

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 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

+98 21 2243 2500

###### Email address

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##### 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**

52/3424,

**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

**City**

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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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**City**

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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

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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*