

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The efficacy of resiliency training on reducing anxiety and depression on patients with type 2 diabetes mellitus

#### Protocol summary

##### Study aim

The efficacy of resiliency training on reducing anxiety and depression on patients with type 2 diabetes mellitus

##### Design

Controlled clinical trial, 24 people in two 12 people groups of intervention and control, Not blinded, Randomized with restricted randomization based on random allocation rule

##### Settings and conduct

The research method is quasi-experimental. This research is based on the aims and nature of the research, a semi-experimental design, and a pre-test, post-test with the control group. From both groups, Beck Anxiety Scale, Beck Depression Scale, Resilient Connor and Davidson were taken. Then the training program for 12 sessions was conducted for the experimental group and after the end of the sessions, to evaluate the effect of this intervention, the two post-test groups were run and the results of the pre-test and post-test were compared in both groups.

##### Participants/Inclusion and exclusion criteria

People who live in Kermanshah, who have had their diabetes for at least 3 years and have criteria for depression, will participate in the study. Older and illiterate people who will not be able to participate will not be included.

##### Intervention groups

The intervention group after registering the pre-test score, participate in training sessions and participate in post-test after receiving the necessary training. The control group only participates in pre-test and post-test stages and does not attend training sessions.

##### Main outcome variables

Anxiety and depression in patients with type 2 diabetes mellitus

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190213042706N1**

Registration date: **2019-04-13, 1398/01/24**

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

Last update: **2019-04-13, 1398/01/24**

Update count: **0**

#### Registration date

2019-04-13, 1398/01/24

#### Registrant information

##### Name

Mohammadhossein Rashidi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3824 7932

##### Email address

mohammadrashidi86@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-04-06, 1398/01/17

#### Expected recruitment end date

2019-05-20, 1398/02/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The efficacy of resiliency training on reducing anxiety and depression on patients with type 2 diabetes mellitus

#### Public title

The efficacy of resiliency training in diabetes

**Purpose**

Treatment

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

All diabetics who have diabetes for more than 3 years  
Resident of Kermanshah Depressed is based on structured clinical interviews Having Depression Based on structured Clinical Interview

**Exclusion criteria:**

Elderly and illiterate patients who are difficult to obtain information from

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, due to the desire to equalize the number of members of the intervention and control group, using restricted randomization based on random allocation rule. To do this, first determine a total sample size then randomly and based on even or odd of last number of visit No. assign 12 person of them to intervention group and leave 12 person to control group. In fact coupling the last digit of the visit number, putting up the patient into intervention group and odd number of them putting up the patient into control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

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

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Shahid Beheshti Blvd., Building No. 2 of the University

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714635568

**Approval date**

2018-12-26, 1397/10/05

**Ethics committee reference number**

IR.KUMS.REC.1397.787

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

Resiliency training

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

Depression Patient's score in Beck Questionnaire

**Timepoint**

Twelve weeks after the start of resiliency training

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes**

empty

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

The intervention group after registering the pre-test score, participate in training sessions and participate in post-test after receiving the necessary training. The control group only participates in pre-test and post-test stages and does not attend training sessions.

**Category**

Lifestyle

**2****Description**

Control group: The control group only participates in pre-test and post-test stages and does not attend training sessions.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Diabetes Special Clinic

**Full name of responsible person**

Mohammad Hossein Rashidi

**Street address**

Mostafa Emami Blvd., Alley 7 Bargh, No. 61

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714635568

**Phone**

+98 83 3824 7932

**Email**

mohammadrashidi86@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Assistance of Research and Technology

**Street address**

Mostafa Emami Blvd., Alley 7 Bargh, No. 61

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714635568

**Phone**

+98 83 3824 7932

**Email**

mohammadrashidi86@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Habib Allah Khazaei

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Bridge of Isar, Farabi Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714635568

**Phone**

+98 83 3824 7932

**Email**

hakhazaei@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Habib Allah Khazaei

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Isar Bridge, Farabi Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714712658

**Phone**

+98 83 3824 7932

**Email**

hakhazaei@gmail.com

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Rashidi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

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**Email**

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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**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The total potential data of this study after unidentifiable individuals can be shared

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

Initiate access at least 6 months after printing results

**To whom data/document is available**

Researchers working in university and academia

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

Researchers are subject to the above requirements, which tend to work more on the subject of the study

**From where data/document is obtainable**

Mohammad Hossein Rashidi Kermanshah, Mostafa Emami  
Blvd.7 bargh Alley, No.61 Postal Code 6714635568  
00989189282125 mohammadrashidi86@gmail.com

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

Maximum 2 weeks

**Comments**