

# 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

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#### 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

###### Street address

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+98 614435890

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###### Web page address

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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

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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**