/2014, Ethics Committee of the Institute of Rheumatology Prague (Ethics Committee of Institute of Rheumatology Prague, Na Slupi 4, 128 50 Praha 2, Czech Republic; +420 234075244; putova@revma.cz), ref: 1446/2014

Study design

interventional single-centre prospective non-randomized controlled study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Systemic sclerosis/scleroderma

Interventions

Control group: standard of care (i.e. standard pharmacological treatment according to the EULAR /ACR recommendations on the management of systemic sclerosis, education, and materials for regular daily home exercise)

Intervention group: standard of care (as described above) + 6 months of specialized intervention program twice a week consisting of supervised physiotherapy (1 hour) and occupational therapy (0.5 hour) focused on the function of hands and face

Intervention Type

Behavioural

Primary outcome measure

Measured at baseline, week 12, week 24, week 48:

1. Function of the hands assessed by:

- HAMIS test (Hand Mobility in Scleroderma)
- delta finger to palm distance
- hand grip strength measured by dynamometry
- CHFS questionnaire (Cochin Hand Function Scale)

2. Function of the face:

- inter-lip and inter-incisor distance
- MHISS questionnaire (Mouth Handicap in Systemic Sclerosis)

Secondary outcome measures

Measured at baseline, week 12, week 24, week 48:

1. Assessment of health/disability:

- HAQ questionnaire (Health Assessment Questionnaire)
 - SHAQ questionnaire (Scleroderma Health Assessment Questionnaire)
2. Quality of life:
- SF-36 questionnaire (Medical Outcomes Short Form-36)

Overall study start date

01/05/2014

Completion date

30/06/2017

Eligibility

Key inclusion criteria

1. Informed consent form signed and dated
2. Reliable and capable of adhering to the protocol and visit schedule
3. At least 18 years of age
4. Fulfilled the 2013 EULAR/ACR classification criteria for systemic sclerosis
5. Skin involvement at least of the fingers/hands and the face
6. Regularly followed at our out-patient department and adheres to the standard-of-care pharmacological therapy indicated by his treating rheumatologist
7. Willing to participate in the study and undergo all planned examinations

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25 patients in the intervention group and 25 patients in the control group

Total final enrolment

59

Key exclusion criteria

Subject has any other condition, including medical or psychiatric, which in the investigator's judgment would make the subject unsuitable for inclusion in the study

Date of first enrolment

01/01/2015

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

Czech Republic

Study participating centre

Institute of Rheumatology

Na Slupi 4

Prague

Czech Republic

12850

Sponsor information

Organisation

Revmatologický ústav

Sponsor details

(Institute of Rheumatology)

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Sponsor type

Hospital/treatment centre

Website

<http://www.revma.cz/en>

ROR

<https://ror.org/00jk0vn85>

Funder(s)

Funder type

Government

Funder Name

Funder Name

Project for Conceptual Development for the institution of Ministry of Health Czech Republic—
Institute of Rheumatology (number 023728)

Results and Publications

Publication and dissemination plan

Planning to publish the results in a rheumatology-oriented peer-reviewed journal with impact factor.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date