Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The impact of mindfulness-based stress reduction, in comparison to exercise on depression symptoms and quality of life in patients with systemic lupus erythematosus

Protocol summary

Study aim

To compare the effect of two interventions, Mindfulness-Based Stress Reduction (MBSR) and exercise therapy, on depression and quality of life in patients with lupus, compared to a control group.

Design

A randomized controlled trial with a parallel three-group design, involving 90 patients (30 per group). Block randomization with a block size of 6 and an allocation ratio of 1:1:1 was performed using SPSS software version 26. The patient follow-up period was 6 months.

Settings and conduct

This study is being conducted at the Baghaipour Rheumatology Clinic, in Yazd. Eligible patients, after providing informed consent, are randomly assigned to three groups: A (drug therapy + online MBSR), B (drug therapy + home-based exercise), and C (drug therapy alone). Assessments are conducted at baseline, 3 months, and 6 months. Blinding of patients and instructors was not feasible; however, outcome assessors and the statistical analyst were blinded to patient group allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18-60 years; at least 6 months since lupus diagnosis; education above 9th grade; not pregnant. Exclusion Criteria: Obvious psychiatric disorders; addiction; acute cardiac or pulmonary disease contraindicating physical activity; severe joint involvement; hospitalization or discontinuation of medication in the last 6 months.

Intervention groups

Group A (Intervention): Standard lupus drug therapy + 8 sessions of 90-minute online group Mindfulness-Based Stress Reduction (MBSR) over 8 weeks. Group B (Intervention): Standard lupus drug therapy + a combined exercise program (resistance with bands and endurance) for 6 months, 5 sessions per week. Group C (Control): Standard lupus drug therapy alone, with no non-pharmacological intervention.

Main outcome variables

Depression score, Quality of life score, Disease activity score, Fatigue score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251216068349N1**
Registration date: **2026-07-14, 1405/04/23**
Registration timing: **prospective**

Last update: **2026-07-14, 1405/04/23**
Update count: **0**

Registration date

2026-07-14, 1405/04/23

Registrant information

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Name of organization / entity

Shahid sadoughi Yazd university of medical science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-16, 1405/04/25

Expected recruitment end date

2026-08-16, 1405/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of mindfulness-based stress reduction, in comparison to exercise on depression symptoms and quality of life in patients with systemic lupus erythematosus

Public title

Comparison of Mindfulness and Exercise of Depression of SLE Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age range: 18 to 60 years Diagnosis of Systemic Lupus Erythematosus (SLE) confirmed for a minimum of 6 months Educational attainment: Above the 9th-grade level Negative pregnancy status / Non-pregnant

Exclusion criteria:

Diagnosis of a clear psychiatric disorder upon initial evaluation by the psychologist at the center Patient's unwillingness to continue the study Discontinuation of medication by the patient for any reason during the past 6 months Hospitalization due to lupus complications during the last 6 months Substance addiction Severe joint involvement preventing physical activity Acute cardiac or pulmonary disease that contraindicates physical activity Occurrence of serious lupus complications during the study period, including severe heart failure, renal failure, or cerebral hemorrhage History of distinct psychiatric disorders, including major depression, psychosis, or use of psychiatric medications Occurrence of pregnancy at any time during the study period

