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The effect of complex physiotherapy on the function of temporomandibular joint in patients with systemic sclerosis

Submission date
12/03/2025

Recruitment status
Recruiting

Registration date
25/06/2025

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Systemic sclerosis (scleroderma) is a rare chronic autoimmune disease that affects multiple organs. Even with treatment, many patients experience ongoing disability that impacts their daily lives, including issues with the jaw joint (temporomandibular joint). This study aims to investigate the effects of a 12-week specialized physiotherapy program designed to address the specific musculoskeletal problems related to the jaw joint in these patients.

Who can participate?
Patients with systemic sclerosis who are experiencing issues with their temporomandibular joint can participate in this study.

What does the study involve?
Participants will be randomly assigned to either the intervention group, which will receive the specialized physiotherapy program, or the control group. The physiotherapy program involves supervised sessions twice a week, each lasting one hour, for 12 weeks. After 12 weeks, participants will switch groups.

What are the possible benefits and risks of participating?
Participants may benefit from improved jaw function and overall quality of life. Risks may include discomfort during physiotherapy sessions or no improvement in symptoms.

Where is the study run from?
Institute of Rheumatology (Czechia)

When is the study starting and how long is it expected to run for?
May 2024 to December 2030

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Michal Gála, gala@revma.cz

Contact information

Type(s)
Public, Scientific, Principal investigator

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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 a 12-week complex physiotherapy program focused on temporomandibular disorders in patients with systemic sclerosis

Acronym
PHYS-TMD-SSc

Study objectives
Our specialized, 12-week, tailored physiotherapy program targetting the individual disease-specific musculoskeletal aspects that negatively impact the function of the temporomandibular joint in patients with systemic sclerosis improves the temporomandibular function, increases the range of motion, reduces pain in the area of the temporomandibular joint and improves the quality of life including mental health

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/08/2024, Ethics Committee of the Institute of Rheumatology in Prague, Czech Republic (Na Slupi 450/4, Prague, 128 00, Czech Republic; +420 234075244; eticka@revma.cz), ref: 13154/2024

Study design
Interventional single-center prospective randomized controlled one-way crossover

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Systemic sclerosis/scleroderma, temporomandibular joint, temporomandibular disorders

Interventions
Control group: standard of care (i.e. standard pharmacological treatment according to the generally accepted recommendations on the management of systemic sclerosis) + collecting data and relevant examinations (three times in total, in week 0, 12, and 24), no specific treatment for temporomandibular joint.

Intervention group: standard of care (as mentioned above) plus collecting data and relevant examinations (as described above) + 12 weeks of a specialized intervention program, twice a week, consisting of supervised physiotherapy (1 hour per session) focused on the individual disease-specific musculoskeletal aspects that negatively impact the temporomandibular joint. The treatment will further include instructions for regular daily home exercises (5 remaining days a week for 20 minutes per session), focused on the temporomandibular joint, posture, and neck.

Randomization will be performed using a standard six-sided die. If the result is even, patients will be assigned to the intervention group, otherwise, patients will be assigned to the control group.

Intervention Type
Behavioural

Primary outcome(s)
1. Symmetry and pain during palpation of the masticatory muscles are measured using palpation at week 0, 12, and 24
2. Symmetry of the joint condyles during movement and pain provoked by palpation are measured using palpation at week 0, 12, and 24
3. Symmetry of the jaw, maximum interincisal value, protrusion, and laterotrusion are measured using the measurement of mouth opening at week 0, 12, and 24
4. TMJ structure is measured using panoramic X-ray image at week 0, 12, and 24
5. TMJ structure is measured using magnetic resonance in standardized projections at week 0, 12, and 24

6. Manifestation of TMJ dysfunction is measured using Helkimo index at week 0, 12, and 24
7. Mouth handicap in systemic sclerosis is measured using MHISS at week 0, 12, and 24

Key secondary outcome(s))
1. Health/disability is measured using SHAQ questionnaire at week 0, 12, and 24
2. Quality of life is measured using SF-36 questionnaire at week 0, 12, and 24
3. Depression is measured using BDI II questionnaire at week 0, 12, and 24
4. Fatigue is measured using FIS at week 0, 12, and 24
5. Anxiety is measured using Beck Anxiety Inventory at week 0, 12, and 24
6. Function of gastrointestinal tract is measured using UCLA GIT 2.0 at week 0, 12, and 24

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. An Independent Ethics Committee-approved written Informed Consent form is signed and dated by the subject.
2. Subject reports at least one of the symptoms of dysfunction TMJ according to the Helkimo index.
3. Subject is considered reliable and capable of adhering to the protocol and visit schedule.
4. Subject is at least 18 years of age.
5. Subject fulfilled the 2013 EULAR/ACR classification criteria for systemic sclerosis.
6. Subject is regularly followed at our department and adheres to the standard-of-care pharmacological therapy indicated by his/her treating rheumatologist.
6. Subject is 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

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.
2. Participant has had a recent dental surgery.
3. The patient undergoes any similar physiotherapeutic intervention during the study.

Date of first enrolment

01/06/2025

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
Czech Republic

Study participating centre
Institute of Rheumatology
Na Slupi 450/4
Prague
Czech Republic
128 00

Sponsor information

Organisation
Revmatologický Ústav

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Not expected to be available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes