

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effectiveness of self-control program on quality of life in adolescents with Diabetic Type 1

#### Protocol summary

##### Study aim

Determination the effect of self-control program on the quality of life of adolescents with diabetes

##### Design

A randomized clinical trial with a control group with pre and post test design, a blinded one with 56 adolescents with type 1 diabetes

##### Settings and conduct

Regarding the number of teenagers covered by the Janan Charity Association, sampling was used in an accessible manner, All files of patients were assigned a number, the file number and number were written on paper; The number and case number were written on paper and mixed in the dish. The first number that was randomly selected from all the numbers was in the test group and the next number in the control group until the end of the study.

##### Participants/Inclusion and exclusion criteria

Diabetes diagnosis for more than 1 year ;Do not have acute side effects;Willing to participate in the study; Do not participate in the same study at the same time;Unwillingness to continue cooperation in research

##### Intervention groups

Self-control training program was held for 6 sessions per week for two sessions and 3 weeks for the test group;After completing the questionnaire, the control group completed a training manual on type 1 diabetes at the end of the training sessions.

##### Main outcome variables

The general score of quality of life The score of quality of life dimensions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181213041951N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

##### Registration date

2019-02-03, 1397/11/14

##### Registrant information

###### Name

zinat mohammadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7595

###### Email address

zinatmohammadi2016@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-30, 1397/11/10

##### Expected recruitment end date

2019-03-15, 1397/12/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effectiveness of self-control program on quality of life in adolescents with Diabetic Type 1

##### Public title

"The Effectiveness of self-control on quality of life in adolescents diabetes"

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
At least one year of diagnosis of diabetes have been past  
Do not have acute side effects  
Willing to participate in the study  
Do not participate in the same study at the same time

**Exclusion criteria:**  
Unwillingness to continue cooperation in research  
Physical-psychological disabilities and other chronic disease

**Age**  
From **12 years** old to **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **56**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple accident

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants were unaware of the allocation of study groups

**Placebo**  
Not used

**Assignment**  
Factorial

**Other design features**  
Sampling was done using available method and the samples were randomly assigned to two groups of intervention and control

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Associate Professor of Research & Technology, Ethics committee of Isfahan University of Medical Scie

##### Street address

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery Azadi Square, Hezar- Jerib Ave.,

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673465

#### Approval date

2018-10-03, 1397/07/11

#### Ethics committee reference number

230.IR.MUI.RESEARCH.REC.1397.

## Health conditions studied

### 1

#### Description of health condition studied

quality of life

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 diabetes mellitus

## Primary outcomes

### 1

#### Description

Quality of Life Score in Quality of Life Questionnaire for Adolescents with Diabetes

#### Timepoint

Before and after training the program of self-control

#### Method of measurement

Quality of Life Questionnaire for Adolescents with Diabetes

### 2

#### Description

Score the dimensions of the quality of life

#### Timepoint

Before and after training the program of self-control

#### Method of measurement

Quality of Life Questionnaire for Adolescents with Diabetes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For the intervention group, self-control skills training classes were conducted in 6 sessions, twice a week, through slides, questions and answers, and lectures.

#### Category

Behavior

### 2

#### Description

Control group: after completing the final questionnaire, the educational pamphlet was given

#### Category

Behavior

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Janan Clinic

**Full name of responsible person**

Ayoub Shahpouri

**Street address**

No,16; Knowledge Ave; Shariati Ave: Najafabad Town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8513774791

**Phone**

+98 31 4246 0640

**Fax**

+98 31 4262 7006

**Email**

janan.ansar@gmail.com

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Deputy Director of Research and Technology

**Street address**

Hezar-Jerib Ave, Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zinat Mohammadi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

NO, 16, Qods Ave, Shahid Azari, Najafabad Town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8517663661

**Phone**

+98 31 4274 8979

**Email**

zinatmohammadi2016@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Soheila Jafari-Mianaei

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Isfahan University of Medical Sciences, Faculty of Nursing & Midwifery, Azadi Square, Hezarjereeb Avenue

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673465

**Phone**

+98 31 3792 7595

**Email**

m\_jafari@nm.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zinat Mohammadi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No,16, Qods Ave, Shahid Azari, Najafabad Town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8517663661

**Phone**

+98 31 4274 8979

**Email**

zinatmohammadi2016@gmail.com

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

This file is secret.

**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**

No - There is not 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**

Protocol and data analysis will be published as an article

**When the data will become available and for how long**

After the finishing of research and publishing the article

**To whom data/document is available**

All the people that the result of the research is useful for them

**Under which criteria data/document could be used**

For increasing quality of life of diabetic teenagers

**From where data/document is obtainable**

Zinat Mohammadi

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

Via E-mail

**Comments**