

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the Effectiveness of Compassionate Therapy and Positive Psychology with Well-being Approach on Alexithymia, Adaptive Behavior, Adherence of Treatment and Biological Factors in Patients with Diabetes Type2

#### Protocol summary

##### Study aim

The effectiveness of each treatment approach focused on CFT & positive psychology with the well being approach and comparing the effectiveness of these two approaches.

##### Design

clinical trial has control group, with parallel groups, single blind side, randomized, three groups of 15 people selected from 100 people, for choosing members have been used simple random selection.

##### Settings and conduct

Before COVID-19 Outbreak : two sections have been held in hospital, each section 2 hours a day. After COVID-19 Outbreak and limitations : six sections have been held online.

##### Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes for more than six months High school education or more Patient willingness and satisfaction to participate in research 30 years old or above

##### Intervention groups

there is 3 groups: group 1. treatment with CFT group 2. treatment with positive psychology and well being approach group 3. control

##### Main outcome variables

The effectiveness and comparative effect of a separate treatment approach based on CFT and positive psychology on Alexithymia, Adaptive Behavior, Adherence of Treatment and Biological Factors in Patients with Diabetes Type2.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191023045222N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **retrospective**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

##### Registration date

2020-06-12, 1399/03/23

##### Registrant information

###### Name

Mahnaz Bahadori

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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+98 61 3443 4091

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p.askary@iauahvaz.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-05-28, 1399/03/08

##### Actual recruitment start date

2020-05-21, 1399/03/01

##### Actual recruitment end date

2020-05-28, 1399/03/08

##### Trial completion date

2020-07-15, 1399/04/25

##### Scientific title

Comparison of the Effectiveness of Compassionate Therapy and Positive Psychology with Well-being

Approach on Alexithymia, Adaptive Behavior, Adherence of Treatment and Biological Factors in Patients with Diabetes Type2

#### Public title

Comparison of the Effectiveness of Compassionate Therapy and Positive Psychology with Well-being Approach on Alexithymia, Adaptive Behavior, Adherence of Treatment and Biological Factors in Patients with Diabetes Type2

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with type 2 diabetes for more than six months High school education or more Patient willingness and satisfaction to participate in research 30 years old or above

##### Exclusion criteria:

Lack of mental disorder type 1 diabetes Gestational Diabetes Diabetes is caused by other factors

#### Age

From **30 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **100**

Actual sample size reached: **45**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

By referring to the endocrinology department of Golestan Hospital, under the supervision of a specialist doctor who is my advisor in this research and by participating in the Great Diabetes Conference by preparing the consent form for participating in the course and demographic form and giving the necessary explanations, out of 500 people, 110 people announced their readiness. Then the names of the individuals were written one by one on the specific size sheets and the names were selected by lottery in the box.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Individuals were divided into three groups. Apart from the control group, which did not intervene and only answered the questionnaires, the other two groups participated in educational-therapeutic classes, but without knowing in which aspect there was a change, effectiveness or effect.

#### 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

Shahid chamran Blvd.

##### City

Hormozgan

##### Province

Hormozgan

##### Postal code

7916613885

#### Approval date

2020-05-18, 1399/02/29

#### Ethics committee reference number

IR.HUMS.REC.1399.105

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Alexithymia

#### Timepoint

It is before the intervention and 8 sessions later (two sessions per week)

#### Method of measurement

Toronto Alexithymia Scale

### 2

#### Description

Adaptive Behavior

#### Timepoint

It is before the intervention and 8 sessions later (two sessions per week)

#### Method of measurement

The Psychosocial Adjustment to Illness Scale (PAIS)

### 3

#### Description

Adherence of Treatment

## Timepoint

It is before the intervention and 8 sessions later (two sessions per week)

## Method of measurement

Modanloo adherence of treatment scale

## Secondary outcomes

### 1

#### Description

mental health

#### Timepoint

After the intervention

#### Method of measurement

use Psycho-social Adjustment with Illness Scale

### 2

#### Description

Quality of Life

#### Timepoint

After the intervention

#### Method of measurement

use Modanloo Adherence of Treatment questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: Compassionate Therapy group

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2 : Positive psychology

#### Category

Treatment - Other

### 3

#### Description

Control group

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golestan Hospital

##### Full name of responsible person

Dr. Leila Moradi

##### Street address

Farvardin Ave., Golestan Town.

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## Province

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## Web page address

<https://hgolestan.ajums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Alireza Rosta

##### Street address

Islamic azad university of Kish, Free Zone  
Organization Square, Sanaei Blvd, Kish

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##### Province

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##### Email

[Info@iaukishInt.Ac.Ir](mailto:Info@iaukishInt.Ac.Ir)

##### Web page address

<https://iaukish.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

100

#### 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**  
Mahnaz Bahadori  
**Position**  
Family counselor & Teacher in Islamic Azad University of Ahvaz  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for scientific inquiries

### Contact

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Shahid Chamran University of Ahvaz  
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## Person responsible for updating data

### Contact

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**Latest degree**

Master  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Participants' personal information will not be published, but data analysis is required in Chapter Four, as it relates to the PhD thesis.

### 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

Participant information was required for admission to psychotherapy, which we obtained after obtaining the consent form. This information is required in the demographic tables of chapters three and four of the thesis.

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

After the dissertation has been defended then approved by the judges, it will be accessible.

### To whom data/document is available

Colleges, professors, researchers and the people who are interested into science and research issues.

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

1- For scientific experiments with license from related authorities. 2- Get the necessary permission from the supervisors, consultants and researchers of this research.

### From where data/document is obtainable

1- Islamic Azad University, Kish International Branch. 2- After being indexed, it is available on more popular sites.

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

Visit the Islamic Azad University, Kish International Branch's library and deliver the request to research unit.

### Comments