Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Centerafter obtaining the necessary permits from Kermanshah University of Medical Sciences. They response to stress scales, quality of life, coping-skills, and locus of controlon 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 diabetesare involved medical aspects in addition to psychological and social factorsThis 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 therapyand acceptance and commitment therapy on the health of diabeticsand the impact of these methods separately. Comparison of these two methods on astudy 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

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Name of organization / entity

Kermanshah University of Medical Sciences

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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
Questionnair Diabetes Quality of Life

7

Description
locus of control
Timepoint
first and end of study
Method of measurement
Rotter "s locus of control sacle

8

Description
commitment to treatment
Timepoint
first and end of study
Method of measurement
questionnair 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
Daibetes 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
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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