

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The study of effects meta-cognitive skills training based -on mindfulness on depression, anxiety, stress and well being of systemic lupus erythematosus patients

Protocol summary

Study aim

to determine the effect of Meta-cognitive Skills Training based on mindfulness on Depression, Anxiety, Stress, and well being of Systemic Lupus Erythematosus Patients

Design

Clinical trials with a control group in the waiting list and two months follow up in the intervention and control group

Settings and conduct

After sampling and assigning 30 patients in each intervention and control group, the study was carried out in the form of meta-cognitive skills training based mindfulness in 8 sessions of 60 minutes for the intervention group at Imam Hossein hall in Shahid Beheshti Hospital in Babol And At this time, for the control group did not intervene. The training was conducted by a psychiatric nurse and with the help of a psychologist, as well as providing a manual for each patient. The intervention group was re-tested two months after the training (with follow-up by the researcher for exercises within two months). The questionnaires used in this study included depression, anxiety and stress Scale(DASS-21) and a yeild psychological well-being questionnaire.

Participants/Inclusion and exclusion criteria

1- patients with aged 16-55 years old 2. study at least 3rd grade 3. Not having mental disorders such as major depressive disorder and anxiety disorder during the past six months (using available information in the case) 4. Having a desire to participate in this research excluding criteria 1. Being in the acute phase of the disease 2. Previous experience in Meta-cognitive Skills and mindfulness-based Training 3. Lack of satisfaction to participate in training sessions 4. absence in two sessions or over in training sessions

Intervention groups

30 patients with Systemic Lupus Erythematosus

Main outcome variables

mindfulness-based meta-cognitive skills training (independent variable) Depression, anxiety, stress, and well being (dependent variable)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037723N2**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **retrospective**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Hamideh Azimi Lolaty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7343

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-26, 1397/04/05

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

2018-06-25, 1397/04/04

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2018-10-23, 1397/08/01

Scientific title

The study of effects meta-cognitive skills training based - on mindfulness on depression, anxiety, stress and well being of systemic lupus erythematosus patients

Public title

The study of effect meta-cognitive skills training based - on mindfulness on lupus patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 16-55 years with Systemic Lupus Erythematosus Having at least third degree Not having mental disorders such as major depressive disorder and anxiety disorder in the past six months (using available information in the case) To be willing to participate in this research

Exclusion criteria:

Being in the acute phase of the disease Previous experience in meta-cognitive skills training based -on mindfulness classes No consent to attend training sessions

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **58**

More than 1 sample in each individual

Actual sample size in each individual: **30**

Patient with systemic lupus erythematosus according to nephrologist diagnosis

Randomization (investigator's opinion)

Randomized

Randomization description

For each patient referring to the nephrology clinic after considering the inclusion and exclusion criteria of a number 60 patients are selected through random sampling (simple randomization) from the existing numbers. Patients according to the extra numbers In the lottery, are included in the study. After selecting these 60 patients, a randomized table of numbers for these patients will be allocated to two groups of 30 (intervention and control).

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 Mazandaran University of Medical Sciences

Street address

central headquarters of Mazandaran University of Medical Sciences and Health Services , the beginning of Valiasr highway , Sari

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.MAZUMS..REC.1397.1489

Health conditions studied**1****Description of health condition studied**

systemic lupus erythmatosus

ICD-10 code

M32

ICD-10 code description

Systemic lupus erythematosus (SLE)

Primary outcomes**1****Description**

Depression score > = 14

Timepoint

Before Intervention - After Intervention - Two Month After Intervention

Method of measurement

Depression,Anxiety Stress Scale(DASS)

2**Description**

Anxiety score > = 10

Timepoint

Before Intervention - After Intervention - Two Month After Intervention

Method of measurement

Depression,Anxiety Stress Scale(DASS)

3

Description

Stress score > = 19

Timepoint

Before Intervention - After Intervention - Two Month After Intervention

Method of measurement

Depression,Anxiety Stress Scale(DASS)

4

Description

Well being score > = 11

Timepoint

Before Intervention - After Intervention - Two Month After Intervention

Method of measurement

yeild Psychological well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes people with lupus disease. The intervention was conducted in 8 sessions of 60 minutes in a group with a manual approved by the psychiatrist, psychiatrist and doctor of clinical psychology and in the presence of a clinical psychologist under the supervision of the supervisor. Intervention of Meta-cognitive Skills Training based mindfulness, including familiarity with cognitive-attention syndrome, rumination and maladaptive coping behaviors, and how to postpone rumination, familiarity with the attention training technique, familiarity with the examination technique, familiarity with the respiratory meditation technique, familiarity with the automatic guidance technique, familiarity with the free association method and familiarity with the cloud illustration method.

Category

Other

2

Description

Control group: Includes people with lupus disease and there is no intervention in them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Babol

Full name of responsible person

Hamideh Azimi Lolaty

Street address

sargord ghasemi street

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beheshti@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Street address

Mazandaran University of Medical Sciences, Three Way Joybar, Beginning of the Highway of Vali Asr, Imam Square

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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

Sari University of Medical Sciences

Proportion provided by this source

50

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
Mazandaran University of Medical Sciences

Full name of responsible person
Hamideh Azimi Lolaty

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Vesal Shirazi Avenue, Amir Mazandaran Boulevard,
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Person responsible for updating data

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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
No - There is not 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
Yes - There is 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

Title and more details about the data/document
Lupus patients

When the data will become available and for how long
4 months

To whom data/document is available
Researcher and sponsor

Under which criteria data/document could be used
For other patients if useful

From where data/document is obtainable
Researcher and sponsor

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

Comments