

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Mindfulness-Based Stress Reduction(MBSR) on illness perception, illness acceptance, difficulties with emotion regulation and cognitive flexibility in Systemic Lupus Erythematosus Patients

Protocol summary

Study aim

the effectiveness of Mindfulness-Based Stress Reduction Therapy on illness perception, illness acceptance, difficulties with emotion regulation, and cognitive flexibility in patients with systemic lupus erythematosus

Design

A randomized clinical trial with a control group on the waiting list, without a blind strain, with a one-month follow-up phase on 20 patients.

Settings and conduct

First, 20 patients with Systemic Lupus Erythematosus will be selected through the purposive sampling of patients referred to the Rheumatology clinic of Al-Zahra Hospital in Isfahan and will be assigned to experimental and control groups. Then patients of both groups will complete the pre-test questionnaires. Patients in the experimental group will be treated with Mindfulness-Based Stress Reduction during weekly sessions over 2 months. The intervention will be provided by a clinical psychologist. During this period, patients in the control group will not receive any intervention. At the end of the intervention for the experimental group, all patients will answer the post-test questionnaires and after one month, the follow-up questionnaires. Upon completion of the project, patients on the waiting list will receive the above intervention.

Participants/Inclusion and exclusion criteria

A minimum of 6 months and a maximum of 3 years have elapsed since the diagnosis of systemic lupus erythematosus Do not have another physical illness at the same time No concomitant psychiatric disorders Do not take any other medicines (except medicines used to treat Lupus) exclusion criteria : staring Lupus flare

Intervention groups

The groups consist of the experimental group and the control group.

Main outcome variables

illness perception, illness acceptance, difficulties with emotion regulation and cognitive flexibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201006048952N1**

Registration date: **2021-03-06, 1399/12/16**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **0**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Shirin Irani

Name of organization / entity

University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 3860

Email address

shirin_irani@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-05-04, 1400/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Mindfulness-Based Stress Reduction(MBSR) on illness perception, illness acceptance, difficulties with emotion regulation and cognitive flexibility in Systemic Lupus Erythematosus Patients

Public title

Effectiveness of Mindfulness on cognitive and emotional factors in Systemic Lupus Erythematosus Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

A minimum of 6 months and a maximum of 3 years have elapsed since the diagnosis of Systemic Lupus Erythematosus Do not have another physical illness at the same time No concomitant psychiatric disorders Do not take any other medicines (except medicines used to treat lupus) Minimum diploma education Score less than 14 in the Hospital Anxiety and Depression Scale

Exclusion criteria:

starting lupus flares

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: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 University of Isfahan

Street address

Hezar Jarib St.

City

Isfahan

Province

Isfahan

Postal code

8134816515

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.UI.REC.1399.094

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**

Illness perception

Timepoint

Before intervention, after intervention, follow up

Method of measurement

Brief Illness Perception Questionnaire(BIPQ)

2**Description**

illness acceptance

Timepoint

Before intervention, after intervention, follow up

Method of measurement

Chronic Illness Acceptance Questionnaire (CIAQ)

3**Description**

Difficulties with emotion regulation

Timepoint

Before intervention, after intervention, follow up

Method of measurement

Difficulties in Emotion Regulation Scale

4**Description**

Cognitive flexibility

Timepoint

Before intervention, after intervention, follow up

Method of measurement

Cognitive Flexibility Inventory (CFI)

Secondary outcomes

1

Description

clinical characteristics of systemic lupus erythematosus patients

Timepoint

Pretest, Post test and follow up

Method of measurement

Blood test, Clinical examinations, Systemic Lupus Erythematosus Disease Activity Index

