Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effectiveness of Hope Therapy with Spiritual Therapy on Self-Care, quality of life, depression and biological variables in Patients diagnosed with Type II Diabetes

Protocol summary

Study aim

1. Determining the effectiveness of hope therapy and spiritual therapy on depression in patients .2. Determining the effectiveness of hope therapy and spiritual therapy on self-care in patients .3. Determining the effectiveness of hope therapy and spiritual therapy on quality of life in patients 4. Determining the effectiveness of hope therapy and spiritual therapy on biological variables in patients with type 2 diabetes

Design

The clinical trial will have a control group with parallel groups, without blinding and randomized block on 75 type 2 diabetic patients

Settings and conduct

This research will be a randomized controlled trial and will be used for sampling and block randomization method and will consist of three parts: pre-test, intervention, post-test and follow-up and will be performed in Tehran Diabetes Center located in Amirabad Street next to Heart Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study 1. No abuse of drugs and psychotropic drugs 2. Age between 45-60years 3. More than a year has passed since the diagnosis of type 2 diabetes. 4. Fasting sugar should not exceed 135 mg / dL. 5. Hemoglobin A1C should not be more than 8%.. 6. Failure to receive psychological treatment during the last 3 months.7. Absence of severe physical diseases caused by diabetes such as kidney failure, vision and so on Exclusion criteria from this study 1. Existence of severe physical diseases caused by diabetes such as kidney failure, vision and .. 2. Receiving psychological therapies during the last 3 months 3. Take any sedatives or neuroleptics. 4. Increase in diabetes-related medications.

Intervention groups

Hope therapy group. Spiritual therapy group that will have 8 sessions of intervention each.Control group that will receive treatments at the end and if they wish.

Main outcome variables

Depression, self-care, quality of life & biological variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200918048746N1**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **retrospective**

Last update: **2020-10-13, 1399/07/22**
Update count: **0**

Registration date

2020-10-13, 1399/07/22

Registrant information

Name

Maryam Peyravi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-16, 1399/06/26

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of Hope Therapy with Spiritual Therapy on Self-Care, quality of life, depression and biological variables in Patients diagnosed with Type II Diabetes

Public title
Effect of Hope with Spiritual on Self-Care, quality of life, depression and biological variables in Patients diagnosed with Type II Diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Completion and signing of informed written consent by the subject. Age between 45-60 years. More than a year has passed since the diagnosis of type 2 diabetes. Hemoglobin A1C should not be more than 8%. Fasting sugar should not exceed 135 mg / dL
Exclusion criteria:
Existence of severe physical diseases caused by diabetes such as kidney failure, vision and .. Receiving psychological therapies during the last 3 months Take any sedatives or neuroleptics Increase in diabetes-related medications abuse of drugs and psychotropic drugs
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized randomized clinical trial method In order to sample and randomize the block randomization method, it is to ensure that exactly the same number of participants enter the intervention and control group at consecutive but equal intervals, in order to hide the allocation, the size of the blocks, Will be considered heterogeneous. (To select a sample after preparing a list of patients referred to Amirabad Diabetes Clinic in Tehran, contact them, select 75 people who wanted to participate in the treatment using the available sampling method, based on the inclusion criteria And were randomly assigned to three groups (hope therapy group = 25 people, spiritual therapy group = 25 people and control group = 25 people). For this purpose, participants first complete the research questionnaires, then blood tests are performed to perform tests for glycosylated hemoglobin and fasting blood sugar (fasting sugar should not exceed 135 mg / dL, hemoglobin A and C should not exceed 8%). In other words, the invitation to participate in the study project will be distributed through a brochure and announcement at the Amirabad Diabetes Center in Tehran. After examining the entry conditions based on what was said above, they are divided into three groups of 25, because we have three study groups, we name each group with the English letters a, b, c. We write the letters a, b, c in three envelopes or on three pieces of paper and close them and mix them like lots so that it is not clear what we have written in which one. By announcing the candidacy of each person to enter the study, we randomly remove one of the envelopes and attribute the person to that group according to the letter inside it. When the second person arrives, we select one of the remaining two envelopes and assign it to that person. Then the third person will be assigned to the group written in the envelope that were not selected in the previous two selections. Work continues until the required number of samples is completed in all three groups.
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 Islamic Azad University, Karaj Branch
Street address
Rajae Shahr, Moazzen Blvd , Islamic Azad University
City
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Province
Alborz
Postal code
3149968111
Approval date
2020-09-09, 1399/06/19
Ethics committee reference number
IR.IAU.K.REC.1399.039

Health conditions studied

1

Description of health condition studied
Patients diagnosed with Type II Diabetes
ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Beck Depression Over 8
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Questionnaire 13 questions Beck

2

Description
Quality of life below 50
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Quality of Life Questionnaire SF36

3

Description
Self care below 47
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Tobert and Glasgow Self-Care Questionnaire

4

Description
More than 5 glycosylated hemoglobin
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Blood Test

5

Description
Blood pressure above 140/90
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Analog blood pressure monitor

