Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Public title

The efficacy of resiliency traning 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

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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
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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
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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
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