

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

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Tehran

Province

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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

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

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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