

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Spiritual-Religious Intervention on Spiritual Health, Self-care Activities and Quality of Life in Patients with Type 2 Diabetes

Protocol summary

Study aim

The study of the effect of religious-spiritual intervention on spiritual health, self-care activities and quality of life in patients with type 2 diabetes in Shiraz Shahid Motahari Clinic, 2017-2018

Design

Obtaining an introduction letter from the authorities at the School of Nursing and Midwifery, University of Medical Sciences and presenting to the clinic - Sample selection by simple random sampling and obtaining informed consent - Completion of questionnaires for demographic characteristics, spiritual health, self-care activities and quality of life by both case and control groups before intervention - Simple block randomization and determination of case and control group members - for the intervention group, 6 sessions of 45-60 minutes once a week for 6 weeks - No intervention was performed in the control group; this group received only the routine care provided by the diabetes clinic - Completion of questionnaires for demographic characteristics, spiritual health, self-care activities and quality of life by both case and control groups one month following intervention - Data analysis.

Settings and conduct

Diabetes Clinic in Motahari Clinic, Shiraz

Participants/Inclusion and exclusion criteria

Diabetic patients aged 18-60 years old - No history of amputation - Desire to receive spiritual interventions - Residency in Shiraz - Being under medical treatment - Ability to understand Persian language - HbA1c level less than 8 /.

Intervention groups

Six one-hour special conversation sessions regarding spiritual topics

Main outcome variables

Change in self-care activities and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171113037441N2**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **retrospective**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5328 0471

Email address

tabatabeih@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-09-29, 1396/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spiritual-Religious Intervention on Spiritual

Health, Self-care Activities and Quality of Life in Patients with Type 2 Diabetes

2017-10-08, 1396/07/16

Ethics committee reference number
1396.107.IR.SUMS.REC

Public title

The effect of spiritual health on the quality of life of diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients aged 18-60 years old
Desire to receive spiritual interventions
Residency in Shiraz
Being under medical treatment
Ability to understand Persian language
HbA1c level less than 8 /

Exclusion criteria:

History of amputation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The method under use is simple randomization, and the unit of randomization is individual

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

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

123456

Approval date

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11.65

ICD-10 code description

Type 2 diabetes mellitus with hyperglycemia

Primary outcomes

1

Description

Self-care score

Timepoint

After the end of the intervention

Method of measurement

questionnaire

2

Description

Mental health

Timepoint

After the end of the intervention

Method of measurement

questionnaire

3

Description

Quality of Life

Timepoint

After the end of the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Religious spiritual intervention is held through 6 one hour sessions. This interventions are based on the Richards and Bergin model.

Category

Lifestyle

2

Description

Control group: in this group will not be any intervention.

Category

N/A

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

Shiraz Motahhari Clinic

Full name of responsible person

Hadithsadat Tabataba'i

Street address

Motahhari Clinic, Namazi Square

City

Shiraz

Province

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Postal code

07144969696

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Email

tabatabaiei@yahoo.com

Web page address

http://fa.irct.ir/user/trial/27891/update/recruitment_center

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

Shiraz University of Medical Sciences

Full name of responsible person

Hadithsadat Tabataba'ih

Street address

Shiraz University of Medical Sciences, Zand street;
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medravabet@sums.ac.ir

Web page address

http://fa.irct.ir/user/trial/27891/update/recruitment_center

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

Hadicesadate Tabatabaieih

Position

Nurs

Latest degree

Master

Other areas of specialty/work

Biochemistry

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

Shiraz University of Medical Sciences

Full name of responsible person

Mahbobeh Magharei

Position

professor working at university

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hadicesadate Tabatabaeih

Position

Nurse

Latest degree

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Other areas of specialty/work

Nursery

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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