Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of coping with stress on anxiety and quality of life in elderly patients with diabetes referring to Shiraz health centers in 2017-18

Protocol summary

Study aim
Reduce anxiety and blood sugar in the elderly diabetic patients
Design
Two intervention and control groups with a sample size of 100 people randomly divided into two groups
Settings and conduct
Training sessions at the Qotb al-Din Diabetes Association
Participants/Inclusion and exclusion criteria
Diagnosed type II diabetes; not receiving training in life skills since diagnosis; ability to attend group meetings; at least six months have been diagnosed as having an elderly type 2 diabetes
Intervention groups
Stress management training is to the intervention group that has 60-year-olds with type 2 diabetes
Main outcome variables
Anxiety , blood sugar level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111017007816N17**
Registration date: **2018-08-14, 1397/05/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-14, 1397/05/23**
Update count: **0**
Registration date
2018-08-14, 1397/05/23

Registrant information
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Mahin Nazari
Name of organization / entity
School of health
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-05-09, 1396/02/19
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of coping with stress on anxiety and quality of life in elderly patients with diabetes referring to Shiraz health centers in 2017-18

Public title
The effect training of on anxiety and quality of life in elderly patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed type II diabetes Not receiving training in life skills since diagnosis Ability to attend group meetings At least six months have been diagnosed as having an Elderly type 2 diabetes
Exclusion criteria:
Type 1 diabetes Under 60 years old Do not tend to attend meetings
Age

From **60 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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
Shiraz University Of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St.

City
Shiraz

Province
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Postal code
7153675541

Approval date
2018-05-08, 1397/02/18

Ethics committee reference number
IR.SUMS.REC.1397.151

Health conditions studied

1

Description of health condition studied
Type II diabetes

ICD-10 code
F00-09

ICD-10 code description
Diabetes Mellitus

Primary outcomes

1

Description
Anxiety treatment

Timepoint
Before and 3 month after intervention

Method of measurement
Questionair

Secondary outcomes

1

Description
Blood glucose

Timepoint
Before and 3 month after intervention

Method of measurement
Lab test

Intervention groups

1

Description
Intervention group: in this group is for 6 sessions, each session lasting an hour and a half and just 1 session per week of interactive lectures practices and partnerships with educational aids, pamphlets, booklets .

Category
Lifestyle

2

Description
Control group: in control group was not intervention performed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Qutb al-Din clinic

Full name of responsible person
دکتر نسیمی

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Shiraz Fakhr Abad Street

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Sponsors / Funding sources

1

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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
Shiraz 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
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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

No - There is not 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 can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

The total number of people referring to the magazine in which the article was published

Under which criteria data/document could be used

Supervisor

From where data/document is obtainable

Dr. Mahin Nazari Email manazari@sums.ac.ir

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

The coordinator's author takes about 1 week to 1 month

Comments