

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Effectiveness of group Acceptance and Commitment Therapy on Self-compassion, Self-efficacy, Illness perception, Self-care activities, Psychological flexibility and HbA1C in type II diabetes

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of Acceptance and Commitment Therapy on Self-compassion, Self-efficacy, Illness perception, Self-care activities, Psychological flexibility and HbA1C in type 2 diabetic patients.

Design

A clinical trial with a pretest and post test design with a control group that 60 patients with diagnosis type 2 diabetes were randomly assigned to two groups of intervention and control

Settings and conduct

Before and after the intervention, from both groups received questionnaires and HbA1C tests

Participants/Inclusion and exclusion criteria

Inclusion criteria Having an age of 40 til 55 years
Diagnosis of Type II diabetes by Endocrinologist Having a degree in secondary education or higher Having Type 2 diabetes at least for one year Exit criteria Receiving another psychological treatments in a recent year and research time Failing to participate in more than two sessions of the study Need to change medication or hospitalization during the study Having diabetes complications that prevent the study

Intervention groups

Intervention group: The intervention group includes routine medicine treatment that depends on Endocrinologist diagnosis and receiving Acceptance and Commitment Therapy in eight 90- minutes sessions for two months. Control group: Control group includes routine medicine treatment that depends on Endocrinologist diagnosis without psychotherapy .

Main outcome variables

Self-compassion, Self-efficacy, Illness perception, Self-care activities, Psychological flexibility and HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181127041774N1**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **1**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

Fahimeh Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

f99n99@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-25, 1396/07/03

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

2017-09-25, 1396/07/03

Actual recruitment end date

2017-11-01, 1396/08/10

Trial completion date

2019-02-01, 1397/11/12

Scientific title

Effectiveness of group Acceptance and Commitment Therapy on Self-compassion, Self-efficacy, Illness perception, Self-care activities, Psychological flexibility and HbA1C in type II diabetes

Public title

Effect of ACT on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40 to 55 years old
Diagnosis of type 2 diabetes by doctor
Having a degree in secondary education or higher
Having Type 2 diabetes at least for one year

Exclusion criteria:

Receiving another psychological treatments in a recent year and research time
Failing to participate in more than two sessions of the study
Need to change medication or hospitalization during the study
Having diabetes complications that prevent the study

Age

From **40 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized

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 Kashan University of Medical Sciences

Street address

Qotb Ravandi Blv

City

Kashan

Province

Isfahan

Postal code

8713781147

Approval date

2017-09-06, 1396/06/15

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.60

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Self-efficacy

Timepoint

Before intervention, After intervention

Method of measurement

The Diabetes Management Self-efficacy Scale (DMSES)

2

Description

Hemoglobin A1c

Timepoint

Before and after the intervention

Method of measurement

Blood-test

3

Description

Self compassion

Timepoint

Before and after the intervention

Method of measurement

Self-compassion scale

4

Description

Self-care

Timepoint

Weekly

Method of measurement

Diabetes Self-Care Activities questionnaire (SDSCA)

5

Description

Psychological flexibility

Timepoint

Before and after the intervention
Method of measurement
Acceptance and Action Diabetes questionnaire (AADQ)

6

Description
Illness perception
Timepoint
Before and after the intervention
Method of measurement
Brief illness perception questionnaire(B-IPQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group includes routine medicine treatment that depends on Endocrinologist diagnosis and receiving Acceptance and Commitment Therapy in eight 90- minutes sessions for two months.
Category
Behavior

2

Description
Control group: control group includes routine medicine treatment that depends on Endocrinologist diagnosis without psychotherapy .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Dr.Majid Mozafari
Street address
Kashan University of Medical Science, Qhotbe Ravandi Blv, Kashan, Esfahan
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Kashan
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Postal code
8715981151
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+98 31 5554 0026
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beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr.Gholamali Hamidi
Street address
Kashan University of Medical Science, Qhotbe Ravandi Blv, Kashan
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Isfahan
Postal code
8715988141
Phone
+98 31 5554 9111
Email
f99n99@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
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
Kashan University of Medical Sciences
Full name of responsible person
Fahimeh Nasiri
Position
MSc student of clinical psychology
Latest degree
Master
Other areas of specialty/work
Psychology
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All information about questionnaires and tests is available

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers who works in academic institutions and university

Under which criteria data/document could be used

If data is only intended to facilitate another research work, and the use of this information alone is not permissible in other articles.

From where data/document is obtainable

Fahimeh Nasiri Contact number:98 9366422655 email: f99n99@yahoo.com

What processes are involved for a request to access data/document

By e-mail with their introduction and explanation of the cause and manner of using the information, they can request information.

Comments