

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Acceptance and Commitment Therapy on Self-care, Self-efficacy, and Emotional Distress in Type 2 Elder Diabetes Patients, Yazd

Protocol summary

Summary

The aim of this study is to determine effectiveness of Acceptance and Commitment Therapy (ACT) on self-care, self-efficacy, and emotional distress in type 2 elder diabetes patients, Yazd in two experimental and control groups. The main inclusion criteria are: being over 60 years old; having diabetes type 2 for more than a year. The main exclusion criteria are: having severe mental problem; receiving any psychological treatment in the past year; the use of narcotic drugs and drug abuse in the past month. 80 elderly patients with type II diabetes, by taking inclusion and exclusion criteria will be randomly selected And randomly assigned to experimental and control groups of 40, then to teach subjects in the intervention group were randomly divided into two groups of 20 persons. Before the intervention questionnaire 4 wish to pre-test will be given to both groups. Following the intervention (act) for experimental group in the form of group meetings, 8 sessions will be executed, while the control group did not receive treatment. The questionnaires were completed again after the end of the sessions and then again two month after (follow-up test) for measuring the maintaining of the effect of therapeutic intervention by the experimental and the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071028873N1**
Registration date: **2017-06-29, 1396/04/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-29, 1396/04/08

Registrant information

Name

zahra maghsoudi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences Yazd

Country

Iran (Islamic Republic of)

Phone

+98 917 153 4268

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acceptance and Commitment Therapy on Self-care, Self-efficacy, and Emotional Distress in Type 2 Elder Diabetes Patients, Yazd

Public title

The Effect of Acceptance and Commitment Therapy on Self-care, Self-efficacy, and Emotional Distress in Type 2 Elder Diabetes Patients, Yazd

Purpose

Treatment

Inclusion/Exclusion criteria

The Criteria for Inclusion in the Study Were: being over 60 years old; having diabetes type 2 for more than a

year; Being able to read and write and willingness to participate in the study. exclusion criteria were: having severe mental problem such as depression; receiving any psychological treatment in the past year; having sever complications resulted from diabetes such as diabetic foot; severe ulcer; amputation, the use of narcotic drugs and drug abuse in the past month.

Age

From **60 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Bahonar square- Shahid Sadoughi University of Medical Sciences

City

YAZD

Postal code

8916978477

Approval date

2016-05-02, 1395/02/13

Ethics committee reference number

IR.SSU.REC.1395.15

Health conditions studied

1

Description of health condition studied

The Effect of Acceptance and Commitment Therapy on Self-care, Self-efficacy, and Emotional Distress in Type 2 Elder Diabetes Patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self Care

Timepoint

Before, After and Two Month After Intervention

Method of measurement

(SDSCA (Summary of Diabetes Self-care Activities))

2

Description

Self Efficacy

Timepoint

Before, After and Two Month After Intervention

Method of measurement

Diabetic Self Efficacy

3

Description

Emotional Distress

Timepoint

Before, After and Two Month After Intervention

Method of measurement

Diabetes Distress Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Acceptance and Commitment Therapy (ACT) is carried out by one Clinical Psychologist and one Nurse in 8 Sessions, Once a Week, Each Session Lasts 90 Minutes.

Category

Behavior

2

Description

No Action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Zahra Maghsoudi
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr Amir Hoshang Mehrparvar
Street address
Shahid Bahonar square
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Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
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Person responsible for updating data

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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