# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The effect of self-management training program on self-efficacy of disease management and quality of life of patients with scleroderma

## Protocol summary

**Study aim**

Determining the effect of the self-management training program on the self-efficacy of disease management and the quality of life of patients with scleroderma

**Design**

The clinical trial with a control group and without blinding and using a randomized block sampling method will be conducted on a total of 64 patients with scleroderma, and a table of random numbers will be used for randomization.

**Settings and conduct**

The implementation of the intervention will be a combination of lectures, group discussions and question and answer method. The place of the intervention will be done according to the presence of a suitable space (rooms with suitable dimensions and normal conditions in terms of temperature and light and free from environmental stimuli) in the rheumatologist's office.

**Participants/Inclusion and exclusion criteria**

inclusion criteria 1- Diagnosis of scleroderma disease based on the classification indices of the American University of Rheumatology and its evaluation and confirmation by a rheumatologist. 2- Age equal to or more than 18 years exclusion criteria 1- Scleroderma patients hospitalized in wards 2- Simultaneously suffering from other musculoskeletal diseases such as lupus, rheumatoid arthritis, Behcet's syndrome, etc

**Intervention groups**

32 patients with scleroderma will be divided into 4 groups of eight people. The intervention is in 6 sessions of 60-75 minutes (self-management) and each session includes three parts reviewing the educational content presented in the previous session, including patients' questions and sharing their experiences, and giving assignments for the next meeting (5-10 minutes), which will be held once a week. The control group will receive routine care and treatments.

**Main outcome variables**

self-efficacy of disease management؛ Quality of Life

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230715058789N1**
Registration date: **2023-09-30, 1402/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-30, 1402/07/08**
Update count: **0**

**Registration date**

2023-09-30, 1402/07/08

**Registrant information**

**Name**

Mohammad Sadegh Hallaj

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 3571 4576

**Email address**

hallaj.ms@ajums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-09-16, 1402/06/25

**Expected recruitment end date**

2023-11-21, 1402/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of self-management training program on self-efficacy of disease management and quality of life of patients with scleroderma

**Public title**
The effect of self-management training program on self-efficacy of disease management and quality of life of patients with scleroderma
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of scleroderma disease based on classification indices of the American University of Rheumatology and its evaluation and confirmation by a rheumatologist Age equal to or greater than 18 years Ability to communicate in Farsi Non-diagnosis of mental disorders based on the statement of the patient and family No use of psychoactive drugs in the last three months Ability to answer questions Failure to participate in any self-management or rehabilitation program within the past three months More than one year has passed since the disease
**Exclusion criteria:**
Scleroderma patients hospitalized in wards Simultaneously suffering from other musculoskeletal diseases such as lupus, rheumatoid arthritis, Behcet's syndrome, etc.
**Age**
From **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **64**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The sampling method will be random and 16 blocks of 4. The randomization unit is individual and randomization will be done using a table of random numbers.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences
**Street address**
Ahvaz, Golestan Blvd
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6183847897
**Approval date**
2023-08-19, 1402/05/28
**Ethics committee reference number**
IR.AJUMS.REC.1402.295

## Health conditions studied

**1**

**Description of health condition studied**
Scleroderma
**ICD-10 code**
M00-M99
**ICD-10 code description**
Diseases of the musculoskeletal system and connective tissue

## Primary outcomes

**1**

**Description**
The self-efficacy of disease management score in the Self-Efficacy for Managing Chronic Disease questionnaire
**Timepoint**
Before the start of the intervention, after the end of the intervention and three months after the end of the intervention
**Method of measurement**
Self-Efficacy for Managing Chronic Disease Questionnaire

**2**

**Description**
the quality of life score in the Systemic Sclerosis Quality of Life Questionnaire
**Timepoint**
Before the start of the intervention, after the end of the intervention and three months after the end of the intervention
**Method of measurement**
Systemic Sclerosis Quality of Life Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: The intervention is in 6 sessions of 60-75 minutes (self-management) and each session includes three parts reviewing the educational content presented in the previous session, including patients' questions and sharing their experiences, as well as presenting a new topic (40-45 minutes), drawing goals. Training and discussion will be about achieving the goal and progress towards the goals related to the sessions (20-25 minutes) and giving assignments for the next session (5-10 minutes), which will be held once a week.

**Category**

Rehabilitation

**2**

**Description**

Control group: This group will receive routine care and treatments, and before the intervention, after the intervention and three months after the intervention of the experimental group, the research questionnaires will be filled by the researcher's interview and questions and answers from the samples of the control group. According to the ethical standards of the research, the self-management program implemented in the intervention group will be given to the control group in the form of a booklet and after the questionnaires are filled by the control group in three months after the intervention.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Mohammad Sadegh Hallaj

**Street address**

Ahvaz, Golestan Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6183847897

**Phone**

+98 61 3374 3001

**Email**

hallaj.ms@ajums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Sadegh Hallaj

**Street address**

Ahvaz, Golestan Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3314 0000

**Email**

hallaj.ms@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Sadegh Hallaj

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Golestan Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3314 0000

**Email**

hallaj.ms@ajums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Mohammad Sadegh Hallaj

**Position**
Masters student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

**Street address**
Golestan Blvd

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
15794-61357

**Phone**
۳۳۱۴۰۰۰۰ - 06133140000

**Email**
hallaj.ms@ajums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Mohammad Sadegh Hallaj

**Position**
Masters student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

**Street address**
Golestan Blvd

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
15794-61357

**Phone**
+98 61 3314 0000

**Email**
hallaj.ms@ajums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available