

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Name

Mahin Nazari

Name of organization / entity

School of health

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

manazari@sums.ac.ir

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

Fars

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

Sponsor

Name of organization / entity

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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**

Shiraz University of Medical Sciences

Full name of responsible person

Tayyibeh Rahmani

Position

MSc. student

Latest degree

Master

Other areas of specialty/work

Geriatrics

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Person responsible for scientific inquiries

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

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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