6

Description
Fasting sugar Less than 135 mg per deciliter
Timepoint
Before the intervention, immediately after the intervention and one month and three months later
Method of measurement
Blood Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Omid therapy in 8 sessions, Omid therapy protocol Description of sessions in Snyder Omid therapy protocol (2010) Summary of contents and activities of the first session of the pre-test, familiarization of members with the therapist and group structure, introduction of training program and purpose From the implementation of the second session, defining, explaining and expressing the characteristics of the goal, expressing the importance of being purposeful in life, explaining how hope grows and the necessity of the third session, finding hope in people, determining willpower, planning power, obstacles and goals in each person), Help people to build their house of hope, talk about ways to achieve the goal, talk about the feelings caused by achieving the goal or failing the goal, ways to increase the chances of achieving the goal, tell the life story of the participants themselves The fourth session of raising hope in people setting promising therapeutic goals, talking about ways to increase the workforce and motivation to achieve goals, defining motivation, important areas of motivation and energy: physical energy, mental energy, talking about mental energy, storytelling Based on the components of the theory of hope and their reformulation, the fifth session continues the discussion Talking about ways to increase workforce and motivation to achieve goals, talking about physical energy as a factor in increasing willpower; Paying attention to nutrition, exercise, talking about the power of the road, preparing a list of current events and important aspects of the participants' lives and determining the importance of each of them. Sixth session. Increasing hope in people, talking about obstacles to achieving the goal, talking about self-talk. Negative as one of the obstacles, the reason for using negative self-talk, expressing strategies to change negative self-talk, setting appropriate goals according to Snyder theory and encouraging people to set goals in each area of life. Seventh Session Maintaining hope in life , Talk about the importance of people in maintaining the well-being of those around them and their spouses, provide solutions to prevent them from deviating from the path to reach the goal, plan passages and appropriate solutions to achieve the set goals by turning these passages into small steps and determining successor passages. Eighth, strategies for creating and maintaining an agent, such as mental training to achieve goals and training participants to become a therapist hope and apply hopeful thinking on a daily basis, summarize sessions, get feedback from group members, and identify sessions. Follow-up and post-test
Category

Lifestyle

2

Description

Second intervention group: spiritual therapy in 8 sessions, spiritual therapy protocol in this study from the group spiritual therapy protocol proposed by Richards and Bergin (2013) including 8 psycho-spiritual components including: trust and recourse to God, prayer, thanksgiving, Patience, forgiveness and ignoring anger, communication with God and inner dialogue with God, self-awareness and listening to the inner voice, reading sacred texts and using spiritual and religious books were used (Aneshzadeh Shorideh, 1397). First, introduce the participants to each other, talk about diabetes and its physical and mental consequences, evaluate the meaning and spirituality in life, how to determine values, goals and follow them, the concept of spirituality and religion and its impact on life, ask about religion , God) we like to know where we are; Where do we come from and where do we go and where is our real home (ways to reach God and its impact on life, telling sacred stories in the Qur'an by participants, the role of worship and religious beliefs in peace, applying reciprocity through relaxation, experience Subjects relax from worship and prayer, compare their dependencies and attachment to God Vance with him, the second session of self-awareness and communication with themselves and listening to the inner voice, examining needs and goals, knowing about themselves, others and their abilities, Paying attention to your diabetes, practicing positive thoughts and avoiding negative thoughts, exploring talents, victories and successes, talking about whether there is other knowledge and spiritual power to solve the problem, completely surrendering ourselves to the supernatural (spiritual) power (absolute, Avoid the disturbing elements of peace, have faith in a higher power. The third session of awareness-raising with a conscious effort to focus attention on positive thinking with participation, meditation, calculation and retribution along with rewarding oneself and gaining insight into resolving internal conflicts. And increasing adaptation to the environment, exposing the individual to unconscious factors affecting behaviors And the search for pathological extremist mechanisms, the study of past relationships and acceptance of its role in the current behaviors of clients and its effect on the mood of the fourth session. Emphasis on accepting personal responsibility in combating obstacles and examining individual and inner traits, self-compassion and self-love. Self-satisfaction, improving interpersonal relationships and teaching ways to deal with social tensions, ways to promote satisfaction with positive interaction with the environment and achieve inner reinforcement, talking about ways to please others to achieve spiritual excellence and drawing Model of formation of this transcendence Session 5 Creating enlightenment and insight in the authorities to discover the inner and outer gifts and blessings of God that we have and rational thinking about them and achieving satisfaction and its effect on promoting self-confidence, self-reliance and self-esteem . Session 6 Learn ways to support others, empathize, love others, take care of others, do something positive for others every day, make others happy to help them grow happy, take physical, psychological, social self-care to achieve spiritual self and Discover its components and keep it alive. Session 7 Practice and talk about how to live happily and enjoy life in the present, avoid pursuing and pursuing happiness and instead be happy, express spiritual memories, how to make sense Purposefulness and happiness with the determination to leave egoism and relationship with God, the event of true happiness with the highest energy of spirituality, living in the present with joy and attention to the values of life, enjoying the beauties, talking about happy moments and quietly doing the eighth session. Reviewing and summarizing the contents of the previous sessions with emphasis on looking after what we have and giving thanks and enduring problems with trust and hope in God. Subjects talk about sweet moments and memories of their lives, their experiences in problems, how to trust God in problems, close their eyes for 35 seconds and complete silence with a single chant of thanksgiving to a merciful God to reach a stage of life and thanks for abilities and Good life opportunities.

Category

Lifestyle

3

Description

Control group: This group will not receive treatment until the end of the sessions and until the quarterly follow-up, but at the end and if desired, the treatments of hope and spirituality will be performed on them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology & Metabolism Research Institute

Full name of responsible person

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Sponsors / Funding sources

1

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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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

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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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

Start the access period, after printing

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

In case of similar and complementary researches, the information of the present research will be available

From where data/document is obtainable

Contact by email : peyravi.maryami@gmail.com

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

The applicant is required to email his / her scientific research documents and after confirmation, he / she can access the information.

Comments