

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of empowerment program on quality of life in adolescents with type 1 diabetes

Protocol summary

Study aim

Effect of an empowerment program on health _ related quality of life of type 1diabetic adolescents.

Design

This is a clinical trial study of N=54 adolescent with T1DM from karbala Iraq

Settings and conduct

This research will be done in 2 stage. Firstly, the adolescent empowerment package is collected based on the necessities mentioned in print and online sources. In the second stage, after obtaining permission from the ethics committee of the Mashhad University of Medical Sciences, sampling will be done in Imam Hussein (PUH) Hospital in Karbala via convenience method. Also assignment will be done randomly via simple random method. Demographic. Michigan Diabetes Knowledge Test and KIDSCREEN questionnaire will be used for data collection. Then the empowerment program for the intervention group will be implemented in groups of 6 to 8 people, and in 10 session, tree session per week. The control group will receive routine care. After 10 weeks of intervention and 4 weeks after completing intervention, the quality of life score will be measured and compared again in the tow group. Data analysis will be done using SPSS 16. To observe ethical points after completing intervention and data collection, this package will be implemented for volunerees of the control group.

Participants/Inclusion and exclusion criteria

Satisfaction with participation in the study Child age between 12_18 years Have a minimum literacy of parents and children. Do not suffer from complications of diabetes. Being a resident of Karbala.

Intervention groups

Intervention group: 12-18 years old teenagers that will receive empowerment program. Control group: 12-18 years old teenagers that will receive routine care

Main outcome variables

health _ related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053762N1**

Registration date: **2022-02-10, 1400/11/21**

Registration timing: **prospective**

Last update: **2022-02-10, 1400/11/21**

Update count: **0**

Registration date

2022-02-10, 1400/11/21

Registrant information

Name

Aramesh Rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

rezaeiana@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-22, 1400/12/03

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program on quality of life in adolescents with type 1 diabetes

2022-01-03, 1400/10/13

Ethics committee reference number
IR.MUMS.NURSE.REC.1400.075

Public title

Effect of empowerment on health _ related quality of life in type 1diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction with participation in the study Age between 12 and 18 years Minimum literacy in the child No complications of diabetes Stay in Karbala

Exclusion criteria:

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization in such a way that people with type 1 diabetes who are eligible to enter the study are selected and placed in the control and intervention group with a simple lottery.

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

Ethics Committee of Mashhad School of Nursing and Midwifery

Street address

Taghiabad Square, School of Nursing and Midwifery, Mashhad

City

Mashad

Province

Razavi Khorasan

Postal code

9177816009

Approval date

Health conditions studied

1

Description of health condition studied

type 1 diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Health Related Quality of Life

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

Kidscreen tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 12-18 years old teenagers that will receive empowerment program. Then the empowerment program for the intervention group will be implemented in groups of 10 to 15 people, and in 10 session, tree session per week. The adolescent empowerment package is collected based on the necessities mentioned in print and online sources. These dimensions are: 1- Theoretical nature of the disease, 2- Limited knowledge of acute complications, 3- How to prevent and deal with each of the acute complications, 4- Self-care in the field of insulin injection, 5- Activity self-care, 6- Nutritional self-care 7- Limited knowledge of long-term complications and prevention of long-term complications.

Category

Lifestyle

2

Description

Control group: Receive routine diabetes care

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital in Karbala, Iraq

Full name of responsible person

Aramesh Rezaian

Street address

No. 6, Delavaran Boulevard, mashhad town

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9177816559

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rezaeiana@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayyur Mobarhan

Street address

University Street, next to Hoveyze Cinema, Ghorashi Building, Deputy of Research and Technology

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Aramesh Rezaeian

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Latest degree

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable