Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, Sari Town
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3367 7343
Email
azimihamideh@gmail.com

Person responsible for scientific 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, Sari Town
City
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Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3367 7343
Email
azimihamideh@gmail.com

Person responsible for updating data

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 Ave, Amir Mazandrani Blvd, Sari Town
City
Sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3367 7343
Email
azimihamideh@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
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