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Process: An independent and impartial statistician, who had no role in the subsequent phases of the study implementation or outcome assessment, generated the random allocation sequence using specialized statistical software (SPSS, version 26). The block design parameters were defined as follows: a block size of 6 and an allocation ratio of 1:1:1 for the three groups: A (Mindfulness-Based Stress Reduction intervention), B (Exercise therapy intervention), and C (Control group). Consequently, within each block of six, the sequence of two participants in Group A, two participants in Group B, and two participants in Group C was determined completely randomly by the software. This blocked random sequence was generated for 90 participants (equivalent to 15 complete blocks of six). Subsequently, the allocation results for each of the 90 sequential sampling positions were recorded on separate sheets, placed inside opaque, sealed envelopes, and numbered consecutively from 1 to 90. All envelopes were stored in a secure location accessible to the principal investigator (who was not involved in outcome assessments). After screening each participant, confirming their eligibility for the study, and obtaining informed consent, a researcher who was unaware of the allocation sequence and had no role in subsequent participant assessments opened the envelope corresponding to the participant's sequential entry number and assigned the individual to one of the three study groups according to the instructions inside the envelope. This process was repeated sequentially for all 90 participants. Due to the non-pharmacological nature of the interventions, blinding of participants and intervention instructors was not feasible. However, the assessors of primary and secondary outcomes (including depression and quality of life questionnaires), as well as the final statistical data analyst, remained blinded to the group allocation of participants until the analysis phase was complete. This method, by employing blocked randomization, ensured optimal balance between the groups throughout the study and, through the use of numbered, sealed envelopes, fully achieved allocation concealment. These two principles, along with the blinding of assessors and the analyst, minimized the risk of selection and measurement biases, thereby strengthening the internal validity of the study results.

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 for Research, School of Medicine, Shahid Sadoughi University of Medical Sciences

Street address

School of Medicine, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

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Approval date
2025-10-06, 1404/07/14
Ethics committee reference number
IR.SSU.MEDICINE.REC.1404.185

Health conditions studied

1

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

Primary outcomes

1

Description
Primary Outcome Variable 1:Mean depression score based on the HADS (Hospital Anxiety and Depression Scale). This questionnaire includes 7 specific questions for depression, with each question scored from 0 to 3, resulting in a total score range of 0 to 21. Higher scores indicate more severe depression. / Primary Outcome Variable 2:Mean quality of life score based on the WHOQOL-BREF questionnaire (World Health Organization). This 26-item questionnaire encompasses four domains: physical health, psychological health, social relationships, and environmental health. The raw score for each domain is transformed into a 0 to 100 scale, with higher scores indicating a better quality of life. / Primary Outcome Variable 3:Mean disease activity score based on the SLEDAI (Systemic Lupus Erythematosus Disease Activity Index). This index comprises 24 clinical and laboratory items, with scores ranging from 0 to 105. Higher scores reflect greater disease activity. / Primary Outcome Variable 4:Mean fatigue score based on the FSS (Fatigue Severity Scale). This 9-item questionnaire is scored on a 7-point Likert scale (from completely disagree to completely agree). The final score is calculated as the average of the 9 items, with a score range of 1 to 7. Higher scores indicate more severe fatigue.
Timepoint
Measurement of primary outcome variables (depression score, quality of life score, disease activity score, and fatigue score) is performed at three time points: 1. Baseline (pre-intervention): initial measurement before any intervention begins / 2. Third month after intervention initiation: interim assessment to evaluate the trend of changes / 3. Sixth month after intervention initiation: final assessment at the end of the follow-up period
Method of measurement
Primary Outcome Variable 1 (Mean Depression Score): Hospital Anxiety and Depression Scale (HADS) / Primary Outcome Variable 2 (Mean Quality of Life Score): World Health Organization Quality of Life Brief Version (WHOQOL-BREF) / Primary Outcome Variable 3 (Mean Disease Activity Score): Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) / Primary Outcome Variable 4 (Mean Fatigue Score): Fatigue Severity Scale (FSS)

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention Group (Mindfulness Group): Receiving standard lupus drug therapy according to the treating rheumatologist's opinion, along with participation in the Mindfulness-Based Stress Reduction (MBSR) program. This program consists of 8 sessions of 90 minutes each, conducted online and in a group format via Google Meet software, held weekly for 8 weeks. The sessions are led by a clinical psychologist trained in MBSR. Session content includes mindfulness exercises, body scan meditation, mindful breathing exercises, mindful yoga, and training on how to cope with chronic pain, fatigue, and mood fluctuations caused by the disease. Participants are required to perform daily home practice (at least 30 minutes per day, 5 days per week) and complete an exercise checklist. Adherence to home practice is monitored through telephone calls every two weeks and one monthly group session until the end of 6 months.
Category
Lifestyle

2

Description
Second Intervention Group (Exercise Group): Receiving standard lupus drug therapy according to the treating rheumatologist's opinion, along with a combined exercise program designed by an exercise physiology specialist. The exercise program includes resistance training (3 days per week, 2 minutes per session) using elastic bands with constant resistance and endurance training (2 days per week, 15 to 30 minutes per session) consisting of walking, running, cycling, or aerobics based on patient preference. Exercise intensity is adjusted based on the Borg Scale (ranging from 4 to 9), and the program is designed progressively on a monthly basis over 6 months (24 weeks). The exercise technique is taught in person during the initial visit, and an instructional video is provided to the patient. Patients complete a self-report exercise checklist, and adherence is monitored through telephone calls every two weeks and one monthly in-person training session under the supervision of an instructor.

Category
Rehabilitation

3

Description
Control Group: Receiving standard lupus drug therapy according to the treating rheumatologist's opinion, without any non-pharmacological intervention. Patients in this group are visited every 3 months according to routine practice and are monitored regarding disease status and medication use by the research team through telephone calls every two weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghaipour Rheumatology Clinic, Shahid Sadoughi Hospital, Yazd
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr. Ali Dehghan
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All individual participant data collected in this study, including baseline information (age, sex, education level, marital status), clinical data (disease activity based on the SLEDAI index, medication dosages, hospitalization history), questionnaire results (HADS depression scores, WHOQOL-BREF quality of life scores, FSS fatigue scores, GHQ-12 mental health scores, FMI-SF mindfulness scores), and anthropometric data (weight, height, body mass index, body fat percentage, skeletal muscle percentage, visceral fat percentage) will be available for sharing after complete anonymization (removal of identifying information such as name, surname, national ID, and exact address). Data from all measurement time points (baseline, month 3, and month 6) for all three study groups (first intervention, second intervention, and control) will be available for sharing. Additionally, the study protocol, informed consent form, and statistical analysis plan will be available for sharing along with the data.
When the data will become available and for how long
Access to anonymized study data will begin 6 months after the completion of the study and publication of the primary results and will be available for a period of 1 years. The estimated start date for access is approximately April 2027.
To whom data/document is available
Data and documents from this study will be accessible to all researchers affiliated with academic, research, and scientific institutions (both domestic and international) who have non-profit research purposes and intend to use the data for secondary analyses, meta-analyses, or systematic reviews.
Under which criteria data/document could be used
Access to the data is conditional upon approval of the applicant's research proposal by the scientific committee of their affiliated university and signing a confidentiality agreement regarding non-disclosure of patient information. Use of the data for commercial and industrial purposes is not permitted.
From where data/document is obtainable
Applicants can request access to the data and documents of this study through the following methods, listed in order of priority: First Method: Email (Priority 1) Send requests to the following email address: Email: sarvenaz.nsina@ssu.ac.ir Second Method: Telephone (Priority 2): Phone number: +98 912 278 4177 Third Method: In-person Visit or Postal Correspondence (Priority 3): Postal address: Baghaipour Rheumatology Clinic, adjacent to Shahid Sadoughi Hospital, Ibn Sina Boulevard, Yazd, Iran (Attn: Dr. Ali Dehghan, Supervisor) Postal Code: 8917613145 Responsible Contacts: Dr. Ali Dehghan (Supervisor and Rheumatology Subspecialist) Dr. Sarvenaz Naseri Sina (Rheumatology Fellow and Principal Investigator) Important Note: Requests must be submitted along with the approved research proposal and a confidentiality agreement.
What processes are involved for a request to access data/document
Requests submitted to receive data and documents from this study are processed through four stages. First, the request is received and registered via email, and a confirmation of receipt is sent to the applicant within 72 hours (maximum 1 week). Next, the request, along with the research proposal and confidentiality agreement, is reviewed by the research team for alignment of research

objectives and ethical considerations (maximum 2 weeks). Upon initial approval, the request is referred to the Research Ethics Committee of Shahid Sadoughi University of Medical Sciences in Yazd for final review (maximum 3 weeks). Following final approval, the anonymized data is prepared and made available to the applicant via a secure link or email (maximum 2 weeks). The total expected time from request submission to data receipt is approximately 6 to 8 weeks.

Comments