

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effectiveness of Eye Movement Desensitization and Reprocessing (EMDR) on internalized stigma in patients with major depressive disorder.

Protocol summary

Study aim

Assessing the impact of Eye Movement Desensitization and Reprocessing on internalized stigma in patients with major depression disorder

Design

A randomized controlled trial with parallel groups and 72 participants, using an online platform called Sealed Envelope for randomization.

Settings and conduct

The researcher will first obtain the necessary permits and, with a letter of introduction, refer to the hospitals affiliated with Yasuj University of Medical Sciences. After obtaining informed written consent, all samples will complete the demographic information form and the Beck Depression Inventory. Then, the pre-test will be taken using the Internalized Stigma Mental Illness questionnaire. The Eye Movement Desensitization and Reprocessing intervention will be performed individually. Immediately after the intervention ends and during the three-month follow-up, the post-test will be taken.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a definitive diagnosis of depression, a history of hospitalization for depression, willingness to participate in the intervention, ability to communicate effectively, signing an informed consent form, completing physical health, and not participating in mindfulness or cognitive behavioral therapies concurrently. Exclusion criteria: individuals who had attempted suicide or self-harmed and individuals with substance or alcohol dependence.

Intervention groups

The Eye Movement Desensitization and Reprocessing intervention will be administered to each individual in the intervention group, depending on individual needs and treatment progress, for a maximum of seven sessions, with a duration of 90 minutes in the first session and 45 minutes in the following sessions every other day. The

control group will receive treatment as usual.

Main outcome variables

Reducing internalized stigma in patients with major depressive disorder.

General information

Reason for update

Acronym

EMDR

IRCT registration information

IRCT registration number: **IRCT20250111064354N1**

Registration date: **2025-03-09, 1403/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2025-03-09, 1403/12/19**

Update count: **0**

Registration date

2025-03-09, 1403/12/19

Registrant information

Name

Negin Shojaosadati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 4619

Email address

nshojayi7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-05, 1403/12/15

Expected recruitment end date

2025-06-08, 1404/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Eye Movement Desensitization and Reprocessing (EMDR) on internalized stigma in patients with major depressive disorder.

Public title

"Investigating the effect of Eye Movement Desensitization and Reprocessing in Internalized Stigma"

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with major depressive disorder have been hospitalized at least once due to the severity of this disorder. Individuals should be ready and willing to participate in Eye Movement Desensitization and Reprocessing sessions. Individuals must be able to communicate and collaborate with researchers and therapists. Participants must sign an informed consent form and be aware of the research and treatment process. Participants must have fully functional five senses, especially vision and hearing. Not participating in mindfulness courses or cognitive behavioral therapies at the same time.

Exclusion criteria:

Participants who have attempted suicide or engaged in serious self-harm resulting in hospitalization within the past month will be excluded from the study. Individuals who are dependent on drugs or alcohol will not be allowed to participate in the study.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible study participants will be randomly assigned to two intervention groups and a control group in blocks of multiples of two (2, 4). This process will be conducted randomly using an online platform called Sealed Envelope. The list of participant allocations to study groups will be extracted through this method based on the total sample size.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Next to Imam Sajjad Hospital

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591994799

Approval date

2025-02-23, 1403/12/05

Ethics committee reference number

IR.YUMS.REC.1403.160

Health conditions studied**1****Description of health condition studied**

Internalized stigma

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Internalized stigma

Timepoint

The post-test will be taken by the internalized stigma of mental illness scale after seven sessions (immediately after the interventions are completed) and in the three-month follow-up.

Method of measurement

The Internalized Stigma of Mental Illness Scale

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group: Eligible study participants will receive eye movement desensitization and reprocessing intervention individually, up to seven sessions depending on individual needs and treatment progress, with a duration of 90 minutes in the first session and 45 minutes in the following sessions, every other day.

Category

Treatment - Other

2

Description

The control group: Participants in this group will receive treatment as usual.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

Mohammad Behnammoghadam

Street address

Imam Hussein Square

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2

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Mohammad Behnammoghadam

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The end of Sepah Street

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emamkhomeini@yums.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossali Motlagh

Street address

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Email

aminhomo@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasuj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Negin Shojaossadati

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Fax**Email**

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Web page address**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

Patient information and data will be made available to other researchers and writers upon request while maintaining confidentiality and privacy.

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

No - There is not 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