

# 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**

Kohgilouyeh-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

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591873118

**Phone**

+98 74 3322 2291

**Email**

rajaeey@yums.ac.ir

**Web page address**

<https://rajaeey.yums.ac.ir/>

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Rajaei hospital

**Full name of responsible person**

Mohammad Behnammoghadam

**Street address**

Nurse Square, Baladian Street

**City**

Gachsaran

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rajaeeg@yums.ac.ir

**Web page address**

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**3**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Mohammad Behnammoghadam

**Street address**

The end of Sepah Street

**City**

Dehdasht

**Province**

Kohgiluyeh-va-Boyerahmad

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**Email**

emamkhomeini@yums.ac.ir

**Web page address**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Seyed Amin Hossali Motlagh

**Street address**

Yasouj University of Medical Sciences, Next to Imam Sajjad Hospital

**City**

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**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591994799

**Phone**

+98 74 3334 6078

**Fax**

+98 74 3334 6079

**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**

Yasouj 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

**Street address**

Yasouj University of Medical Sciences, Next to Imam  
Sajjad Hospital

**City**

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**Province**

Kohgilouyeh-va-Boyr Ahmad

**Postal code**

7591994799

**Phone**

+98 74 3323 4115

**Email**

mbehnam1363@gmail.com

**Person responsible for scientific 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

**Street address**

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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

mbehnam1363@gmail.com

**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

**Street address**

Yasouj University of Medical Sciences, Next to Imam  
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**City**

Yasuj

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**Postal code**

7591994799

**Phone**

+98 74 3323 4115

**Fax****Email**

nshojayi7@gmail.com

**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