Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of medical team supportive intervention through social networks on health anxiety and acceptance of disability in patients with systemic lupus erythematosus referred to selected educational and medical centers affiliated to Shiraz University of Medical Sciences-2020

Protocol summary

Study aim
Determining the effect of supportive intervention of treatment team through social networks on health anxiety and disability acceptance in patients with systemic lupus erythematosus

Design
A randomized controlled clinical trial with parallel groups, single blind, randomized trial

Settings and conduct
The study is performed in the clinic of Hafez Hospital affiliated to Shiraz University of Medical Sciences. In this study, the person who collects the results of the study and the statistician will be blind to the groups until the end of the study and the completion of data analysis and reporting.

Participants/Inclusion and exclusion criteria
Main inclusion criteria: Patient with systemic lupus erythematosus and has a mobile phone and is able to use mobile software; Main exclusion criteria: severe recurrence of the disease and inability of the patient to continue participating in the study

Intervention groups
The members of the intervention group receive daily material with aspects of spiritual, psychological and informational support. People in the control group don't receive supportive intervention through social networks.

Main outcome variables
health anxiety, disability acceptance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191021045178N2**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Nilofar Pasyar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of medical team supportive intervention through social networks on health anxiety and acceptance of disability in patients with systemic lupus erythematosus referred to selected educational and medical centers

affiliated to Shiraz University of Medical Sciences-2020

Public title
Effect of supportive intervention in patients with systemic lupus erythematosus
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the diagnosis of systemic lupus erythematosus by a physician Age range over 18 years Has a mobile phone and is able to use mobile software Ability to understand and speak Persian language Do not have acute mental and cognitive disease diagnosed based on the contents of the file No other known and effective physical disease The patient has only lupus erythematosus
Exclusion criteria:
Having Known and influential physical illness Having Mental illness Having Drug-Induced Lupus Erythematosus or Lupus of the Skin
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **124**
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. Finally, 124 people are included in the study as a sample. Then, using blocking software, 124 people will be randomly placed in blocks A and B. Using this method, the number of people assigned to each block will be equal to 62 people. Finally, by tossing coins, each block will be placed in two groups of control and intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the data collector and the data analyzer are blinded to the grouping of patients into two groups of intervention and control.
Placebo
Not used
Assignment
Parallel

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
Vice Chancellor for Research, 7th floor, Shiraz University of Medical Science, Zand st.
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2021-02-07, 1399/11/19
Ethics committee reference number
IR.SUMS.REC.1399.1012

Health conditions studied

1

Description of health condition studied
systemic lupus erythematosus
ICD-10 code
M32
ICD-10 code description
Systemic lupus erythematosus (SLE)

Primary outcomes

1

Description
Health anxiety
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
Salkowski & Warwick Health Anxiety Questionnaire (2002)

2

Description
acceptance of disability
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
acceptance of disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The members of the intervention group are members of one of the virtual social networks managed by the researcher and the materials that include providing supportive intervention to patients with systemic lupus erythematosus are provided to them through this virtual social network. Virtual supportive intervention will be provided daily for 8 weeks, taking into account various aspects of spiritual, psychological and informational support. Content will be provided on the WhatsApp social network. A WhatsApp channel will be created with the management of the research team. The intervention group will receive text and multimedia messages at 4 time intervals during the day. The maximum number of messages per period is 3 messages. The content is assessed based on the pre-test and it is possible to change the program according to the needs of the participants. Scientific content based on authoritative and up-to-date articles and books on systemic lupus erythematosus as well as the Lupus Patients Support Association will be presented. The content is polled every weekend and it is possible to make changes based on the feedback received. Feedback is obtained through an online questionnaire or by sending participants' comments to the researcher's WhatsApp personal page. In order to emphasize the key content, the main points are placed in the channel again every Thursday. A psychologist colleague is assisted as a researcher in presenting psychological content. According to the needs assessment and request of the participants, the content they need in the field of research policy will be sent to them separately on the WhatsApp personal page.

Category

Behavior

2

Description

Control group: They do not receive supportive intervention through social media. They receive care includes routine nursing care and training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Hafez Hospital in Shiraz

Full name of responsible person

Aida Sam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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
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Associate Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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