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The effect of comprehensive physiotherapy using the Gloreha Sinfonia robotic system on hand function in systemic sclerosis

Submission date
26/07/2026

Recruitment status
No longer recruiting

Registration date
24/08/2026

Overall study status
Ongoing

Last Edited
24/08/2026

Condition category
Musculoskeletal Diseases

[X] 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
Patients with systemic sclerosis, a rare autoimmune disease, suffer from connective tissue damage in the hands, among other areas. This condition affects patients in their daily activities, even with regular treatment. This study will focus on the use of the Gloreha Sinfonia robotic system as part of comprehensive hand rehabilitation over a period of 12 weeks.

Who can participate?
Patients with systemic sclerosis who have problems with hand and finger function and its mobility.

What does the study involve?
Participants will be randomly divided into two similarly sized groups, one of which will be the experimental group and the other the control group. Both groups will undergo full conventional physiotherapy, with the experimental group's therapy supplemented by exercises using the Gloreha Sinfonia robotic system. The examination should take 1 hour, during which the participants will undergo initial/final measurements, including filling out questionnaires, anthropometric and goniometric examinations, and measurements using the robotic device itself. After the examination, exercises lasting 2 hours (for the experimental group) and 1.5 hours (for the control group) will take place once a week (for both groups) for at least 12 weeks (again for both groups), starting the week after the examination. The follow-up examination will consist of a follow-up measurement, where the patient's current condition will be assessed after 1 month without robotic or conventional therapy.

What are the possible benefits and risks of participating?
The benefit should be increased range of motion and improved function in the hands and fingers. Physiotherapy may be accompanied by mild irritation of soft tissues during relaxation, or fatigue of the muscles being worked on. One of the risks may also be that the patient's condition does not improve.

Where is the study run from?
Czech Technical University in Prague - Faculty of Biomedical Engineering, and the Institute of Rheumatology (Czech Republic)

When is the study starting and how long is it expected to run for?
August 2026 to February 2027

Who is funding the study?
Czech Technical University in Prague (Czech Republic)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
The effect of Gloreha Sinfonia robotic system physiotherapy on hand function compared with standard physiotherapy in patients with systemic sclerosis: a randomized controlled trial

Study objectives
1. To verify the benefits and feasibility of integrating the Gloreha Sinfonia robotic device into the concept of intensive hand rehabilitation for patients with systemic sclerosis (SSc) and to evaluate its impact on the recovery of motor functions and range of motion.
2. To evaluate the effectiveness of comprehensive physical therapy as supportive care complementing robotic therapy for overall improvement in hand function.
3. Analyze the long-term impact of this robot-assisted therapy on patients' quality of life during follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2025, Ethics committee of Institute of Rheumatology Prague (Na Slupi, 4, Praha, 128 00, Czech Republic; +420 (0)234 075 244; tomcik@revma.cz), ref: 14350/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Systemic sclerosis (SSc)

Interventions
Pseudo-random number generation (PRNG):
Eligible participants will be randomly assigned to either the experimental group or the control

group using a computer-generated randomization sequence based on a pseudorandom number generator (PRNG). The randomization sequence will be generated prior to participant enrollment, and participants will be allocated in a 1:1 ratio.

Experimental group:
Participants will receive conventional physiotherapy supplemented by robotic-assisted therapy using the Gloreha Sinfonia device. The intervention will be performed once a week for at least 12 weeks, with each exercise session lasting 2 hours.

Control group:
Participants will receive conventional physiotherapy only. The intervention will be performed once a week for at least 12 weeks, with each exercise session lasting 1.5 hours.

Assessments (both groups):
All participants will undergo a baseline examination (1 hour) consisting of goniometric measurements, robotic device assessments, and standardized questionnaires validated for systemic sclerosis (SSc). The same set of measurements will be repeated at the end of the 12-week intervention period. A follow-up assessment will be conducted 4 weeks after the completion of the therapy to evaluate the sustainability of the outcomes during a period without active treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gloreha Sinfonia

Primary outcome(s)
1. Robotic kinematic parameters of hand function in patients with systemic sclerosis measured using the Gloreha Sinfonia software, evaluating both active and passive range of motion (ROM) of the finger joints expressed as a percentage, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

Key secondary outcome(s)
1. Fatigue severity and impact in patients with systemic sclerosis measured using the Fatigue Impact Scale (FIS), a validated patient-reported questionnaire assessing the impact of fatigue on daily activities and quality of life, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

2. Functional activity level in patients with systemic sclerosis measured using the Human Activity Profile (HAP), a validated patient-reported questionnaire assessing physical activity level and functional capacity, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

3. Functional disability and health status in patients with systemic sclerosis measured using the Health Assessment Questionnaire (HAQ), a validated patient-reported outcome measure assessing functional ability and disability in daily activities, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

4. Skin involvement severity in patients with systemic sclerosis measured using the modified Rodnan Skin Score (mRSS), a validated clinical assessment tool evaluating skin thickness in systemic sclerosis, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

5. Hand function and disability in patients with systemic sclerosis measured using the Cochin Hand Function Scale (CHFS), a validated patient-reported questionnaire assessing the impact of hand impairment on daily activities, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

6. Hand mobility and structural impairment in patients with systemic sclerosis measured using the Hand Mobility in Scleroderma (HAMIS) test, a validated clinical assessment tool evaluating the range of motion and mobility of the hands and fingers, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

7. Finger flexion and joint contracture severity in patients with systemic sclerosis measured using the Finger-to-Palm (FTP) distance test, a validated clinical assessment measure evaluating the ability to close the fist and the degree of finger joint restriction, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

8. Manual joint range of motion in patients with systemic sclerosis measured using manual goniometry, assessing the active range of motion (AROM) of the finger joints expressed in degrees, at baseline (Week 0), post-intervention (Week 12), and follow-up (Week 16)

Completion date
15/02/2027

Eligibility

Key inclusion criteria
1. Ability to understand, sign, and date the Independent Ethics Committee-approved written Informed Consent form
2. Aged ≥ 18 and ≤ 75 years
3. Confirmed diagnosis of systemic sclerosis (SSc) verified by a rheumatologist
4. Established disease with no signs of acute exacerbation
5. Reduced range of active motion in the hand and finger joints, but retaining residual functional mobility (absence of total joint ankylosis or fixed muscle contractures)
6. Ability and willingness to adhere to the visit schedule, examination procedures, and full study protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Active skin lesions, digital ulcers, or local infections on the target hand or fingers
2. Severe or fixed joint contractures preventing safe fitting or operation of the robotic glove
3. Symptomatic subcutaneous calcinosis in areas subject to pressure from the device
4. Severe Raynaud's phenomenon with critical digital ischemia
5. Recent surgery or trauma to the target hand or fingers within the last 6 months
6. Severe sensory loss or cognitive impairment preventing safe operation of the device
7. Concurrent treatment or rehabilitation that could interfere with the study outcomes
8. Any other medical condition that, in the opinion of the investigator, compromises patient safety or data validity

Date of first enrolment
31/08/2026

Date of final enrolment
28/09/2026

Locations

Countries of recruitment
Czech Republic

Sponsor information

Organisation
Czech Technical University in Prague

ROR
https://ror.org/03kqpb082

Organisation
Institute of Rheumatology

ROR
https://ror.org/00jk0vn85

Funder(s)

Funder type

Funder Name
České Vysoké Učení Technické v Praze

Alternative Name(s)
Czech Technical University in Prague, ČVUT

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

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			27/07/2026	No	Yes