Intervention groups

1

Description

The standard mindfulness-based stress reduction treatment (MBSR) protocol will be used to educate patients. This protocol includes 8 sessions of mindfulness-based stress reduction therapy, each of which regularly and separately includes the complete content as follows: Instructional videos for the therapist (theoretical concepts to be taught to patients along with instruction on how to Presenting materials, explanations and examples), therapist training booklets, client training booklets, teaching mindfulness techniques (formal and informal exercises), audio files of techniques and worksheets for clients' homework. In each treatment session, the researcher will provide theoretical basics for patients. In the first to fifth sessions, after presenting the theoretical concepts, a practical mindfulness technique related to the same theoretical concepts will be taught to the clients to better understand the content. And they are asked to do the technique in the meeting. Formal and informal exercise training will then be provided, and patients should complete one round of formal exercise per session. Doing both formal and informal exercises will be part of your homework for next week. The training booklets provided by the treatment protocol for learning and educating clients at home are translated, compiled and compiled for clients under the title of "Home Learning Booklet" for clients and presented to them each session along with homework worksheets. will be. Worksheets include tables where clients should record formal and informal mindfulness exercises and the types of meditations they perform at home on a weekly basis and bring them to the next session.

Category

Behavior

2

Description

Control group: The standard mindfulness-based stress reduction treatment (MBSR) protocol will be used to educate patients. This protocol includes 8 sessions of mindfulness-based stress reduction therapy, each of which regularly and separately includes the complete content as follows: Instructional videos for the therapist (theoretical concepts to be taught to patients along with

instruction on how to Presenting materials, explanations and examples), therapist training booklets, client training booklets, teaching mindfulness techniques (formal and informal exercises), audio files of techniques and worksheets for clients' homework. In each treatment session, the researcher will provide theoretical basics for patients. In the first to fifth sessions, after presenting the theoretical concepts, a practical mindfulness technique related to the same theoretical concepts will be taught to the clients to better understand the content. And they are asked to do the technique in the meeting. Formal and informal exercise training will then be provided, and patients should complete one round of formal exercise per session. Doing both formal and informal exercises will be part of your homework for next week. The training booklets provided by the treatment protocol for learning and educating clients at home are translated, compiled and compiled for clients under the title of "Home Learning Booklet" for clients and presented to them each session along with homework worksheets. will be. Worksheets include tables where clients should record formal and informal mindfulness exercises and the types of meditations they perform at home on a weekly basis and bring them to the next session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Shirin Irani

Street address

Soffeh St.

City

Isfahan

Province

Isfahan

Postal code

8134816515

Phone

+98 31 3233 3860

Email

s.irani@edu.ui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shirin Irani

Street address

Hezarjarib St.

City

Isfahan

Province
Isfahan

Postal code
8134816515

Phone
+98 31 3233 3860

Email
s.irani@edu.ui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shirin Irani

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
University of Isfahan

Full name of responsible person
Shirin Irani

Position
Ph.D candidate of Psychology

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
No.139 - Ferdowsi Allay , Sheikhbahaiy St.

City
Isfahan

Province
Isfahan

Postal code
8134816515

Phone
+98 31 3233 3860

Email
s.irani@edu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Isfahan

Full name of responsible person
Shirin Irani

Position

Ph.D candidate of Psychology

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
No. 139,Ferdowsi Allay , Sheikhbahaiy St.

City
Isfahan

Province
Isfahan

Postal code
8134816515

Phone
009832333860

Email
s.irani@edu.ui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
University of Isfahan

Full name of responsible person
Shirin Irani

Position
Ph.D candidate of Psychology

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Sheikhbahaiy St.

City
Isfahan

Province
Isfahan

Postal code
8134816515

Phone
009832333860

Email
s.irani@edu.ui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
This file will not be published because it contains personal and private information of the participants.

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

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some of the documents obtained from this study will be available for the use of researchers interested in this field only after the completion of this trial, maintaining legal conditions, and criteria.

When the data will become available and for how long

accessibility= 12 months after printing results

To whom data/document is available

only academic researchers

Under which criteria data/document could be used

The use of the documents of this clinical trial will be possible only for academic researchers in a limited way, only with the permission of the person in charge of this clinical trial.

From where data/document is obtainable

please send an email to shirin_irani@ymail.com

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

Send a complete written request to the corresponding person, providing the details and reasons why you need to use the test documentation. Your request will be reviewed and you will be notified of the result.

Comments