

# 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**

Isfahan

**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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3244

##### Email

Eslami@hlth.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

##### Street address

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

##### City

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##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### Email

sh\_haghjoo@med.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

Elham Molavi Vardanjani

##### Position

MSc student of Health Education

##### Latest degree

Bachelor

##### Other areas of specialty/work

Health Promotion

##### Street address

School of Health, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, Iran

##### City

Isfahan

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##### Email

Elhammolavi96@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ahmadali Eslami

**Position**

PhD of Health Education, Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**Person responsible for updating data****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**

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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