Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Doctor Amir Peymani

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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

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Person responsible for updating data

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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