

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effect of Eye Movement Desensitization and Reprocessing (EMDR) on fear of hypoglycemia in type 2 diabetic pathient

#### Protocol summary

##### Study aim

The effect of eye movement desensitization and reprocessing on fear of hypoglycemia in type 2 diabetic patients

##### Design

The study design was that subjects were divided into intervention and control groups. This study was a single-blind study. Randomization was performed using blue and red cards. One nurse in the Velayat hospital distributed red and blue cards to 72 patients who were eligible for the study, Each patient chose a card and none of the patients were aware of the card allocation to the intervention or control groups. The red card was assigned to the intervention group and the blue card to the control group.

##### Settings and conduct

The study was conducted in the internal ward of Qazvin Velayat hospital and 72 patients with type 2 diabetes were admitted to the hospital at the time.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type 2 diabetes; at least 25 years old; Confirmation of diabetes by a specialist; Treated with oral anti-diabetic or insulin medications  
Non-inclusion criteria: history of anxiety disorders; phobia and other mental disorders; history of seizures; history of strabismus and other visual disorders

##### Intervention groups

There were two intervention and control groups in this study. In the intervention group, eye movements desensitization and reprocessing were performed in two 45 minute sessions and in the control group no intervention was performed.

##### Main outcome variables

fear of hypoglycemia

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181201041813N1**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

#### Registration date

2019-11-13, 1398/08/22

#### Registrant information

##### Name

hamidreza salimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3527 5377

##### Email address

h.salimi@qums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-12-21, 1397/09/30

#### Expected recruitment end date

2020-01-19, 1398/10/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Eye Movement Desensitization and Reprocessing (EMDR) on fear of hypoglycemia in type 2 diabetic pathient

**Public title**

The Effect of Eye Movement Desensitization and Reprocessing (EMDR) on fear of hypoglycemia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having at least 25 years of age confirming diabetes type 2 by a specialist in medicine being treated with oral anti-diabetes medications or insulin

**Exclusion criteria:**

history of strabismus and other visual impairments  
history of seizure history of anxiety disorders, phobias and other psychiatric disorders,

**Age**

From **25 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After selection of 72 patients , randomization was performed using blue and red cards. One of the nursing staff distributed the cards among the patients and each patient chose a card. Those who chose red cards entered the intervention group and those who chose blue cards entered the control group. None of the patients and the person who distributed the cards between them had any information about the cards

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participants in this study were not aware of the random allocation of the groups, but the researcher was fully aware.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Approval date**

2018-12-11, 1397/09/20

**Ethics committee reference number**

IR.QUMS.REC.1397.230

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

Diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes****1****Description**

fear of hypoglycemia

**Timepoint**

In this study, fear of hypoglycemia was measured at baseline, one month after intervention, and three months after intervention

**Method of measurement**

fear of hypoglycemia questioner

**Secondary outcomes**

empty

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

In the intervention group, eye movements desensitization and reprocessing were performed in two separate 45-minute sessions for each patient in the Internal Ward of the velayat Hospital. In each intervention session, the intervention was performed by the researcher in several stages. Each phase consisted of 24 sweep cycles using finger gestures, each cycle being equal to one second, and the interval between patient and therapist equal to one meter during the intervention. The patient was asked to recall past hypoglycemic events while following his finger movements.

**Category**

Treatment - Other

**2****Description**

Control group: The control group received no intervention and patients were recalled to complete the questionnaire at baseline, one month after the study, and three months after the study.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Velayat Medical-Educational Hospital

**Full name of responsible person**

Hamidreza Salimi

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 6001

**Email**

hamidrezasalimi1995@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Doctor Amir Peymani

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 6001

**Email**

hamidrezasalimi1995@yahoo.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Hamidreza Salimi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 6001

**Email**

hamidrezasalimi1995@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Hamidreza Salimi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 6001

**Email**

hamidrezasalimi1995@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Hamidreza Salimi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Bahonar Blvd, Qazvin Town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34199-15315

**Phone**

+98 28 3333 6001

**Email**

hamidrezasalimi1995@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Study data will be presented as individuals unrecognizable upon completion of the study. The intervention protocol will also be available to researchers after the paper is published.

**When the data will become available and for how long**

1 year after publishing the results

**To whom data/document is available**

University of Medical Sciences

**Under which criteria data/document could be used**

The data will be provided when the researcher arrives with the necessary equipment from medical universities. These include plans approved by medical science universities that have received a code of ethics. And researchers will be allowed any statistical analysis.

**From where data/document is obtainable**

Qazvin University of Medical Sciences

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

The researcher should apply by submitting a letter from the relevant medical university.

**Comments**