

# 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

azimihamideh@gmail.com

##### 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

#### **City**

Babol

#### **Province**

Mazandaran

#### **Postal code**

4716681451

#### **Phone**

+98 11 3225 2071

#### **Fax**

+98 11 3222 0662

#### **Email**

beheshti@mubabol.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Hamideh Azimi Lolaty

##### **Street address**

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

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4816715793

##### **Phone**

+98 11 3337 4750

##### **Email**

midnasibeh@yahoo.com

#### **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

**Street address**

Vesal Shirazi Avenue, Amir Mazandaran Boulevard,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

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Mazandaran University of Medical Sciences

**Full name of responsible person**

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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**