

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Developing and evaluating of an educational intervention based on social cognitive theory in promoting self-care behaviors in type 1 diabetes adolescents

Protocol summary

Study aim

Determining the effect of educational intervention based on the aspects of social cognitive theory in promoting self-care behaviors in adolescents with type 1 diabetes in Isfahan

Design

The clinical trial has two groups of 40 intervention and control groups, with parallel groups, randomized

Settings and conduct

This study was performed on 80 adolescents with type 1 diabetes who regularly visit Isfahan Endocrine and Metabolism Center. They were divided into two intervention and control groups and each group was divided into 40 cases. The questionnaires will be completed before the intervention by the samples and only the intervention group will receive the training

Participants/Inclusion and exclusion criteria

Sample entry: Samples must be resident in Isfahan and have a willingness to participate in the study. Exit Samples: People with certain diseases are excluded from the study.

Intervention groups

The intervention group will participate in four training sessions based on social cognitive theory in order to improve their health care behavior and then will receive virtual training for 3 months and patients in the control group only received routine services in the diabetes clinic and did not undergo an educational intervention

Main outcome variables

Self-efficacy, Self-care, Self-regulation, Expecting Outcome, Social Support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190113042341N1**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **retrospective**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

Registration date

2019-04-11, 1398/01/22

Registrant information

Name

Elham Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3242 3792

Email address

elhammolavi96@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing and evaluating of an educational intervention based on social cognitive theory in promoting self-care behaviors in type 1 diabetes adolescents

Public title

Impact of educational intervention on the promotion of juvenile behaviors infected with type 1 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Isfahan resident Have type 1 diabetes Age is 19-10 years old Inclination to participate in the study (informed consent)

Exclusion criteria:

The disease that affects the research Any conditions that the researcher feels will interfere with the participation of individuals or the evaluation of the results.

Age

From **10 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the available cases , randomly, the files of people who routinely visit the center are selected and contacted, and if they wish, they would collaborate with the researcher, and then cases will be divided into two groups include test and control groups.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hazer Jerib Street, Isfahan, Iran

City

Isfahan

Province

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Postal code

8174673461

Approval date

2018-02-27, 1396/12/08

Ethics committee reference number

IR.MUI.REC.1396.3.868

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**

Self-efficacy score in self-care behavior

Timepoint

Before intervention, directly after intervention, 3 months after intervention

Method of measurement

Questionnaire

2**Description**

Self-regulation score in self-care behavior

Timepoint

Before intervention, directly after intervention, 3 months after intervention

Method of measurement

Questionnaire

3**Description**

The score of social support perceived in self-care behavior

Timepoint

Before intervention, directly after intervention, 3 months after intervention

Method of measurement

Questionnaire

4**Description**

Expected outcome score in self-care behavior

Timepoint

Before intervention, directly after intervention, 3 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

" Intervention group: " Participants will attend in 4 educational session for about 60-minute and then, to promote socially perceived social support, the group will be divided into 5 groups of 8 people and each person will be considered as a peer in each group. That these people should follow their group for 3 months and provide self-care. The purpose of these sessions is to educate participants on how to conduct positive and negative behaviors, whether or not to behave self-care, stress control, and stress management methods.

Category

Behavior

2

Description

"Control group:" Patients in the control group only received routine services in the diabetes clinic and did not undergo an educational intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Center of Isfahan University of Medical Sciences

Full name of responsible person

Ahmadali Islami

Street address

Isfahan Endocrine and Metabolism Research Center, Sedigheh Tahereh Medical Research Complex, Khorram Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Isfahan University of Medical Sciences, Hazer Jerib Street, Isfahan, Iran

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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

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

Elham Molavi Vardanjani

Position

MSc student of Health Education

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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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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Position

PhD of Health Education, Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

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Full name of responsible person

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

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

Data Dictionary

No - There is not a plan to make this available