

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Finding the effectiveness of acceptance and Commitment Group Training (ACT) and Emotion Regulation Group Training on Glycemic control index (HbA1c, diabetic quality of life and empowerment in patients diagnosed with type2 diabetes.

Protocol summary

Study aim

Finding the effectiveness of Acceptance and Commitment Group Training (ACT) and Emotion Regulation Group Training on Glycemic control index (HbA1c), Diabetic Quality of life and Empowerment in Patients diagnosed with type 2 Diabetes.

Design

Treatment consisted of: two experiment groups and one control group, not blinded, using available sampling method and randomly divided in three groups (acceptance and commitment-based therapy: 15 patients, emotion regulation: 15 patients and control group: 15 patients.

Settings and conduct

English The main purpose of this study is supportive study is to compare therapeutic methods: within groups; Acceptance and Commitment therapy group and Emotion Regulation and control group, on hemoglobin glucose, diabetic quality of life and empowerment in patients with Type 2 diabetes. these two treatments are studied within two experimental groups and the control group did not received any treatment. the study was not blinded. Corona Virus Pandemic coincidence with the Study and the need of the study groups to be in quarantine, training sessions are held virtually.

Participants/Inclusion and exclusion criteria

1. Conscious consent to participate in research 2. Age range 40-60 3. Not participating in other similar researches at the same time 4. Being at least 8 years under graduation 5. Being at least 2 years diagnosed with type 2 diabetes by a doctor 6. No psychiatric disorders

Intervention groups

Acceptance and commitment group training: 8 sessions of 90 minutes. Emotion regulation group training: 8 sessions of 90 minutes.

Main outcome variables

Hemoglobin Glucose: Blood Serum Level Test, Diabetic Quality of Life: Diabetic Quality of Life Questionnaire (DQOL), Empowerment: Diabetes Empowerment Scale (F-DES-28).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200607047677N1**
Registration date: **2020-08-17, 1399/05/27**
Registration timing: **retrospective**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

Registration date

2020-08-17, 1399/05/27

Registrant information

Name

Elham Eghrari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3768 6529

Email address

elham.eghrari@iautj.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-18, 1398/11/29

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2020-02-19, 1398/11/30

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-09-10, 1399/06/20

Scientific title

Finding the effectiveness of acceptance and Commitment Group Training (ACT) and Emotion Regulation Group Training on Glycemic control index (HbA1c, diabetic quality of life and empowerment in patients diagnosed with type2 diabetes.

Public title

Effectiveness of Psychologic therapies on psychological symptoms and hemoglobin glucose in patients diagnosed with type2 diabetes.

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 40_60 Being at least 8 years under graduation Being at least 2 years diagnosed with type 2 diabetes by a doctor Conscious consent to participate in research No psychiatric disorders Not participating in other similar researches at the same time

Exclusion criteria:

More than 2 sessions absence of in training sessions Suffering other acute medical disease

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

To select a sample, after preparing a list of those who refer to the Khorasan Razavi Diabetes Association and contact them, 45 people who meet the criteria for participating in the research will be selected. The selected members will be randomly divided into 3 groups and there will be 15 people in each group. Random allocation of the research sample to two intervention groups and a control group will be done based on six permuted blocks so that in each six block, two allocations to intervention group one, two allocations to intervention group two and two allocations to control group will be allocated. In this case, a total of 36 blocks are created, each block is numbered with a number and then the number of six blocks is selected based on the random numbers table until the sample size reaches 45 and finally 15 people in each group are assigned.

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 Azad University of Torbate Jam

Street address

1th Floor, No. 84, Farhad 22 St., Malek Abad Blvd, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9185713111

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.IAU.TJ.REC.1399.001

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus type2

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hemoglobin Glucose

Timepoint

Before the intervention (pretest), immediately after the intervention (post test), three month after the intervention(follow up)

Method of measurement

Serum Hemoglobin Glucose Level test

2**Description**

Diabetic quality of life

Timepoint

Before the intervention (pretest), immediately after the

intervention (post test), three month after the intervention(follow up)

Method of measurement

Diabetic Quality of life Questionnaire

3

Description

Empowerment

Timepoint

Before the intervention (pretest), immediately after the intervention (post test), three month after the intervention(follow up)

Method of measurement

the Diabetes Empowerment scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Acceptance and Commitment Group training. Intervention method: Protocol is based on Acceptance and Commitment therapy of Hayes et al., Which will be held in 8 sessions of 90 minutes for 8 consecutive weeks.

Category

Behavior

2

Description

Second intervention group: Emotion Regulation training. Intervention method: Training of emotion regulation sessions based on the protocol of Barlow et al., Which will be held in 8 sessions of 90 minutes in 8 consecutive weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

International Iranian Diabetes Prevention and Control Foundation

Full name of responsible person

Bahram Foruzandehfar

Street address

No. 56between Sajjad 2 and 4, Sajjad Boulevard, Khorasan Razavi Province, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9186694748

Phone

+98 51 3765 0400

Email

bfrouzan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

No sponser

Full name of responsible person

Elham Eghrari

Street address

1th Floor, No.84. Farhad St. 22. Malek Abad Blvd. Mashhad. Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9185713111

Phone

+98 51 3768 6529

Email

elhameghrari@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

No sponser

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elham Eghrari

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

1th Floor, No. 84, Farhad 22 St., Malek Abad Blvd,

Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

9185713111

Phone

+98 51 3865 6829

Email

elhameghrari@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elham Eghrari

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable