

# The effect of a specialized physiotherapy program in female patients with systemic sclerosis and inflammatory muscle disorders

<b>Submission date</b> 28/04/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/05/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Systemic sclerosis (scleroderma) is a long-lasting disease that affects your skin, connective tissue, and internal organs. It happens when your immune system causes your body to make too much of the protein collagen, an important part of your skin. As a result, your skin gets thick and tight, and scars can form on your lungs and kidneys.

Inflammatory myopathies are a group of diseases that involve chronic (long-standing) muscle inflammation, muscle weakness, and, in some cases, muscle pain. Myopathy is a general medical term used to describe a number of conditions affecting the muscles.

Scleroderma and idiopathic inflammatory myopathies (myositis) are rare chronic autoimmune diseases characterized by multiple organ involvement. Despite clinical improvement following pharmacotherapy, most patients develop a persistent disability that affects all aspects of life, including sexual function. Our study aims to investigate the effect of an 8-week, specialized physiotherapy program focused on the individual disease-specific musculoskeletal aspects that negatively impact sexual function.

### Who can participate?

Female adults over 18 years of age, who fulfilled the 2013 EULAR/ACR classification criteria for systemic sclerosis or Bohan/Peter 1975 criteria for polymyositis/dermatomyositis

### What does the study involve?

The intervention part includes 8 weeks of intensive supervised physiotherapy program that will be adapted to each patient's current health and functional status focused on the sexual function and quality of sexual life. Participants in both groups (intervention and control) will fill out several well-established and validated questionnaires assessing the sexual health, quality of life, level of disability, and presence of depression before and after the physiotherapy program.

### What are the possible benefits and risks of participating?

Patients participating in the project can learn more about the impact of rheumatic diseases on sexual health, and those, who will be in the intervention group, can benefit from the opportunity

to try physiotherapeutic approaches to treat their sexual difficulties and movement disabilities. The only risk of taking part in the project is that physiotherapy will not improve patients' problems. It is very unlikely that physiotherapy could make the problem any worse or deteriorate patients' condition.

Where is the study run from?

Department of Rehabilitation in the Institute of Rheumatology in Prague (Czechia)

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

March 2019 to August 2021

Who is funding the study?

1. Grantová Agentura, Univerzita Karlova (Czechia)
2. Ministerstvo Školství, Mládeže a Tělovýchovy (Czechia)
3. Ministry of Health Czech Republic, Institute of Rheumatology

Who is the main contact?

Barbora Hermankova, [hermankova@revma.cz](mailto:hermankova@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

The effect of an 8-week specialized physiotherapy program on sexual dysfunctions of female patients with systemic sclerosis and idiopathic inflammatory myopathies: a pilot study

## Acronym

PHYS-SD-SSc/IIM

## Study objectives

A specialized, 8-week, tailored physiotherapy program targetting the individual disease-specific musculoskeletal aspects that negatively impact the sexual function in patients with systemic sclerosis and idiopathic inflammatory myopathies improves the sexual function, pelvic floor function, disability, and quality of life (compared to controls treated with the standard of care).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 17/12/2019, Ethics Committee of the Institute of Rheumatology in Prague (Na Slupi 4, 128 50 Praha 2, Czech Republic; +420 234075244; putova@revma.cz), ref: 12898/2019

## Study design

Interventional single-center prospective non-randomized controlled pilot study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## 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, idiopathic inflammatory myopathies/myositis

## Interventions

Control group: standard of care (i.e. standard pharmacological treatment according to the generally accepted recommendations on the management of systemic sclerosis, or idiopathic inflammatory myopathies, instructions for regular daily home exercise), no specific treatment for sexual dysfunctions.

Intervention group: standard of care (as described above) + 8 weeks of a specialized intervention program, twice a week, consisting of supervised physiotherapy (1 hour) focused on the individual disease-specific musculoskeletal aspects that negatively impact the sexual function.

All patients meeting the inclusion criteria (without any exclusion criteria) will be continuously addressed if they are willing to participate in the study, and based on their availability (social /family/employment duties, or commuting possibilities). Patients will be allocated to the intervention group based on their availability and willingness to adhere to the planned schedule. Those patients that will meet the inclusion criteria but will not be able to commute twice a week to Prague for physiotherapy for any reason (time reasons, living far away, not driving a car, and having difficulties showing up at scheduled times, do not want to undergo the program, but are willing to fill out questionnaires, etc.), will be included in the control group and only fill out questionnaires at two-time points. The intervention will last 8 weeks. There is no follow-up period planned.

### **Intervention Type**

Mixed

### **Primary outcome measure**

Measured at baseline and week 8:

1. Sexual function assessed with the Female Sexual Function Index questionnaire (FSFI) and the Brief Index of Sexual Functioning for Women questionnaire (BISF-W)
2. Quality of sexual life assessed by Sexual Quality of Life – Female questionnaire (SQoL-F)

### **Secondary outcome measures**

Measured at baseline and week 8:

1. Health/disability assessed by Health Assessment Questionnaire questionnaire (HAQ)
2. Quality of life assessed by Medical Outcomes Short Form-36 questionnaire (SF-36)
3. Depression assessed by Beck's Depression Inventory-II questionnaire (BDI II)

### **Overall study start date**

01/03/2019

### **Completion date**

17/08/2021

## **Eligibility**

### **Key inclusion criteria**

1. An Independent Ethics Committee approved written Informed Consent form is signed and dated by the subject
2. Subject is considered reliable and capable of adhering to the protocol and visit schedule
3. Subject is female at least 18 years of age
4. Subject fulfilled the 2013 EULAR/ACR classification criteria for systemic sclerosis or Bohan /Peter 1975 criteria for polymyositis/dermatomyositis
6. Subject is regularly followed at our out-patient department and adheres to the standard-of-care pharmacological therapy indicated by his treating rheumatologist
7. Subject is willing to participate in the study and undergo all planned examinations
8. Subject reported low sexual function at least in two of three questionnaires assessing sexual function: Female Sexual Function Index (FSFI), Brief Index of Sexual Functioning for Women (BISF-W), Sexual Function Questionnaire (SFQ-28). Low sexual function in FSFI and SFQ-28 was

established based on diagnostic cut-off scores, and in BISF-W, sexual dysfunction was determined based on the 15th percentile obtained from a comparison of healthy control scores of the same age

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

Three to five patients per diagnosis in the intervention group and three to five patients per diagnosis in the control group

**Total final enrolment**

12

**Key exclusion criteria**

1. 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**

01/05/2021

**Date of final enrolment**

17/06/2021

**Locations****Countries of recruitment**

Czech Republic

**Study participating centre**

**Institute of Rheumatology**

Na Slupi 450/4, Nové Město

Prague

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**Sponsor information**

**Organisation**

Revmatologický Ústav

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

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

**Funder(s)****Funder type**

University/education

**Funder Name**

Grantová Agentura, Univerzita Karlova [GAUK 1578119]

**Alternative Name(s)**

Grantová Agentura UK, Charles University Grant Agency, GA UK, GA, UK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Czech Republic

**Funder Name**

Ministerstvo Školství, Mládeže a Tělovýchovy

**Alternative Name(s)**

The Ministry of Education, Youth and Sports, MŠMT, MŠMT, MEYS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Czech Republic

**Funder Name**

Ministry of Health Czech Republic, Institute of Rheumatology [023728]

## Results and Publications

**Publication and dissemination plan**

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

**Intention to publish date**

31/12/2021

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

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/05/2023	24/05/2023	Yes	No