

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Investigating the effect of implementing self-care training through smartphones on physical symptoms and quality of life of patients with systemic lupus erythematosus

Protocol summary

Study aim

Determining the effect of implementing self-care training through smartphones on physical symptoms and quality of life of patients with systemic lupus erythematosus.

Design

A clinical trial with a control group, with parallel groups without blinding, randomized on 50 patients, which will be used for randomization by computer software.

Settings and conduct

In this research, researchers first go to Honry's Clinic, located in Jahrom City, and add patients who meet the inclusion criteria to the study with the help of a rheumatology subspecialist. After completing the samples and performing randomization, a group will be formed for the patients of the intervention group in Eitta, and the training sessions, which include four sessions, will be sent to them on a weekly basis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of lupus disease (based on the diagnosis of a rheumatologist) Be infected for at least 6 months Willingness to participate in research Minimum literacy Having smartphones and internal software such as Soroush or Eitta Age 18 to 65 years exclusion criteria: Unwillingness to continue cooperation during the research Having advanced diseases such as cancer or chronic Renal failure Having mental disorders

Intervention groups

In the intervention group, patients who meet the conditions for entering the study will be formed into a group in the Eitta messenger, and all patients will be added to that group, Then self-care training will be given to the group on a weekly basis, but the control group will only undergo routine training provided by the attending physician.

Main outcome variables

Education via smartphone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210114050037N3**

Registration date: **2023-09-04, 1402/06/13**

Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**

Update count: **0**

Registration date

2023-09-04, 1402/06/13

Registrant information

Name

Ali asghar Rahmanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 3628

Email address

lynurse8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of implementing self-care training through smartphones on physical symptoms and quality of life of patients with systemic lupus erythematosus

Public title

Investigating the effect of implementing self-care training through smartphones on physical symptoms and quality of life of patients with systemic lupus erythematosus

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of lupus disease (based on the diagnosis of a rheumatologist) Be infected for at least 6 months
Willingness to participate in research Minimum literacy
Having smartphones and internal software such as Soroush or Eitta Age 18 to 65 years

Exclusion criteria:

Unwillingness to continue cooperation during the research Having advanced diseases such as cancer or chronic Renal failure Having mental disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of samples is done using the block method and through statistical software.

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 Jahrom University of Medical Sciences

Street address

At the end of Ostad Motahari Boulevard

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2023-08-21, 1402/05/30

Ethics committee reference number

IR.JUMS.REC.1402.045

Health conditions studied

1

Description of health condition studied

systemic lupus erythematosus

ICD-10 code

G73.7

ICD-10 code description

Myopathy in diseases classified elsewhere

Primary outcomes

1

Description

physical symptoms

Timepoint

Measurement of physical symptoms before the beginning of the educational intervention and one month after the end of the intervention

Method of measurement

Lupus Physical Symptoms Questionnaire

2

Description

Quality of Life

Timepoint

before the beginning of the educational intervention and one month after the end of the intervention

Method of measurement

Lupus quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After all the patients have completed the questionnaire, virtual training in the Eitta software for the intervention group will begin. In this way, a group will be formed in the Eitta software and all patients of the intervention group will be added to it, Then the audio files and related videos are uploaded to the group on a weekly basis.

Category

Other

2

Description

Control group: During the implementation of the educational intervention for the intervention group, the control group will not receive any training except routine training by the attending physician.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Honari Specialty and sub specialty clinic

Full name of responsible person

Ali asghar Rahmanian kushkaki

Street address

Ostad Motahari Boulevard, above Ostad Motahari Hospital, corner of the alley25

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7415713945

Phone

+98 71 5434 2006

Email

honarclinic@jums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

kavoos solhjoo

Street address

At the end of Ostad Motahari Boulevard

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Phone

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Email

Solhjoo@JUMS.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Ali asghar Rahmanian kushkaki

Position

Non Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

zohreh Badiyepeymaie Jahromi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Ali asghar Rahmani kushkaki

Position

Non faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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lynurse8@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available