Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of acceptance and commitment therapy on psychosocial adjustment and diabetes distress in patients with type 2 diabetes

Protocol summary

Study aim
The effectiveness of acceptance and commitment therapy on psychosocial adjustment and diabetes annoyance in patients with type 2 diabetes

Design
This clinical trial has a control group, with parallel groups, randomized, without blinding will be performed on 30 people (men and women) with type 2 diabetes. Random allocation software is used for randomization.

Settings and conduct
This research is a quasi-experimental study that was performed to determine the effective effect of third-wave therapy on the studied variables of the face in Bojnourd and psychological clinic.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Receive a definite diagnosis of type 2 diabetes from the relevant specialist; Conscious consent to participate in research; at least diploma education; Age between 59 to 40 years. Non-inclusion criteria: other acute or chronic disorders

Intervention groups
Intervention group: people with type 2 diabetes will undergo acceptance and commitment-based therapy (ACT) for 10 sessions of 120 minutes (two sessions per week) for 74 days. Control group: This group will not receive any intervention.

Main outcome variables
Psychosocial adjustment; diabetes distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210525051395N1**
Registration date: **2021-07-17, 1400/04/26**
Registration timing: **prospective**
Last update: **2021-07-17, 1400/04/26**
Update count: **0**

Registration date
2021-07-17, 1400/04/26

Registrant information

Name
mohammad taheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-21, 1400/04/30

Expected recruitment end date
2021-10-07, 1400/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of acceptance and commitment therapy on psychosocial adjustment and diabetes distress in patients with type 2 diabetes

Public title
The effectiveness of acceptance and commitment therapy on psychosocial adjustment and diabetes distress

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Receive a definite diagnosis of type 2 diabetes from the relevant specialist Conscious consent to participate in research Minimum diploma education Age between 59 to 40 years
Exclusion criteria:
Other acute or chronic disorders
Age
From **40 years** old to **59 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study will be based on a simple random method. Therefore, each patient is randomly assigned a number by a table of random numbers, based on which, if it is an odd number; the patient in the intervention group and if the number is even; the patient will be in the control group.
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 Tehran University of Social Welfare and Rehabilitation Sciences
Street address
Koodkiar dead end alley, Daneshjoo Boulevard, Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2021-05-16, 1400/02/26
Ethics committee reference number
IR.USWR.REC.1400.029

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Psycho-social adjustment
Timepoint
Before intervention; after intervention and follow-up after 3 months
Method of measurement
Psychosocial adjustment questionnaire

2

Description
Diabetes distress
Timepoint
Before intervention; after intervention and follow-up after 3 months
Method of measurement
Diabetes distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Acceptance and commitment therapy for self-management of type 2 diabetic patients, which was presented by the founders of this treatment in 2004. It has five main axes that are performed on the medical, psychological, and self-care aspects of diabetes. the Patients in this group will receive acceptance and commitment treatment in 10 120-minute sessions (one session per week) for 74 days.
Category
Treatment - Other

2

Description
Control group: Here we have 15 people on whom pre-test and post-test are performed but no intervention is performed.
Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Hor Health Center

Full name of responsible person
Ibrahim Bazkhanei

Street address
Hor Street; in front of Taamin-e-Ejtemaei Hospital; Chamran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Khankeh

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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Mohammad Taheri

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Rehabilitation counseling

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available