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

Submission date
28/04/2021

Recruitment status
No longer recruiting

Registration date
05/05/2021

Overall study status
Completed

Last Edited
24/05/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

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
Czech Republic
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Sponsor information

Organisation
Revmatologický Ústav

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

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?

Results article	results	23/05/2023	24/05/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes