Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effects of mindfulness-based stress reduction (MBSR) in groups and online setting on the severity of pemphigus vulgaris disease and treatment compliance in patients with pemphigus vulgaris

Protocol summary

Study aim

Investigating the effects of mindfulness-based stress reduction (MBSR) in groups and online setting on the severity of pemphigus vulgaris disease and treatment compliance in patients with pemphigus vulgaris

Design

This study is a randomized, double-blind, placebo-controlled trial with parallel groups. 26 patients with pemphigus vulgaris are randomly assigned to the intervention or control group using block randomization.

Settings and conduct

This study is a randomized, double-blind, controlled clinical trial conducted at Imam Reza Hospital, Mashhad. 26 patients with pemphigus vulgaris will be randomly assigned to either the intervention group (receiving online MBSR) or the control group (receiving a 30-minute educational session on the disease). Participants will complete the MMAS and DASS-21 scales before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Diagnosis of pemphigus vulgaris through clinical and cytopathological examination, aged 20-60, at least middle school education, stress score above 8, anxiety score above 15 on Depression, Anxiety, and Stress Scale - 21(DASS-21), no major psychiatric history, and consent to participate. Exclusion criteria :Missing more than two sessions.

Intervention groups

In the intervention group, participants will complete an 8-week program, with weekly 90-minute online sessions in groups of five, led by a psychiatry resident trained in Mindfulness-Based Stress Reduction (MBSR) and supervised by an instructor. The control group will receive a 30-minute educational session on pemphigus vulgaris guided by a dermatologist's advice.

Main outcome variables

Morisky Medication Adherence Scale Score: Depression, Anxiety: and Stress Scale 21 Score:

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241113063699N1**
Registration date: **2024-11-20, 1403/08/30**
Registration timing: **prospective**

Last update: **2024-11-20, 1403/08/30**
Update count: **0**

Registration date

2024-11-20, 1403/08/30

Registrant information

Name

Zahra Ghasemi Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-11, 1403/09/21

Expected recruitment end date

2025-03-01, 1403/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effects of mindfulness-based stress reduction (MBSR) in groups and online setting on the severity of pemphigus vulgaris disease and treatment compliance in patients with pemphigus vulgaris

Public title
Investigating the effects of mindfulness-based stress reduction (MBSR) in groups and online setting on the severity of pemphigus vulgaris disease and treatment compliance in patients with pemphigus vulgaris

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Pemphigus Vulgaris Based on Clinical Examination and Cytopathological Evaluation Age Range: 20 to 60 Years Minimum Education: At least a middle school diploma A score above 8 on the stress scale and a score above 15 on the anxiety scale of the DASS-21 questionnaire No current or past history of major psychiatric disorders Consent to participate in the study and completion of the informed consent form

Exclusion criteria:
Absence of more than two sessions.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to two groups: intervention and control. They are randomly allocated (using random blocks) to either the intervention or control group (via the Sealed Envelope website). The assigned codes (A/B) are written separately on pieces of paper, which are folded in a way that prevents the code from being visible (allocation concealment). It is important to note that, with the enrollment of each eligible patient and after obtaining informed consent, one piece of paper is randomly selected, and based on the code inside (A/B), the patient is placed in either the intervention or control group

Blinding (investigator's opinion)
Double blinded

Blinding description
control group. Randomization is carried out through a randomization system (for example, using the Sealed Envelope website), where the allocations are written as concealed codes (A/B). The allocation codes (A/B) are written on separate pieces of paper, which are then folded and kept concealed from the researchers. These papers are randomly drawn from the envelope by the researchers, and based on the code inside, the patient is assigned to either the intervention or control group. Patients are unaware of which group (intervention or control) they belong to. They only know that they are receiving an intervention or treatment but are not informed of which specific treatment group they are in. Those assessing the outcomes, such as disease severity or treatment compliance, do not know which group the patient belongs to. This ensures that the evaluations are carried out impartially and without any preconceived bias

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address
School of Medicine, University pardis, Eastern Entrance at Azadi Square, Kalantari Highway, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2024-09-17, 1403/06/27

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.314

Health conditions studied

1

Description of health condition studied
Pemphigus Vulgaris

ICD-10 code
L10.0

ICD-10 code description
Pemphigus vulgaris

Primary outcomes

1

Description
Morisky Medication Adherence Scale score
Timepoint
Before the intervention and 4 weeks after the completion of the intervention
Method of measurement
Morisky Medication Adherence Scale

2

Description
Depression, Anxiety, and Stress Scale - 21 Items (DASS-21) score
Timepoint
Before the intervention and 4 weeks after the completion of the intervention
Method of measurement
Depression, Anxiety, and Stress Scale - 21 Items (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: week program, with one 90-minute online session per week, conducted in groups of five participants. These sessions will be led by a psychiatry resident trained in Mindfulness-Based Stress Reduction (MBSR) and supervised by the relevant instructor
Category
Lifestyle

2

Description
Control group: session providing necessary education on pemphigus vulgaris, its symptoms, disease progression, both pharmacological and non-pharmacological treatments, required care, and follow-up procedures. This session will be conducted based on the dermatologist’s advice and will include answering the patient’s questions.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology and Hair Clinic Of imam Reza Hospital
Full name of responsible person
Zahra Ghaseminejad
Street address
Dermatology and Hair Clinic, Imam Reza Hospital, Imam Reza Square, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Research Institutes, Mashhad University of Medical Sciences, daneshgah Street
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person

Zahra Ghaseminejad

Position
Psychiatry resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Ebne sina Psychiatric Hospital Mashhad, Hor Ameli North Street

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Position
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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