Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of group reality therapy with a routine education program on adherence to the therapeutic regimen and improvement of health indicators in patients with Diabetes Type 2

Protocol summary

Study aim

Effectiveness of group reality therapy in comparison with hospital routine education on adherence to treatment regimen and health indicators in patients with type 2 diabetes

Design

The clinical trial included a control group with randomized parallel groups that was not blinded.

Settings and conduct

The study site is the Diabetes Center of Amir-Almonin Hospital in Ahvaz. After obtaining the code of ethics from the university ethics committee, the researcher selected 60 patients with diabetes based on the inclusion criteria and divided them into two groups of 30, then randomly assigned them to one of the two experimental or control groups. Questionnaires and tests were performed before the intervention. Then, group reality therapy training were performed for the experimental group and routine hospital training were performed for the control group. The instruments were measured again 2 month and 3 months after the intervention.

Participants/Inclusion and exclusion criteria

inclusion criteria: -Have at least literacy -Failure to employ yourself, your spouse or first-degree relatives in health centers-Tendency to participate in the study - At least two months have passed since the diagnosis of diabetes by the doctor -Not having a history of uncontrolled underlying diseases such as epilepsy -The patient has not taken any training in the field of reality therapy before Exclusion criteria: -Not attending more than one training session -Psychiatric treatments or the use of psychotropic drugs and substance abuse during research

Intervention groups

the intervention group was the patients with type 2 diabetes who referred to Amir Al-Monin Hospital and received group reality therapy. The control group also included patients who received routine education of hospital.

Main outcome variables

Outcomes include: changing patient health indicators; adherence to diabetes treatment regimens.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041915N2**
Registration date: **2020-10-06, 1399/07/15**
Registration timing: **retrospective**

Last update: **2020-10-06, 1399/07/15**
Update count: **0**

Registration date

2020-10-06, 1399/07/15

Registrant information

Name

Kourosh Zarea

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8071

Email address

zarea_k@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-10, 1398/09/19

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date
2019-12-10, 1398/09/19
Actual recruitment end date
2020-02-20, 1398/12/01
Trial completion date
2020-03-18, 1398/12/28

Scientific title
Comparison of the effectiveness of group reality therapy with a routine education program on adherence to the therapeutic regimen and improvement of health indicators in patients with Diabetes Type 2

Public title
Group Reality Therapy on adherence to the therapeutic regimen and improvement of health indicators in Diabetes patient
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having minimum literacy skills Not working, spouse or first-degree relatives in health centers Willingness to participate in the study At least two months have passed since diagnosis of diabetes Not having a history of uncontrolled underlying diseases such as epilepsy The patient has never received any training in the field of reality therapy
Exclusion criteria:
Not participating in more than one training session Psychiatric treatments or the use of psychotropic drugs and substance abuse during study
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 60 patients referred to Amir Almonin Hospital in Ahvaz patients were selected based on inclusion criteria. Then they were allocated into two groups of 30 people (intervention group and the control group) by a coin randomly.
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
Ahvaz jundishapur university of medical sciences
Street address
Ahvaz Jundishapur university of medical sciences<
Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.AJUMS.REC.1398.657

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
Score of adherence to therapeutic regime based on questionnaire of adherence to therapeutic regime in patients with diabetes
Timepoint
The measurement of adherence to therapeutic regime was measured before the study, 1 and 2 months after the start of the group reality therapy.
Method of measurement
Questionnaire of adherence to therapeutic regime in patients with diabetes

2

Description
Primary variable was cholesterol levels.
Timepoint
The measurement of blood cholesterol level before the study, 1 and 2 months after the start of group reality therapy.
Method of measurement
Cholesterol level detection kit in the laboratory

3

Description
Primary variable was Blood Gloucester Hemoglobin(HBA1C) levels.
Timepoint
level of Blood Gloucester Hemoglobin (A1C Hb) before the study, 1 and 2 months after the start of the group reality therapy was measured.
Method of measurement
The HbA1C hemoglobin measurement kit in the laboratory was used

4

Description
Fasting Blood Sugar level
Timepoint
level of Fasting Blood Sugar before of the study, 1 and 2 months after the start of the group reality therapy was measured.
Method of measurement
The Fasting Blood Sugar measurement kit in the laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The treatment protocol of the intervention group consisted of 10 sessions of 45 minutes (one session per week) for 2 months in the form of lectures and face-to-face training for the intervention group. Topics discussed in these sessions include information about diabetes, its causes and factors, how to take care of yourself, blood sugar control strategies, psychological support such as stress, anxiety, etc., strengthening positive thinking and ways Success, examining how to live better, etc. During each session, the topics and discussions of the previous sessions were also examined. The program of group reality therapy training sessions was based on the latest articles and books and consultations with experts based on Glaser's theory of choice and the theory of confrontation with the theory and was presented by the researcher with the help of the researcher (clinical psychologist). Then, the educational materials were provided to both groups in the form of educational booklets and CDs after the study. At the end of the training sessions, the intervention group was given the opportunity to apply new skills in their daily lives, during which the researcher contacted them by telephone and was given a telephone number to If necessary, call and raise their problems.
Category
Behavior

2

Description
Control group: In the control group, routine care include patient education, lab checkup that provided by the Diabetes Control Center of Amir-Almomenin hospital was used.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-Almomenin hospital of Ahvaz
Full name of responsible person
kourosh zarea
Street address
Ahvaz Jundishapur university of medical sciences< Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8621
Email
zarea_k@ajusm.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur university of medical sciences<
City
Ahvaz
Province
Khouzestan
Postal code
6135864565
Phone
+98 61 3373 8621
Email
zarea_k@ajums.ac.ir
Grant name
Faculty member grant
Grant code / Reference number
NCRCCD-9829
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

kourosh zarea

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ahvaz Jundishapur university of medical sciences<
Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

8764568981

Phone

+98 61 3373 8621

Email

zarea_k@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

kourosh zarea

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Ahvaz Jundishapur university of medical sciences<
Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

8764568981

Phone

+98 61 3373 8621

Email

zarea_k@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

kourosh zarea

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ahvaz Jundishapur university of medical sciences<
Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

8764568981

Phone

+98 61 3373 8071

Fax

+98 61 3373 8333

Email

zarea_k@ajums.ac.ir

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

Some sections of data if can not be identified I can provide to whom may use scientific purposes.

When the data will become available and for how long

6months later

To whom data/document is available

Scientific institutions

Under which criteria data/document could be used

No other one

From where data/document is obtainable

Ahvaz Jundishapur University of medical sciences

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

the informed request should be signed

Comments