

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effective of spiritual group therapy on anxiety and hope in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of spiritual group therapy on anxiety and hope in patients with type 2 diabetes

Design

The sample size was divided into two groups of control and intervention by randomized blocks method. The total sample size was 108 in control and intervention groups.

Settings and conduct

Spiritual group therapy will be held in a class of the Hamadan Diabetes Association Center in groups of 8 to 12 people , for 8 weeks and 1 session per week.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having type 2 diabetes, literacy for reading and writing, consent to participate in the research, speaking Persian language, Islamic religion, lack of crisis experience and psychiatric drug use in the last three months, Not attending psychotherapy sessions in the last six months, no psychiatric disorder, a lack of severe non-diabetic physical illness, exclusion criteria include absent more than two sessions.

Intervention groups

The eight sessions of spiritual group therapy are as follows: Session 1: Statement of goals. Session 2: Awareness with the meaning of spirituality. Session 3: Awareness with the meaning of anxiety and ways to control it. Session 4: Getting to know the concept of hope and ways to increase it. Session 5: Practice prayer and trust and understand forgiveness and repentance. Session Six: Forgiving and generalizing it to control anger and patience. Seventh Session: Thanksgiving and appreciation for positive changes in spirituality. Eighth Session: Kindness and compassion . The control group does not receive any counselling.

Main outcome variables

Anxiety and hope

General information

Reason for update

Acronym

DM

IRCT registration information

IRCT registration number: **IRCT20170411033378N7**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **prospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

Efat Sadeghian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

sadeghian_e@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2019-11-22, 1398/09/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-07-21, 1399/04/31

Scientific title

The effective of spiritual group therapy on anxiety and

hope in patients with type 2 diabetes

Public title

The effective of spiritual group therapy on anxiety and hope in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type 2 diabetes based on medical records At least 20 years of age Literacy of reading and writing Has not taken any psychiatric medication in the three months recent Not attending psychotherapy sessions in the past 6 months Speaking Persian language Having Islam religion Consent to participate in the research No psychiatric disorder according to medical record Not having a serious physical illness other than diabetes Lack of crisis experience in the three months recent

Exclusion criteria:

Absent more than 2 sessions

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by available method with considering inclusion criteria, then divided into two intervention and control groups by randomized allocation. Random allocation will be by permuted block randomization. It is individual randomization. First, a random list is generated using R software in which the intervention group (A) and the control group (B) are based on blocks such as ABAB. And AABB, ABBA and ... are randomly generated based on the number of samples. Then these lists are put into an envelope and one of the envelopes is randomly selected by referring patients and then individuals are assigned to group A Or B are allocated. Due to the educational intervention and having the control and experimental group there is no possibility of blinding the participants.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

In front of People's Park, Shahid Fahmideh Boulevard, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838698

Approval date

2019-09-15, 1398/06/24

Ethics committee reference number

IR.UMSHA.REC.1398.469

Health conditions studied

1

Description of health condition studied

Diabetes, Spiritual Health, Anxiety, Hope

ICD-10 code

3

ICD-10 code description

Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Primary outcomes

1

Description

Anxiety score of the Cattell Anxiety Scale Hope Score of the Snyder Hope Scale

Timepoint

Measurement of anxiety before intervention, immediately after intervention and one month after intervention Measurement of hope before intervention, immediately after intervention and one month after intervention

Method of measurement

Cattell Anxiety Scale Snyder Hope Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group counseling based on spiritual health in 8 sessions 80-minute, using a spirituality

package provided by the researcher.

Category

Treatment - Other

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

Hamadan Diabetes Association Center

Full name of responsible person

Efat Sadeghian

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In front of People's Park, Shahid Fahmideh Boulevard,
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sadeghianefat@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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In Front Of People's Park, Shahid Fahmideh
Boulevard, Hamadan University of Medical Sciences,
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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Academic

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

Hamadan University of Medical Sciences

Full name of responsible person

Efat Sadeghian

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

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

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole data will be published after the unidentifiable individuals are shared. which will be published as the final report and artical.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions and people in the industry can apply for them.

Under which criteria data/document could be used

Anyone who would like to use cited articles is possible by email.

From where data/document is obtainable

Applicants can email their request for receving the relevent documents and data to sadeghianefat@gmail.com or send it to postal address Hamadan; Shahid Fahmideh Street, Front of Mardom park; Faculty of Nursing and Midwifery; Psychiatric Nursing Department, Dr Effat Sadeghian; Postal code: 38698-65178; or Call: 38380535-081 and Fax: 38380447-081.

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

Applicants can email their request for receving the relevent documents and data to sadeghianefat@gmail.com or send it to postal address Hamadan; Shahid Fahmideh Street, Front of Mardom park; Faculty of Nursing and Midwifery; Psychiatric Nursing Department, Dr Effat Sadeghian; Postal code: 38698-65178; or Call: 38380535-081 and Fax: 38380447-081. The response will be sent to the Applicants at least one week after reviewing the request.

Comments