Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of acceptance based emotion regulation on diabetes control scale on type 2 diabetes.

Protocol summary

Study aim

1- Determining the effectiveness of acceptance-based emotion regulation group therapy on diabetes scale.

Design

present randomized clinical trial is semi-experimental and includes three stages: pre-test, post-test and follow-up with equivalent control groups. 60 people with type 2 diabetes were selected and randomly divided into three groups.

Settings and conduct

The study started with 60 patients who were divided into three intervention and control groups by random replacement method: Treatment sessions for each of the intervention groups were provided on two separate occasions so that the number of people in the groups was 10 people. Thus, there were 4 intervention groups in this research. Treatment sessions for people who were on the waiting list were held after the end of the follow-up. Also, the follow-up phase was implemented 6 months after the last group therapy session, and the group members completed the questionnaires of this phase and performed their blood sugar test.

Participants/Inclusion and exclusion criteria

inclusion: 1) diagnosis of type 2 diabetes by an endocrinologist and metabolism specialist, 2) age range of 35 to 65 years, 3) treatment under the supervision of a doctor with endocrine and metabolism expertise, 4) Having a medical record under the supervision of an endocrinology and metabolism specialist,

Intervention groups

Acceptance based emotion regulation Acceptance and commitment group Treatment as usual group

Main outcome variables

The outcome variables of the research are diabetes control scales, which include self-care, quality of life, and glycosylated hemoglobin(HbA1c).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230401057794N1**
Registration date: **2023-04-21, 1402/02/01**
Registration timing: **retrospective**

Last update: **2023-04-21, 1402/02/01**
Update count: **0**

Registration date

2023-04-21, 1402/02/01

Registrant information

Name

Elnaz Hajati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2251 4091

Email address

elnazhajati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

2019-10-23, 1398/08/01

Actual recruitment end date

2019-12-22, 1398/10/01

Trial completion date

2020-03-10, 1398/12/20

Scientific title

Effectiveness of acceptance based emotion regulation on diabetes control scale on type 2 diabetes.

Public title
Psychotherapy on diabetes
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis if type 2 diabetes by endocrinologist Age between 35-65 Treatment under endocrinologist Medical report
Exclusion criteria:
New drug treatment with the start of intervention Not suffering from other type of diabetes Sever psychiatric disorder Substance abuse disorder
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method of the current research is restricted randomization, and random allocation rule is used to select people in the intervention groups. At first, codes were assigned to all three groups, and then by lottery, the order of the groups was determined in order of acceptance based emotion regulation, acceptance and commitment, and the waiting list. In the next step, the code was assigned to the sample people. Then each code was drawn by lottery and assigned to the groups based on the order they were placed until the codes were finished. 20 people were in the acceptance based emotion regulation group, 20 people were in the acceptance and commitment group, and 20 people were in the waiting list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
خیر

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee if iran university
Street address
satarkhan
City
tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-10-16, 1398/07/24
Ethics committee reference number
IR.IUMS.REC.1398.760

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11.6
ICD-10 code description
Type 2 diabetes mellitus with other specified complications

Primary outcomes

1

Description
Quality of life
Timepoint
Pre test, post test, follow up
Method of measurement
The adult of diabetes-dependent quality of life

2

Description
Self-care
Timepoint
Pre test, post test, follow up
Method of measurement
Summary of diabetes self-care activities

3

Description
HbA1c
Timepoint
Pre test, post test, follow up
Method of measurement
Blood Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The acceptance based emotion regulation The therapeutic intervention takes place during 14 sessions, and during these sessions, the role of emotions, their function, how to identify and properly express them, strategies for regulating unpleasant emotions and the role of values in giving meaning to life conditions are discussed. Each session is held once a week for 1:30. The people present in this intervention sit around each other in a room and the therapist, after introducing and teaching the points of the session, leads them to joint discussion and group exercises. The content of each session is prepared with the help of educational aids such as PowerPoint and session summaries and is provided to them.

Category
Treatment - Other

2

Description
Control group 1: acceptance and commitment group/ The therapeutic intervention takes place during 12 sessions and during these sessions the role of values, adherence to them and acceptance of inevitable aspects of life are discussed. The content of each session is detailed in the protocol of this treatment. Each session is held once a week for 1:30. The people present in this intervention sit around each other in a room and the therapist, after introducing and teaching the points of the session, leads them to joint discussion and group exercises. The content of each session is prepared with the help of educational aids such as PowerPoint and session summaries and is provided to them.

Category
Treatment - Other

3

Description
Control group 2: Treatment as usual/This group receive drug treatment and routine education of the Diabetes Association.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian diabetes association

Full name of responsible person
Dr.Rajab

Street address
Satarkhan

City
Tehran

Province
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123345555

Phone
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Fax

Email
iraniandiabetessociety@yahoo.com

Web page address
http://diabeteshom.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Banafshe Gharaee

Street address
Satarkhan

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Province
Tehran

Postal code
1449614535

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+98 21 86701

Email
info@iums.ac.ir

Web page address
http://iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

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
Iran University of Medical Sciences

Full name of responsible person
Banafshe Gharraee

Position
Professor
Latest degree
Ph.D.
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)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Main result
When the data will become available and for how long
6 month after publication
To whom data/document is available
University
Under which criteria data/document could be used
For research
From where data/document is obtainable
elnazhajati@yahoo.com
What processes are involved for a request to access data/document
elnazhajati@yahoo.com
Comments