

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of therapy on glycemic control, anxiety and depression in adolescents with type I diabetes.

Protocol summary

Summary

Scientific : The effect of therapy on glycemic control, anxiety and depression in adolescents with type I diabetes. Setting and conduct: Clinical Trial, a randomized, Phase 3-2 clinical trials. Intervention: This randomized clinical trial study was conducted on 74 adolescents with type I diabetes with age of 11-24 years on Ahvaz Golestan and Abuzar hospitals, Iran, in 2014. Patients were assigned to 3 intervention group (n= 12 in first and second group and n= 13 in third group) and control group (n= 37) randomly. Matches of the patients in both groups were done related to age, sex, education, ethnicity, diabetes duration and family history as well as parents' income. Data was collected by demographic and clinical characteristics checklists and Beck anxiety and depression inventory. At the first and before the intervention, patients' educational and supportive needs were assessed during an interview, and then patients in both groups filled out the questionnaires. Also, Fasting Blood Sugar (FBS) and HbA1C were tested before the study with glucometer and calorimetry laboratory test respectively by a laboratory technician in both studied groups. Patients in 3 intervention group were educated with group discussion in one section (2 hours) in a week during 2 months. Patients in control group received no intervention and was emphasized that participate in no educational programs until the end of the study. After ending the intervention, patients were followed for 3 months with telephone

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092419284N1**

Registration date: **2014-11-19, 1393/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-19, 1393/08/28

Registrant information

Name

Marjan Naseri

Name of organization / entity

University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 614435890

Email address

naseri.ma@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Ahvaz University of Medical Sciences

Expected recruitment start date

2014-07-25, 1393/05/03

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of therapy on glycemic control, anxiety and depression in adolescents with type I diabetes.

Public title

Effect of training on blood glucose control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having 21-11 years of age; In ahvaz Location; Disease for at least 6 months; Lack of training and support so far Group; No Uncontrolled underlying disease such as epilepsy, etc; Lack of long-term complications of diabetes (retinopathy, nephropathy, neuropathy); Inclination To participate in training programs; Lack of diseases that affect measur HbA1C levels (eg, anemia, haemoglobinopathy, uremia, renal failure and hemodialysis); No History of anxiety and depression and other mental illness diabetes before. Exclusion criteria: Psychotropic drugs and psychiatric treatment or substance abuse during the study; Hospitalization during the period of study.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

--

Secondary trial Id

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Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan.

City

Ahvaz

Postal code

00986135715794

Approval date

2014-06-28, 1393/04/07

Ethics committee reference number

1393.117

Health conditions studied

1

Description of health condition studied

Type 1 Diabetes

ICD-10 code

E10, E11,

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Anxiety

Timepoint

Before and three months after intervention.

Method of measurement

Beck Anxiety Inventory

2

Description

Fasting blood sugar

Timepoint

Before and three months after intervention.

Method of measurement

Its scales mg / dl with blood tests taken

3

Description

Glycosylated hemoglobin

Timepoint

Before and three months after intervention.

Method of measurement

Scale is the percentage of blood samples taken

4

Description

Depression

Timepoint

Before and three months after intervention.

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

Group Education

Timepoint

With intervention, training, and three months later to be weighed

Method of measurement

Inventory and FBS-HbA1C test

Intervention groups

1

Description

Experimental trial to evaluate training to determine the impact on glycemic control in diabetic adolescents with anxiety and depression made, Its effectiveness is measured three months later Before and after training to assess FBS-HbA1C blood test taken.

Category

Lifestyle

2

Description

The control group consisted of taking blood tests to check for interferences and FBS-HbA1C during the study did not receive the intervention, After three months, the group will be re-tested.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Dr.Ryahy

Street address

Golestan hospital, Golestan road, Ahvaz, Khozestan

City

Ahvaz

2

Recruitment center

Name of recruitment center

Aboozar Hospital

Full name of responsible person

Dr.Ryahy

Street address

Aboozar Hospital , Ave Nurse,Blvarpasdaran, Circle Shhydbndr, Ahvaz, Khuzestan.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ahvaz University of

Medical Sciences

Full name of responsible person

Dr. Ahmad Hosseini

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan.

City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Marjan Naseri

Position

MSc student of nursing education

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Doctor Rostami

Position

P H D

Other areas of specialty/work**Street address**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Marjan Naseri

Position

MSc student of nursing education

Other areas of specialty/work**Street address**