

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