

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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