ISRCTN12877295 https://doi.org/10.1186/ISRCTN12877295

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

Submission date
04/05/2020

Recruitment status
No longer recruiting

Registration date
22/05/2020

Overall study status
Completed

Last Edited
22/05/2020

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 the 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
Dr Michal Tomcik

ORCID ID
https://orcid.org/0000-0002-8616-7850

Contact details
Institute of Rheumatology
Na Slupi 4
Prague
Czech Republic
12850
+420 (0)234075101
tomcik@revma.cz

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/00jk0vn85

Funder(s)

Funder type
Government

Funder Name
Ministry of Health Czech Republic grant nr. 16-33574A

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

Results and Publications

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