

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of educational program to improving health literacy based on Bandura's learning-cognitive theory on self-efficacy and social anxiety in adolescents with type 1 diabetes.

Protocol summary

Study aim

Determining the effect of health literacy promotion training program based on Bandura social-learning theory on self-efficacy and social anxiety of adolescents with type 1 diabetes

Design

The present quasi-experimental study with intervention and control group, without blinding, randomized on 60 adolescents with type 1 diabetes, was performed using the Rand function of Excel software.

Settings and conduct

The present study is a quasi-experimental study. It has two groups of intervention and control. Adolescents with inclusion criteria were admitted to the endocrine clinic of the Children's Medical Center and the endocrine clinic of the Mofid Children's Hospital. Oral and written consent was obtained from the adolescent and their parents. Before the start of the training sessions, the pre-test was completed by the researcher in the form of a telephone interview. After the necessary coordination, the trainings were held in the form of games and virtually. One month later, the post-test was completed by telephone by the researcher.

Participants/Inclusion and exclusion criteria

- Admission criteria: Age range 15-18years Willingness to participate in the study Native to Tehran Literate Ability to talk and communicate - Exclusion criteria: Passing the Diabetes Health Literacy course Acute and debilitating complications of the disease Having a mental illness

Intervention groups

Intervention group: During 4 training sessions of 60 to 90 minutes, a health literacy promotion program based on social learning theory will be implemented. - Control group: In this group, no intervention will be done.

Main outcome variables

Health literacy in diabetes; Social anxiety; Self-efficacy; The incidence of complications of diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210422051045N1**

Registration date: **2022-01-28, 1400/11/08**

Registration timing: **retrospective**

Last update: **2022-01-28, 1400/11/08**

Update count: **0**

Registration date

2022-01-28, 1400/11/08

Registrant information

Name

vida Rahimi hassanabad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8822 3165

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of educational program to improving health literacy based on Bandura's learning-cognitive theory on self-efficacy and social anxiety in adolescents with type 1 diabetes.

Public title

Investigating the effect of improving diabetes health literacy on self-efficacy and social anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 15-18 years Willingness to participate in the study Confirmation of type 1 diabetes by an endocrinologist Literate Has the ability to talk and communicate Native to Tehran

Exclusion criteria:

Acute and debilitating complications of the disease Having a chronic illness other than diabetes Having a mental illness

Age

From **15 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. In this method, the name of each of the adolescents with type 1 diabetes in each group is poured into a ball separately, and finally the members of each group are determined completely randomly.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, health literacy constructs based on the Bandura's social learning theory will be taught.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

School of Nursing and Midwifery Tehran University of Medical Sciences, Mirkhani Street, Tohid square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-05-27, 1399/03/07

Ethics committee reference number

IR.TUMS.FNM.REC.1399.038

Health conditions studied

1

Description of health condition studied

Type 1 Diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Health literacy score in the health literacy questionnaire of adolescents with diabetes

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Health Literacy Questionnaire for Adolescents with Diabetes

2

Description

Functional self-efficacy score in the Diabetes Functional Self-efficacy Questionnaire

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Functional self-efficacy questionnaire in diabetes

3

Description

Social Anxiety Score in Paklak Adolescent Social Anxiety Questionnaire

Timepoint

Before the intervention, one month after the intervention

Method of measurement

Paklak Social Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

<https://mch.sbmu.ac.ir/>

1

Description

Intervention group: Intervention group: The present study is a quasi-experimental study and has an intervention group of 30 adolescents with type 1 diabetes who meet the inclusion criteria. The content of the training, scenarios and games designed by 10 professors, psychologists and pediatric endocrinologists and subspecialists will be validated using authoritative scientific sources and during 4 consecutive training sessions for 4 days for 60 to 90 minutes using Learning methods of lectures, questions and answers, role play, games, use of pictures and educational clips (based on Bandura's social learning theory) will be held completely virtually through Skyroom. The first to fourth sessions will be related to nutrition, exercise, insulin therapy, blood sugar self-monitoring and follow-up, respectively.

Category

Behavior

2

Description

Control group: The present study is a quasi-experimental study and has a control group of 30 adolescents with type 1 diabetes who meet the inclusion criteria. Before performing the intervention, a pre-test was taken from the control group at the same time as the intervention group. There was no intervention in this group. One month after the intervention in the intervention group, a post-test was taken from this group at the same time as the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid pediatric endocrinology and diabetes clinic

Full name of responsible person

Dr. Hedieh Saneifard

Street address

Mofid Children's Hospital, Dr. Ali Shariati St.

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Tehran

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15514- 15468

Phone

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Web page address

2

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Dr. Aria Sotoudeh

Street address

No. 62, Children's Medical Center Hospital, Dr. Gharib St., at the end of Keshavarz Boulevard

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Geranmayeh

Street address

No. 62, School of Nursing and Midwifery, Tehran University of Medical Sciences, Mirkhani St., Tohid Sq

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Email

fnm-researchdeputy@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Vida Rahimi hassanabad

Position

Master of pediatric nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/documentAfter identifying the individuals, the overall results will
be published in a file format.**When the data will become available and for how long**Access period starts 6 months after the results are
published**To whom data/document is available**

Research subjects and research team

Under which criteria data/document could be usedNo other analysis is allowed by people other than the
research team.**From where data/document is obtainable**Contact with project manager: Vida Rahimi Hassanabad
09229832590**What processes are involved for a request to access data/document**

Have a study permit

Comments

