

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

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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

AgeFrom **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

Khuzestan

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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
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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

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