

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of self-care education on anxiety, self-efficacy and depression in adolescents with diabetes

Protocol summary

Study aim

The effect of self-care education on anxiety, self-efficacy and depression in adolescents with diabetes

Design

Clinical trial with control and intervention group for 100 patients

Settings and conduct

Research environment Nephrology ward of Hazrat Ali Asghar Hospital Non-random assignment to intervention and control groups

Participants/Inclusion and exclusion criteria

Admission requirements: Definitive diagnosis of diabetes
Age 12 to 18 years Non-entry conditions: Non-cooperation of adolescents

Intervention groups

Intervention group: includes 4 sessions that are held once a week (4 weeks). Each session lasts 60 minutes. The afternoon intervention is performed from 2 to 6 pm in order to prevent interference in the program in the adolescent school classes. Meetings were held in groups of 4-6 participants. Training is done through lectures (using PowerPoint), questions and answers, group discussions and role plays. Session 1: Teaching adolescents about the nature of diabetes, prognosis, complications of diabetes. The second session includes teaching methods of disease control and the importance of appropriate daily activities and medication and their side effects. The third session includes training in diet and exercise activities and controlling the complications of diabetes and the correct method of insulin injection and daily blood sugar control. Session 4 Reviewing the contents of past sessions and increasing self-confidence in performing self-care. In the control group, routine care is performed.

Main outcome variables

Anxiety, self-efficacy and depression

General information

Reason for update

Acronym

دیابت

IRCT registration information

IRCT registration number: **IRCT20141216020344N9**

Registration date: **2022-03-05, 1400/12/14**

Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**

Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education on anxiety, self-efficacy and depression in adolescents with diabetes

Public title

The effect of self-care education on anxiety, self-efficacy and depression

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 12 to 18 years Definitive diagnosis of diabetes

Exclusion criteria:

Lack of cooperation of adolescents

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.IUMS.REC.1400.1019

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and immediately after intervention and one month after intervention

Method of measurement

Beck Anxiety Questionnaire

2

Description

Self-efficacy

Timepoint

Before intervention and immediately after intervention and one month after intervention

Method of measurement

General self-efficacy questionnaire

3

Description

Depression

Timepoint

Before intervention and immediately after intervention and one month after intervention

Method of measurement

Beck Depression Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes 4 sessions that are held once a week (4 weeks). Each session lasts 60 minutes. The afternoon intervention is performed from 2 to 6 pm in order to prevent interference in the program in the adolescent school classes. Meetings were held in groups of 4-6 participants. Training is done through lectures (using PowerPoint), questions and answers, group discussions and role plays. Session 1: Teaching adolescents about the nature of diabetes, prognosis, complications of diabetes. The second session includes

teaching methods of disease control and the importance of appropriate daily activities and medication and their side effects. The third session includes training in diet and exercise activities and controlling the complications of diabetes and the correct method of insulin injection and daily blood sugar control. Session 4 Reviewing the contents of past sessions and increasing self-confidence in performing self-care

Category

N/A

2

Description

Control group: In the control group, routine care is performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital in Tehran

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 912 622 3904

Email

khoshnezhad.hr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hossein Keyvani

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۹۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

admins@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2045

Email

khoshnezhad.hr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

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Latest degree

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

Yes - There is a plan to make this available

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

Yes - There is 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

Data is encrypted in order to make the identity of
individuals unidentifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr Hamidreza Khoshnezhad Ebrahimi Email
address:khoshnezhad.hr@iums.ac.ir

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

After submitting the application via academic email, we
will provide the information files to the individuals within
a maximum of one week.

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

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

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Latest degree

Specialist

Other areas of specialty/work

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