

# 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 Motahhari 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](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;  
Shiraz

**City**

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**Postal code**

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**Phone**

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**Email**

medravabet@sums.ac.ir

**Web page address**

[http://fa.irct.ir/user/trial/27891/update/recruitment\\_center](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

**Street address**

Shiraz University of Medical Sciences; Zand Avenue

**City**

Shiraz

**Province**

Fars

**Postal code**

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**Phone**

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**Email**

tabatabaieih@sums.ac.ir

**Web page address**

[http://fa.irct.ir/user/trial/27891/update/recruitment\\_center](http://fa.irct.ir/user/trial/27891/update/recruitment_center)

**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

**Street address**

Hazrat Fatemeh Faculty of Nursing and Midwifery;

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**Web page address**

[http://fa.irct.ir/user/trial/27891/update/scientific\\_queries\\_contact](http://fa.irct.ir/user/trial/27891/update/scientific_queries_contact)

## 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**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shiraz University of Medical Sciences; Zand Avenue;  
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**Web page address**

[http://fa.irct.ir/user/trial/27891/update/data\\_updater\\_contact](http://fa.irct.ir/user/trial/27891/update/data_updater_contact)

## 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