Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effectiveness of Acceptance and Commitment Therapy with the Lifestyle Intervention of promoting health on disease perception, disease adjustment, and HbA1c Levels in Type II Diabetes patients

Protocol summary

Study aim
The purpose of this study is to compare the efficacy of acceptance and commitment therapy with lifestyle intervention of promoting health in a sample of type II diabetes patients.

Design
60 type 2 diabetes patients who, after matching by age and gender, are divided to three groups,Two experimental and one control,will participate in the research

Settings and conduct
Diabetes and metabolic disorders specialty clinic

Participants/Inclusion and exclusion criteria
Sample persons are type II diabetes patients and should not have received psychological intervention since a year ago. People who can not participate in the study include those with type 1 diabetes or those who are suffering from mental disorders, as well as those who have physical problems culminating in type 2 diabetes.

Intervention groups
In the research, the first group will have psychological treatment of acceptance and commitment. The second group has the lifestyle intervention of promoting health for type 2 diabetes patients. The third group is the control group.

Main outcome variables
Disease perception ;Disease adjustment ; Level of Hb A1C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039185N1**
Registration date: **2018-05-28, 1397/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-28, 1397/03/07**
Update count: **0**

Registration date
2018-05-28, 1397/03/07

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-08-11, 1397/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the effectiveness of Acceptance and Commitment Therapy with the Lifestyle Intervention of

promoting health on disease perception, disease adjustment, and HbA1c Levels in Type II Diabetes patients

Public title
Effect of ACT on diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes patients lack of getting psychological treatment since a year ago
Exclusion criteria:
Type 1 diabetes patients Patients with Psychological disorders and Physical problems culminating in diabetes
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple random sampling. Having matched the samples in terms of age and gender, a number in the range of one to three will be given to evry group. Then the numbers randomly will be assigned to the title of evry group, like control group, ACT group and lifestyle group by a computeized program
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 Semnan University of Medical Science
Street address
Mahdishahr ;Education and psychology faculty of semnan university
City
Semnan
Province
Semnan
Postal code
3564111156
Approval date
2018-03-14, 1396/12/23
Ethics committee reference number
IR.SEMUMS.REC.1396.257

Health conditions studied

1

Description of health condition studied
diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Disease Perception
Timepoint
Before and after of Intervention
Method of measurement
The Brief Illness Perception Questionnaire (BIPQ)

2

Description
Disease adjustment
Timepoint
Before and after of Intervention
Method of measurement
Problem Areas in Diabetes Questionnaire(PAID)

3

Description
HbA1C
Timepoint
Before and after of Intervention
Method of measurement
Blood analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Acceptance and commitment therapy (ACT). The name of ACT stemming from one of its main message: Accept what you can’t change and control it and commit to improve everything you can enrich and change it in your life. The purpose of ACT is attaining psychological flexibility. ACT has six core processes:

Contacting the present moment; Defusion of thoughts; Acceptance; Values; Commitment and Self as a context. This protocol takes around two months to run. It has eight sessions. In fact the intervention aims at improving the quality of life of diabetes patients to cope with their disease toward having an active life. This program lays emphasis on medical issues along with psychological matters.

Category

Behavior

2

Description

Intervention group: Lifestyle intervention for promoting health. In fact this protocol is a medical approach for diabetes. It emphasizes on self-care behaviors like blood sugar tests, walking, mild exercise and diet. In this course patients will learn about risks and disease resulting from diabetes and will learn how to prevent them. This program comprises six sessions taking three weeks. This approach lays little emphasis on psychological variables.

Category

Lifestyle

3

Description

Control group: None intervention, only as evidence group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes and metabolic disorders speciality clinc

Full name of responsible person

Dr Fatemeh Bandarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of semnan- Psychology faculty

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?

No

Title of funding source

This is a PHD Dissertation

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

Faculty of Psychology and Education of Semnan university

Full name of responsible person

Nasim Soltanian

Position

PHD Candidate

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Total research results will be published in scientific journals
When the data will become available and for how long
The documentation and research results are likely to be published in 2018-2019
To whom data/document is available
The full research document will be available to Semnan faculty of Psychology. Research results will be available to researchers as an article and book
Under which criteria data/document could be used
Using the results with the number and type of community and the research sample as well as the intervention can be used.
From where data/document is obtainable
Faculty of Psychology and Educational Sciences of Semnan University. Information and Documentation Center of Iran (IranDoc) Or sending a message to researcher : n.soltanian@semnan.ac.ir or n.soltanian@gmail.com
What processes are involved for a request to access data/document
Visiting the Irandoc center or Semnan University Library Or one week after sending email to the writer
Comments