

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of self-management intervention on quality of life, health status and self-management in patients with scleroderma

Protocol summary

Study aim

Determining the effect of self-management intervention on quality of life, health status and self-management in patients with scleroderma .

Design

The design of the study will be a randomized clinical trial with a control group - parallel groups - two-way blind.

Settings and conduct

the officials of Hafez Educational and Medical Center affiliated to Shiraz University of Medical Sciences - To Two way blind the study, participants are given a full explanation of how to perform the intervention before the intervention,

Participants/Inclusion and exclusion criteria

Patients with a definitive diagnosis of scleroderma who have been diagnosed with the disease for one year and have sufficient experience of the details and problems of the disease If they do not want to continue the collaboration at any stage of the research, they can be excluded from the study. Misery and inability of the patient .

Intervention groups

Both groups will be under routine care. Self-management education program will be implemented only for intervention groups

Main outcome variables

Quality of life - Health status assessment - Self-management Description of Outcome Variable 1: Quality of Life Before the intervention and after the intervention Quality of Life Questionnaire Description of Outcome Variable 2: Health status assessment Before the intervention and after the intervention Health status assessment questionnaire Outcome variable description 3: self management Before the intervention and after the intervention Self-management questionnaire Intervention Description: The intervention will be performed as a self-management program training for the intervention group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191021045178N4**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Nilofar Pasyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3623 6293

Email address

pasyarn@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management intervention on quality of life, health status and self-management in patients with scleroderma

Public title

The effect of self-management program on quality of life, health status and self-management of scleroderma patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients referred to the rheumatology department and rheumatology clinic with a definite medical diagnosis of scleroderma. 2. Patients who have been diagnosed with scleroderma for one year and have sufficient experience of the details and problems of the disease. 3. Have the desired physical, mental and cognitive ability to participate in research. 4. Be able to express and speak in Persian. 5. People who want to participate in the study.

Exclusion criteria:

1. If they do not want to continue cooperation at any stage of the research, they can be excluded from the study. 2. Illness and inability of the patient to lead to hospitalization and the person is not able to continue participating in the research. 3. Occurrence of any physical or mental accident during the last six months and during the study period that affects his physical and mental condition. 4. Having a chronic mental illness

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, first, according to the list of patients in the clinic, a list of patients who meet the inclusion criteria is determined. Then sampling will be done by systematic random method. Select the appropriate distance (k) and select the names at equal intervals along the list. The distance or k is obtained by dividing the number of members of the study population by the number of members in the sample. It should be noted that the starting point for this regular selection process is random and is done from a table of random numbers. To include people in the study as an example. Then, using blocking software, people will be randomly placed in two blocks, A and B. Using this method, the number of people assigned to each block will be equal. Finally, by tossing coins, each block will be placed in two groups of control and intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, participants are given a full explanation of how to perform the intervention before the intervention, but participants are unaware of the allocation of study groups. Also, in collecting data and completing questionnaires, the help of a researcher who is not aware of the division of groups will be used. Also, the statistician who analyzes the data will not know about the allocation of groups.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.SUMS.REC.1399.1211

Health conditions studied

1

Description of health condition studied

Self-management

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life before and after the intervention, Quality of life questionnaire score 2: Health status assessment before and after the intervention, Health status assessment questionnaire score 3: Self-management before and after the intervention, Self-management questionnaire score

Timepoint

before and after the intervention

Method of measurement

Quality of Life Questionnaire Health Status Assessment
Questionnaire Self-Management Questionnaire

Secondary outcomes**1****Description**

Quality of Life

Timepoint

Before and after the intervention

Method of measurement

Quality of life questionnaire for patients with
scleroderma

2**Description**

General health assessment

Timepoint

Before and after the intervention

Method of measurement

Stanford General Health Scale

3**Description**

self management

Timepoint

Before and after the intervention

Method of measurement

Self-efficacy questionnaire for self-management in
chronic patients

Intervention groups**1****Description**

Intervention group: Self-management education
program-Get routine care

Category

Other

2**Description**

Control group: Get routine care

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hafez Educational and Medical Center affiliated to
Shiraz University of Medical Sciences

Full name of responsible person

Niloofar Pasyar

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زند، روبروی خیابان فلسطین، ساختمان مرکزی دانشگاه علوم
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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

یونس قاسمی

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Niloofar Pasyar

Position

Assistant Professor - Faculty member of Shiraz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Providing information without personal details of the participants will be confidential

When the data will become available and for how long

After studying and printing the results

To whom data/document is available

The results of the research will be provided to the participants and relevant organizations upon request.

Under which criteria data/document could be used

Obtaining permission from the relevant authorities in the faculty, university and hospital. Keeping participants' information confidential

From where data/document is obtainable

Shiraz. Zand St., Library of Shiraz School of Nursing and

Midwifery

What processes are involved for a request to access data/document

The request for the results will be sent to the library of

Shiraz School of Nursing and Midwifery. It will be provided to them with the coordination done.

Comments