

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of spiritual care on quality of life in patients with diabetes

#### Protocol summary

##### Study aim

Provides a simple executive solution to improve the quality of life for patients with diabetes

##### Design

Randomized clinical trials, double blind, single center

##### Settings and conduct

The present study was conducted at the Malayer diabetes center and on people with diabetes. Samples and data analyzers did not know how to place the samples in the intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having diabetes; complete awareness of time, place, and individuals; age range 18 to 65 years; the desire to participate in the study Exclusion criteria: Unwilling to participate in the study; inability to reading and writing

##### Intervention groups

Intervention group: The intervention included holding group spiritual care sessions for the intervention group during 5 sessions of 45 to 60 minutes based on spiritual-religious strategies. Control group: The control group did not receive any interventions during this intervention period, except for standard treatment measures.

##### Main outcome variables

Quality of life for diabetic patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161223031522N7**

Registration date: **2018-02-24, 1396/12/05**

Registration timing: **retrospective**

Last update: **2018-02-24, 1396/12/05**

Update count: **0**

##### Registration date

2018-02-24, 1396/12/05

#### Registrant information

##### Name

Vahid Naseri Salahshour

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3505

##### Email address

v.naserisalahshour@arakmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2015-11-01, 1394/08/10

##### Expected recruitment end date

2016-11-30, 1395/09/10

##### Actual recruitment start date

2015-11-01, 1394/08/10

##### Actual recruitment end date

2016-11-30, 1395/09/10

##### Trial completion date

empty

#### Scientific title

The effect of spiritual care on quality of life in patients with diabetes

#### Public title

The effect of spiritual care on quality of life in patients with diabetes

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Suffering from diabetes mellitus Complete awareness of time, place, and individuals 18 to 65 years old The desire to participate in the study

##### Exclusion criteria:

Unwilling to participate in the study Inability to reading

and writing

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **112**

Actual sample size reached: **112**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The samples are divided into intervention and control groups using randomized block allocation method.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Samples and data analyzers did not know how to allocate to intervention and control groups

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Rah ahan Sq, Aalam alhoda St

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

#### Approval date

2015-10-02, 1394/07/10

#### Ethics committee reference number

IR.ARAKMU.REC.1394.189

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

### ICD-10 code

E08

### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Quality of life in patients with diabetes

#### Timepoint

Before the intervention and 2 months after the intervention

#### Method of measurement

SF36 standard questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: the intervention included holding spiritual group meetings for the intervention group during 5 sessions of 45 to 60 minutes based on spiritual-religious strategies.

#### Category

Lifestyle

### 2

#### Description

Control group: the control group samples did not receive any interventions during this intervention period except for standard treatment.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Malayer diabetes center

##### Full name of responsible person

Karim Mirzaei

##### Street address

Nabovat Blvd.

##### City

Malayer

##### Province

Hamadan

##### Postal code

6488165718

##### Phone

+98 81 3525 0182

##### Email

## Sponsors / Funding sources

### Phone

+98 86 3417 3505

### Email

m.sajadi@arakmu.ac.ir

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Arjomandzadegan

**Street address**

Basij Sq, Sardasht Region

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3417 3638

**Email**

Rsearch@arakmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Mahbobeh Sajadi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Basij Sq, Sardasht Region

**City**

Arak

**Province**

Markazi

**Postal code**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mahbobeh Sajadi

**Position**

Assistant professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Vahid Naseri Salahshour

**Position**

Msc Student of Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Phone**

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**Email**

vahidnaseri1994@yahoo.com

## 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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.

**When the data will become available and for how**

**long**

The beginning of the access period is 12 months after the results are published.

**To whom data/document is available**

Researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

In order to utilize scientific purposes and mention the source used.

**From where data/document is obtainable**

Dr Mahboubeh Sajjadi, Ph.D. of Nursing, Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Arak, Iran. E-mail address: sajadimahbobeh@yahoo.com

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

After receiving the email from the requester, the information will be sent within 2 to 3 business days.

**Comments**