

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The Comparison of Effectiveness of Self-Compassion Education and Lifestyle Modification Education On Psychological Symptoms and Self\_Care in type 2 Diabetic Patients

#### Protocol summary

##### Study aim

The Comparison of Effectiveness of Self-Compassion Education and Lifestyle Modification Education On Psychological Symptoms and Self-Care in type 2 Diabetic Patients

##### Design

A randomized clinical trial with parallel groups

##### Settings and conduct

After collecting the pre-test data, one experimental group of patients with type 2 diabetes received 8 sessions of 45-minute self-compassion based on psychological and self-care components and the other group received 8 sessions of lifestyle modification training. Each week, they were subjected to the above-mentioned components for 90 minutes, then the post-test from all three groups was re-tested, and finally, the effectiveness of the two methods was first measured on each of the psychological and self-care symptom indicators.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were type 1 diabetes with physician approval for at least one year, hemoglobin A1c levels above 7%, no psychological treatment since diagnosis, no acute or chronic medical illnesses in medical records such as Epilepsy, Skeletal Diseases, Heart and Respiratory Failures, etc., which can cause problems in blood sampling and prolonged sessions, lack of severe mental illnesses such as psychotic disorders and inadequate use of psychotropic drugs or substance abuse. Now to the psychologist's approval. Severe complications of diabetes that lead to hospitalization, absence of more than two sessions in treatment sessions and major stress due to unforeseen events will also be considered as exclusion criteria.

##### Intervention groups

For the first group, lifestyle modification training, for the second group, self-compassion training. The third group

will be the control group that will receive no intervention.

##### Main outcome variables

Psychological Symptoms; Self-Care

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200212046474N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

##### Registration date

2020-02-22, 1398/12/03

##### Registrant information

##### Name

Ali Mozaffaripour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 5322 2757

##### Email address

a.mozafari@aiukishint.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-11, 1398/09/20

##### Expected recruitment end date

2020-03-09, 1398/12/19

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Comparison of Effectiveness of Self-Compassion Education and Lifestyle Modification Education On Psychological Symptoms and Self\_Care in type 2 Diabetic Patients

**Public title**

The Comparison of Effectiveness of Self-Compassion Education and Lifestyle Modification Education On Psychological Symptoms and Self\_Care in type 2 Diabetic Patients

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having type 1 diabetes with a doctor's approval for at least one year hemoglobin A1c levels above 7% no acute or chronic medical illness in medical records such as epilepsy, illness Skeletal disorders, heart and respiratory failure, etc., which can cause problems with blood sampling and prolonged sessions no psychiatric treatment since diagnosis lack of severe mental illnesses such as psychotic disorders lack of psychotropic drugs or substance abuse at the moment to the approval of the psychologist

**Exclusion criteria:**

Severe complications of diabetes that lead to hospitalization absence of more than two sessions in treatment sessions major stress due to unforeseen events

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 45

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization The block randomization method is performed by the statistical consultant as follows: Randomization is performed in two groups of Self-Compassion Education and Lifestyle Modification Education. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = Lifestyle Modification Education, B = Self-Compassion Education In this study, with two groups A and B, we create the following two groups and assign each of the numbers 1 to 2: -AB-BA Then we use a random number table to select one of these blocks

whenever the numbers 1 and 2 appear, and if there is another number, we consider it null and move on to the next choice. In fact, we have obtained a random sequence of numbers with a random number table that we consider the order of assignment for each number. This way the number of people in the groups will be approximately equal.

**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 Hormozgan University Of Medical Sciences

**Street address**

North Karegar Street 17 Veteran Street 24 P 64

**City**

Tehran

**Province**

Tehran

**Postal code**

1437697419

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.HUMS.REC.1398.314

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

Diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes****1****Description**

Psychological Symptoms

**Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

**Method of measurement**

Psychological Symptoms (SCL-90-R) 90-Question Scale  
(Dragoutis et al., 1973)

## 2

### **Description**

self-care

### **Timepoint**

Measurement will be done in pre-test, post-test and follow-up three months after post-test

### **Method of measurement**

Self-Care Scale (Tobert & Glasgow, 1990)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group one: Skills that were taught by Alijani et al. (2015) in 8 sessions (two sessions per week and 90 minutes each).

#### **Category**

Lifestyle

### 2

#### **Description**

Intervention group II: Skills taught by Gilbert et al. (2012) in a specialized and workshops in 8 sessions (two sessions per week for 90 minutes each).

#### **Category**

Lifestyle

### 3

#### **Description**

Control group: The control group received no intervention

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Diabetes Association and Guilanbari County Hospitals

##### **Full name of responsible person**

Ali Mozafari Pour

##### **Street address**

South Kurdistan Highway - 17th Street - Janbazan Street - 24p 61st 4th West

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

2246578941

#### **Phone**

+98 21 2288 1908

#### **Email**

a.mozafari@aiukishint.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Alireza Roosta

##### **Street address**

Islamic Azad University of Kish International Branch, Free Zone Organization Square, Sana'i Boulevard, Kish Island.

##### **City**

Kish

##### **Province**

Hormozgan

##### **Postal code**

7941775883

##### **Phone**

+98 76 4442 2720

##### **Email**

a.mozafari@aiukishint.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Islamic Azad University

#### **Proportion provided by this source**

20

#### **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**

Islamic Azad University

##### **Full name of responsible person**

Ali Mozaffaripour

##### **Position**

Ph.D student

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Psychology

##### **Street address**

No 6. Fattahpour Alley, Gilan Gharb

**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
7941775883  
**Phone**  
+98 83 5322 2757  
**Fax**  
**Email**  
A.mozafari@aiukishint.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ali Mozaffaripour  
**Position**  
Ph.D student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
**Street address**  
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**Email**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
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**Latest degree**

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**Email**  
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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

Only part of the data, such as information about the main outcome or the like, can be shared.

### When the data will become available and for how long

Start of access period 6 months after printing results

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

any type of analysis on the data delivered is permitted

### From where data/document is obtainable

Ali Mozafari, No. 6. Fattahpour Alley, Gilan Gharb.

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

The request will be sent by email to:  
a.mozafari@aiukishint.ac.ir

### Comments