Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of spiritual concepts on anxiety and depression in type 2 diabetic patients referred to diabetic clinic in Emam Reza Clinic affiliated to Shiraz University of Medical Sciences, 1396

Protocol summary

Study aim

The aim of this clinical trial is to assess the effect of spiritual course on anxiety and depression in diabetes type 2 patients.

Design

Randomized clinical trial.

Settings and conduct

146 subjects are divided into two groups, 73 subjects in each group of case and control. Subjects who meet the inclusion criteria are selected from patients with diabetes type 2 through purposive sampling and simple random sampling. Then using block randomization with the block size of 4, they are divided into two groups of control and intervention. Subjects in the intervention group will participate in a training workshop on spiritual and religious points to help them elevate their ability to solve the problem and relieve their emotions more easily; the workshop consists of 4 training sessions and lasts for 2 weeks. Data will be collected from the control and intervention groups In three stages using Beck Anxiety Inventory and Spielberger State-Trait Anxiety Inventory: in the beginning of the study and then once again immediately after completion of the intervention. During the intervention, the two methods of problem-based learning and group discussion will be used; the training will include topics such as self-knowledge and self-awareness, recognition of weaknesses and strengths, acceptance of mistakes, important role of quality of life in psychological and physical aspects, etc.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with diabet type 2, being Muslim and Shiite and having an ordinary spiritual level; Exclusion criteria: lack of willingness to continue participation in the study, failure to attend.

Intervention groups

Subjects in the intervention group will attend a 2-week workshop and will participate in 4 sessions of spiritual trainings to elevate their ability to solve the problem and relieve their emotions more easily.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090908002432N7**
Registration date: **2018-09-16, 1397/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-16, 1397/06/25**
Update count: **0**

Registration date

2018-09-16, 1397/06/25

Registrant information

Name

Azadeh Amiri

Name of organization / entity

Shiraz University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

amiriea@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-24, 1397/04/03

Expected recruitment end date

2018-11-24, 1397/09/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of spiritual concepts on anxiety and depression in type 2 diabetic patients referred to diabetic clinic in Emam Reza Clinic affiliated to Shiraz University of Medical Sciences, 1396

Public title
Depression in diabetes type 2 patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diabet type 2 Being Muslim and Shiite Having an ordinary spiritual level
Exclusion criteria:
Lack of willingness to continue participation in the study Failure to attend and miss more than one training session of the workshop Any other problem preventing the subject to continue the participation in the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **146**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects who meet the inclusion criteria are selected from patients with diabet type 2 through convenience sampling. Then participants will randomly assign to intervention and control groups. In order to evenly distribute the participants, a block randomization list (with block-sizes of 4 at 6 variation) will prepare by a statistician, and will give to two persons in reception unit in the form of sequentially numbered, sealed opaque envelopes, to provide concealment allocation to the group.
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
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand Street, Shiraz University of Medical Sciences, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613119
Approval date
2018-06-24, 1397/04/03
Ethics committee reference number
IR.SUMS.REC.1397.214

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention, after the intervention and 2-months later
Method of measurement
Depression, Anxiety and Stress Scales (DASS-42) questionnaire

Secondary outcomes

1

Description
Depression
Timepoint
Before the intervention, after the intervention and 2 -months later
Method of measurement
Beck questionnaire

Intervention groups

1

Description
Intervention group: Subjects in the intervention group will participate in a training workshop on spiritual and religious points to help them elevate their ability to solve the problem and relieve their emotions more easily; the workshop consists of 4 training sessions and lasts for 2 weeks.

Category
Lifestyle

2

Description
Control group: The control group receives routine care.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Polyclinic affiliated to Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person
Azadeh Amiri

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Namazee Square ,Zand Street, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Basir Hashemi

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Zand Street, Shiraz University of Medical Sciences, Shiraz

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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
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
Azadeh Amiri

Position
Master of Science In Nursing, Faculty member of School of Nursing and Midwifery

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available