

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Development and Psychometrics of a tool for measurement of Knowledge, Attitude and Preventive Behaviors of Type 2 Diabetes among Adolescents and its Application in an Interventional Study Using Peer Education

Protocol summary

Study aim

Determining the effect of peer education on knowledge, attitude and preventive behaviors related to type 2 diabetes among Adolescents of Tehran City

Design

This study has an intervention and control group that are randomly selected. Randomization is based on the list of schools and the list of students of selected schools.

Settings and conduct

After the necessary coordination, first the city of Tehran is divided into 5 parts according to the geographical map (northeast, southeast, center, northwest and southwest) and a municipal region is selected from each part, then refer to the education of the region. The list of high schools of the first period is prepared and according to the list of schools, a girls 'school and a boys' school are randomly selected (10 schools in total) and in each school from each grade based on the sample size and the share allocated to that school, knowledge Students will enter the study randomly based on the inclusion criteria. The questionnaires that were designed and psychometric in the first stage will be used in this stage to collect information and perform the intervention. .

Based on the educational needs assessment of the target group, educational content is provided for them (definition of type 2 diabetes, causes and modifiable causes of type 2 diabetes, symptoms and complications, and ways to prevent type 2 diabetes). In this study, the peer method will be used for the intervention.

Participants/Inclusion and exclusion criteria

Inclusion requirements: Students studying in the first year of high school, students' willingness to participate in the study, Exclusion requirements: People with type 1 and 2 diabetes

Intervention groups

In this study, we have two groups: intervention group

and control group. The intervention group received education in type 2 diabetes

Main outcome variables

Preventive behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048361N1**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Ameneh Pooresmaeilidorosteh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5614 6580

Email address

am.pooresmaeili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Development and Psychometrics of a tool for measurement of Knowledge, Attitude and Preventive Behaviors of Type 2 Diabetes among Adolescents and its Application in an Interventional Study Using Peer Education

Public title
"The effect of peer education on knowledge, attitude and preventive behaviors related to type 2 diabetes among Adolescents of Tehran City"

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
High school students studying in the first period The willingness of students to participate in study Lack of diabetes, type one and two
Exclusion criteria:
People with type 1 diabetes and type 2 diabetes

Age
From **13 years** old to **15 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method in the first stage of the study (psychometrics) is multi-stage sampling. First, the city of Tehran is divided into 5 parts (northeast, southeast, center, northwest and southwest) according to the geographical map, and a municipal district is selected from each part, then a list of high schools for the first period is prepared. According to the list of schools, a school for girls and a school for boys are randomly selected (a total of 10 schools) and in each school from each grade based on the sample size and the share allocated to that school, students according to the inclusion criteria, will enter the study randomly. Sampling of the second part of the study (intervention): From the selected areas for sampling the psychometric section of an area was randomly selected and 4 schools were selected from girls' schools and these 4 schools were randomly assigned to the intervention and control group. Will be given (2 schools in the intervention group and 2 schools in the control group). The choice of schools will be such that the intervention group is geographically far enough from the control group so as not to interfere

with education.

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 Shahid Beheshti University of Medical Sciences
Street address
No. 12, Shahid Sebghati Alley, Salman Farsi Ave., Islamshahr
City
Islamshahr
Province
Tehran
Postal code
33139-37897

Approval date
2020-01-04, 1398/10/14

Ethics committee reference number
IR.SBMU.PHNS.REC.1398.146

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Awareness scores obtained after the test

Timepoint
At the beginning of the study (before the intervention) and 2 months after the intervention

Method of measurement
questionnaire

2

Description

Attitude scores obtained after the test

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention

Method of measurement

questionnaire

3

Description

Behavior scores obtained after the test

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Preventive behaviors

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: In this study, the educational intervention process will begin in a peer-to-peer manner by selecting a group of teaching peers. 12 students will be selected as peer educators. Selected peers, in 8 sessions of 1.5 hours with educational content including the areas mentioned in the questionnaire (definition of type 2 diabetes, causes and modifiable causes of type 2 diabetes, complications and ways to prevent type 2 diabetes) Will find. The trainings will be done to the peer group through lectures and questions and answers, using educational aids such as whiteboards and booklets. Then the training to the intervention group is started by the teaching peers for 2 months in eight sessions and each session lasts for 30 minutes. The method of providing trainings to the intervention group by peers is mainly through lectures, questions and answers, group discussions, installation of educational tracts containing health messages in public places of the school and inserting health messages on the blackboard of the classroom before the teachers arrive.

Category

Prevention

2

Description

Control group: While studying, the control group does not receive educational intervention. At the end of the work,

educational intervention will be presented to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected schools in Tehran

Full name of responsible person

Ameneh pooresmaeildorosteh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarqi

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No. 2660, Valiasr Ave., Shahid Beheshti School of Pharmacy, Tehran

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zarghi@sbmu.ac.ir

Web page address

<https://fa.irct.ir/user/trial/50221/update/sponsor>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
PhD student in health education and health promotion
Latest degree
Master
Other areas of specialty/work
Health Promotion
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Person responsible for updating data

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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

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

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

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

Data Dictionary

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