

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Study of the Efficacy of Coping-Therapy and Acceptance and Commitment Therapy (ACT) on Biological and Psychological Indices of Patients with Type II Diabetes

Protocol summary

Summary

The purpose of this study is to evaluate comparatively the effectiveness of coping therapy and acceptance and commitment therapy on biological, psychological biomarkers and adherence to the treatment of Type 2 diabetic patients. The sample of this clinical trial is selected by stratified random (according to gender) from among all diabetic patients in Kermanshah Taleghani Hospital Diabetes Center after obtaining the necessary permits from Kermanshah University of Medical Sciences. They response to stress scales, quality of life, coping-skills, and locus of control on the basis of inclusion and exclusion criteria before and after intervention. In addition, Serum tests for HBA1C are taken from patients in both stages. FBS and 2 HPP results are recorded for two weeks in order to evaluate variations in fasting blood glucose and its graph is recorded. Patients are randomly divided into three groups with stress management training, acceptance and commitment therapy on diabetes control training and diabetes control training (routine training for the control group). Finally, the differences between pre-and post-intervention investigate by multivariate analysis of covariance. Now a holistic research approach is running in more than 17 countries on the other hand diabetes are involved medical aspects in addition to psychological and social factors. This study comprehensively could expand the knowledge about the symptoms of diabetes including extensive clinical and psychological factors. Moreover, few previous studies have been done regarding to the effect of coping therapy and acceptance and commitment therapy on the health of diabetics and the impact of these methods separately. Comparison of these two methods on a study can be result to recognize more effective treatments and non-effective treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022132706N1**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Parastoo Abaspour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 3860

Email address

kcounselingcenter@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

kermanshah University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study of the Efficacy of Coping-Therapy and Acceptance and Commitment Therapy (ACT) on Biological and Psychological Indices of Patients with Type II Diabetes

Public title

Effect of psychological Treatment on Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria :Confirmation of Disease ; Patient' s Satisfication Exclusion Criteria: Psychiatric Diseases and Treatment for it ; Distatisfication

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Postal Code 6714673159, Shahid Beheshti BLD., Kermanshah

City

Kermanshah

Postal code

Approval date

2017-01-11, 1395/10/22

Ethics committee reference number

kums.rec.1395.606

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

e11

ICD-10 code description

diabetes (mellitus)(nonobese)(obese): adult-onset maturity-onset nonketotic stable type II

Primary outcomes

1

Description

FBS

Timepoint

Once in 2 Weeks

Method of measurement

Blood Sample

2

Description

2HPP

Timepoint

Once in 2 Weeks

Method of measurement

Blood Sample

3

Description

HBA1C

Timepoint

First and Endof Study

Method of measurement

Blood Sample

4

Description

Stress

Timepoint

First and End of Study

Method of measurement

Questionnair Coping With Stress

5

Description

Life Events and Changes in Family Life

Timepoint

First and end of study

Method of measurement

The Family Inventory of Life Events and Changes (FILE)

6

Description

Quality of Life in Diabetic Patients

Timepoint

First and End of Study

Method of measurement

Questionnaire Diabetes Quality of Life

7**Description**

locus of control

Timepoint

first and end of study

Method of measurement

Rotter "s locus of control scale

8**Description**

commitment to treatment

Timepoint

first and end of study

Method of measurement

questionnaire commitment to treatment

Secondary outcomes

empty

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

Intervention group1: Coping Therapy Treatment

Category

Treatment - Other

2**Description**

Intervention group 2: Acceptance and Commitment Therapy

Category

Other

3**Description**

Control group: Diabetes Inhibition

Category

Lifestyle

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

Diabetes Center in Taleghani Hospital

Full name of responsible person**Street address****City**

Kermanshah

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

kermanshah University of Medical Sciences

Full name of responsible person

Mrs. Rafiee

Street address

kermanshah University of Medical Sciences,
kermanshah

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

kermanshah University of Medical Sciences

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Parastoo Abaspour

Position

Psychologist in Counseling Center

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Master of Science Student

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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