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The effect of complex physiotherapy on the lower extremities including manual techniques and gait training on the AlterG device in patients with systemic sclerosis – a pilot study

Submission date
27/07/2026

Recruitment status
Recruiting

Registration date
03/09/2026

Overall study status
Ongoing

Last Edited
03/09/2026

Condition category
Skin and Connective Tissue 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
Patients with systemic sclerosis (SSc), a rare autoimmune disease, may experience changes in the skin, connective tissue, muscles, and joints, among other areas. This condition can negatively affect patients' mobility, walking ability, and daily activities, even with regular treatment. This study will focus on the use of the AlterG anti-gravity treadmill as part of comprehensive lower limb rehabilitation over a period of 12 weeks. The study will evaluate the effect of this rehabilitation approach on walking ability, lower limb mobility, functional performance, pain during walking, and quality of life in patients with systemic sclerosis.

Who can participate?
Patients with systemic sclerosis who have problems with lower limb function, mobility, or walking ability.

What does the study involve?
All subjects 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 comprehensive conventional physiotherapy, with the experimental group's therapy supplemented by exercises using the AlterG anti-gravity treadmill.
The examination will take approximately 1 hour, during which subjects will undergo initial and final measurements including completion of questionnaires, physical examinations, joint mobility measurements, functional assessments, and measurements obtained from the AlterG device.
After the initial examination, rehabilitation sessions will take place once a week for both groups for a period of 12 weeks. The experimental group will receive rehabilitation sessions lasting approximately 2 hours, including training on the AlterG device, while the control group will receive conventional physiotherapy sessions lasting approximately 1.5 hours.

The follow-up examination will consist of a follow-up measurement performed 1 month after completion of the rehabilitation programme without ongoing physiotherapy or AlterG training, to assess whether any changes are maintained.

What are the possible benefits and risks of participating?
The potential benefit of participation should be improved walking ability, increased range of motion in the lower limbs, reduced pain during walking, improved physical function, and better quality of life.

Physiotherapy may be accompanied by mild discomfort during exercise, temporary muscle fatigue, or soft tissue irritation. One of the possible risks may also be that the patient's condition does not improve during the study period.

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

Who is funding the study?
Czech Technical University in Prague.

When is the study starting and how long is it expected to run for?
August 2026 to February 2028.

Who is the main contact?
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Study information

Scientific Title
The effect of complex physiotherapy including manual techniques and AlterG Gait Training compared with standard physiotherapy on lower extremity function in patients with systemic sclerosis: a pilot randomized controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2025, Ethics Committee of the Institute of Rheumatology Prague (Na Slupi 480 /4, Praha, 128 00, Czech Republic; + 420 234 075 244; tomcik@revma.cz), ref: 14350/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Device feasibility, Supportive care, Assistive technologies in physiotherapy

Study type(s)

Health condition(s) or problem(s) studied
Patients diagnosed with systemic sclerosis (SSc) and eligible for rehabilitation using assistive technologies.

Interventions
Randomization:
Eligible participants will be randomly assigned to either the experimental group or the control group using a computer-generated randomization sequence based on a pseudo-random number generator (PRNG). The randomization sequence will be generated before participant enrolment, and participants will be allocated in a 1:1 ratio.

Experimental group:
Participants will receive conventional physiotherapy supplemented by gait training using the AlterG anti-gravity treadmill. The intervention will be performed once a week for 12 weeks, with each physiotherapy session lasting approximately 2 hours. The experimental group will additionally complete a 20-30 minute AlterG training session during each therapy visit. Outcome assessments will be performed at baseline, after 3 months of intervention, and at a 5-weeks follow-up.

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 an initial baseline assessment lasting approximately 1 hour, including goniometric measurements, evaluation using the AlterG device, and completion of standardized questionnaires validated for patients with systemic sclerosis. The same assessment protocol will be repeated after the 12-week intervention period. A follow-up evaluation will be performed 1 month after the end of the therapy to assess the persistence of treatment effects during a period without active intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AlterG

Primary outcome(s)
1. Gait parameters during assisted walking therapy measured using the AlterG Anti-Gravity Treadmill software, including objective gait parameters such as walking speed, body weight support (%), cadence, distance walked, and incline, at baseline (Week 0); post-intervention (Week 12); follow-up (Week 17)

2. Lower limb joint range of motion measured using manual goniometry, assessing active range of motion of selected lower limb joints (hip, knee, and ankle) in degrees, at baseline (Week 0); post-intervention (Week 12); follow-up (Week 17)

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); follow-up (Week 17)

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); follow-up (Week 17)

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); follow-up (Week 17)

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); follow-up (Week 17)

Completion date
15/02/2027

Eligibility

Key inclusion criteria
1. Informed Consent: Ability to understand, sign, and date the Independent Ethics Committee - approved written Informed Consent form
2. Patients with systemic sclerosis experiencing impaired lower limb function, mobility, or walking ability
3. Age: Subject is aged ≥ 18 and ≤ 75 years
4. Diagnosis: Confirmed diagnosis of Systemic Sclerosis (SSc) verified by a rheumatologist
5. Subject fulfilled the 2013 EULAR/ACR classification criteria for systemic sclerosis
6. Disease State: Established disease with no signs of acute exacerbation
7. Compliance: 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. Any medical or psychiatric condition that, in the investigator’s judgment, may interfere with participation in the study or affect the study outcomes
2. Acute exacerbation of systemic sclerosis or unstable disease status requiring changes in medical treatment within the study period
3. Presence of severe cardiovascular, respiratory, neurological, or musculoskeletal conditions that may limit safe participation in the rehabilitation program
4. Recent surgical procedure or acute injury affecting mobility or the ability to perform the study intervention
5. Inability to independently walk or inability to safely participate in rehabilitation using the assistive technology
6. Pregnancy or breastfeeding during the intervention period, if considered relevant according to the study protocol
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
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