

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.

Other areas of specialty/work

Nursery

Street address

Basij Sq, Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

m.sajadi@arakmu.ac.ir

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

Basij Sq, Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

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