Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 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 onAlexithymia, 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
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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 Modanlo 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
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Farvardin Ave., Golestan Town.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Rosta
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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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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 require 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