

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Moderating role of coping style and social support in effect of Acceptance and Commitment Therapy (ACT) on HbA1c, quality of life and self-care in type II diabetics

Protocol summary

Summary

In the present study, Acceptance and Commitment Therapy (ACT) is considered an effective intervention to achieve the treatment goal of diabetes that of maintaining close to normal range of glycosylated hemoglobin and the prevention of its complications. For this purpose, after applying inclusion criteria, 100 type II diabetic patients will be randomly assigned to two groups (n = 50). Participants in the experimental group, besides continuing medication treatment as usual and a 1-day education workshop, will participate in Acceptance and Commitment therapy for 10 sessions, once a week. Participants in the control group will continue medication as usual and will receive a 1-day educational workshop. At baseline, glycosylated hemoglobin (HbA1c) test will be measured from participants of the two groups and several questionnaires will be administered, including the Summary of Diabetes Self-Care Activities (SDSCA), The audit of diabetes-dependent quality of life (ADDQoL) and Multidimensional Scale of Perceived Social Support (MSPSS) and The brief COPE Questionnaire (COPE). After 3 months of completion of the study, all participants will have glycosylated hemoglobin (HbA1c) test for the second time and will complete all baseline questionnaires in addition to the Acceptance and Action Diabetes Questionnaire (AADQ). Finally, the effect of acceptance and commitment therapy on improving the symptoms of diabetes will be assessed via data analysis through Ancova and hierarchical regression statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091710860N1**
Registration date: **2013-02-02, 1391/11/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-02, 1391/11/14

Registrant information

Name

Zeinab Shayeghian

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

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Email address

shayeghian@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University scholarship + Personal source

Expected recruitment start date

2013-03-01, 1391/12/11

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Moderating role of coping style and social support in effect of Acceptance and Commitment Therapy (ACT) on HbA1c, quality of life and self-care in type II diabetics

Public title

The effect of Acceptance and Commitment Therapy (ACT) on treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- age range is between 40 to 60 years old; 2- Minimum educational degree is Diploma; 3- disease duration is between one and five years; 4 - It is necessary that the subjects during the study don't use psychotherapy programs and Drug changes outside of the educational and therapeutic intervention of study. Exclusion criteria: 1 - Being affected by other types of diabetes; 2- Being affected by severe diabetic complications that may impede the investigation.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

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**

Tarbiat Modares University

Street address

Nasr Bridge, Cross of Chamran and Jalal Al Ahmad

City

Tehran

Postal code**Approval date**

2012-12-15, 1391/09/25

Ethics committee reference number

52/34245

Health conditions studied**1****Description of health condition studied**

typell Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Self Care

Timepoint

before treatment. after treatment. 3 months after treatment

Method of measurement

Summary of Diabetes Self-Care Activities toober and et al 2002

Secondary outcomes**1****Description**

HbA1c

Timepoint

befor treatment. after treatment. 3 months after treatment

Method of measurement

blood tests Mg/dl

2**Description**

Quality of life

Timepoint

befor treatment. after treatment. 3 months after treatment

Method of measurement

The audit of diabetes-dependent quality of life (ADDQoL)

Intervention groups**1****Description**

It is a group therapy intervention. ACT treatment will be implemented in 8 session and three phases, as follows: The first phase (sessions 3-1) education and information, in this phase, patients, after communication of the therapist and patient to each other, receive extensive information about diabetes (diet, exercise, stress, etc.) and its complications, and effects of psychological factors on control and reversion and ACT concepts. The second phase (sessions 6-4) coping and stress management, it's about avoidance of coping with diabetes and self-care. The third phase (10-7) to accept and act, it's training of acceptance and educational elements of treatment and values.

Category

Lifestyle

2**Description**

Participants in the control group will continue medication as usual and will receive a 1-day educational workshop.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Labbafinejad Hospital

Full name of responsible person

Dr Kobra Roohi Gilani

Street address

Labbafinejad Clinic, Ninth Bostan, Pasdaran Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Ma'someh Darabi

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Tarbiat Modares University, Humanities Faculties

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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

Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Research Institute for Endocrine Sciences

Full name of responsible person

Dr Parisa Amiri

Position

Assistant

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Tarbiat Modares University

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PhD student of Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty