

# 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

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bfrouzan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

No sponser

**Full name of responsible person**

Elham Eghrari

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**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

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**Person responsible for scientific inquiries**

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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