

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

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North Karegar Street 17 Veteran Street 24 P 64

City

Tehran

Province

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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

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

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2246578941

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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.

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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

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

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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