Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, Hamadan University of Medical Sciences, Hamadan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

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

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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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Nursery

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Person responsible for updating data

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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