Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of self-care group training and acceptance and commitment group therapy on quality of life and psychological well-being in patients with type 2 diabetes

Protocol summary

Study aim
Comparison of the effectiveness of self-care needs-based education and acceptance and commitment group therapy on quality of life and psychological well-being in patients with type 2 diabetes

Design
The present study is a quasi-experimental and pretest-post test design with control group. Using simple randomization method in three groups based on Acceptance and Commitment Therapy (n = 20), Self-Care Needs Education (20) = n) and control group (n = 20) will be assigned.

Settings and conduct
The statistical population of the study consisted of patients with type 2 diabetes referring to Kish Island Medical Centers aged 25-45 years.

Participants/Inclusion and exclusion criteria
Inclusion criteria were: Type 2 diabetes with physician-approved for at least one year, hemoglobin A1c level above 7%, minimum age 25 and maximum 45, minimum cycle education, no psychological treatment from The time of diagnosis, absence of acute or chronic medical illness in the medical records of patients such as epilepsy, skeletal diseases, heart and respiratory failure, etc. which can cause problems in blood sampling and long sessions tolerance, lack of Severe mental illnesses such as psychotic disorders and non-use of psychotropic drugs or substance abuse are currently approved by the psychologist.

Intervention groups
Prior to the sessions and with informed consent, glycosylated hemoglobin testing will be performed for participants in both groups. They will also complete the research questionnaires. They will then receive acceptance and commitment therapy (12 sessions 90-minute per week) and self-care needs training (5 sessions 90-minute per week).

Main outcome variables
quality of life and psychological well-being

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191223045871N1**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **retrospective**

Last update: **2020-04-20, 1399/02/01**
Update count: **0**

Registration date
2020-04-20, 1399/02/01

Registrant information
Name
Abas Molavi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 76 4447 1906
Email address
molavi79@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-22, 1398/07/30
Expected recruitment end date
2019-11-21, 1398/08/30
Actual recruitment start date
2019-10-22, 1398/07/30
Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2020-03-10, 1398/12/20

Scientific title

Comparison of the effectiveness of self-care group training and acceptance and commitment group therapy on quality of life and psychological well-being in patients with type 2 diabetes

Public title

The Effect of Self-Care and Acceptance and Commitment-Based Therapy on Diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria were: Type 2 diabetes with physician-approved for at least one year, hemoglobin A1c level above 7%, minimum age 25 and maximum 45, minimum cycle education, no psychological treatment from Time of diagnosis

Exclusion criteria:

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Hormozgan University of Medical Sciences

Street address

Kish Hospital,Harireh Blvd,Hrmoz square,Kish Island,Iran

City

Kish Island

Province

Hormozgan

Postal code

1518833111

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.HUMS.REC.1398.313

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life

Timepoint

Before intervention, after intervention and three months after intervention

Method of measurement

World Health Organization Quality of Life Scale

2

Description

Psychological Wellbeing

Timepoint

Before intervention, after intervention and three months after intervention

Method of measurement

Reef Psychological Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will complete the research questionnaires. She will then receive self-care training (5 90-minute sessions per week)

Category

Rehabilitation

2

Description

Intervention group: They will complete the research questionnaires. It will then undergo acceptance and commitment treatment (12 sessions of 90 minutes per

week).

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Kish hospital

Full name of responsible person
Abas Molavi

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Kish Hospital, Harireh Blvd, Hormoz square, Kish Island,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Masheh square, Islamic Azad University, KishIsland, Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Abas Molavi

Position
Clinical supervisor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Psychology

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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 main consequences

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Everyone

Under which criteria data/document could be used
Citing the source

From where data/document is obtainable
molavi79@yahoo.com

What processes are involved for a request to access data/document
One month after receiving the email

Comments