Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of peer education on self-care behaviors and mean of glycosylated hemoglobin in 12-18 year old adolescents with type 1 diabetes referring to Imam Reza(AS) Clinic in Shiraz, 2018

Protocol summary

Study aim

1- Determination and comparison of the mean score of self-care behaviors in the intervention and control groups before and 3 months after the intervention. 2- Comparison of mean score of self-care behaviors between two intervention and control groups before and 3 months after intervention 3- Determination and comparison of the mean of glycosylated hemoglobin in the intervention and control groups before and 3 months after the intervention. 4. Comparison of the mean of glycosylated hemoglobin between the two intervention and control groups before and 3 months after the intervention

Design

The clinical trial has a community-based, practice-oriented control group, with parallel groups, randomized, Random allocation of the samples in the intervention and control groups using the permutation block method

Settings and conduct

Referring to Imam Reza (AS) Clinic of Diabetes Shiraz, a simple, purposeful sampling among adolescents with type 1 diabetes who are eligible to enter the study

Participants/Inclusion and exclusion criteria

Entry Requirements: 1- Age 18-12 years 2- Confirmation of Type 1 Diabetes by a Specialist 3. Not having physical restrictions on self-care 4.Glycosylated hemoglobin levels greater than 7.5% 5- Having a medical record in the diabetes clinic 6. The history of diabetes for more than a year 7. Satisfaction of adolescents and their parents to participate in the study Exit terms: 1. Unwillingness to continue participating in the study 2.Having mental illness prevents learning 3.Taking effective medications for learning and alertness 4. Case of other chronic diseases

Intervention groups

Four 90-minute class sessions organized by peers for the intervention group. while the control group receives routine training (educated by the clinic staff).

Main outcome variables

Mean of self-care behaviors ,Mean of glycosylated hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180904040944N1**
Registration date: **2018-10-06, 1397/07/14**
Registration timing: **prospective**

Last update: **2018-10-06, 1397/07/14**
Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Afsaneh Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4341 6127

Email address

stud2420430530@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-26, 1397/08/04

Expected recruitment end date

2018-11-15, 1397/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer education on self-care behaviors and mean of glycosylated hemoglobin in 12-18 year old adolescents with type 1 diabetes referring to Imam Reza(AS) Clinic in Shiraz, 2018

Public title

Effect of peer education on self-care behaviors and mean of glycosylated hemoglobin in adolscents with type 1 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-12 years Confirmation of type 1 diabetes by specialist physician Not having physical restrictions on self-care Glycosylated hemoglobin levels greater than 7.5% Having a medical record in a diabetes clinic The history of diabetes for more than a year Satisfaction of adolescents and their parents to participate in the study

Exclusion criteria:

Unwillingness to continue participating in the study Having mental illness prevents learning Taking effective medications for learning and alertness Cases of other chronic diseases

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: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign the samples in the intervention and control groups, the permutation block method will be used and the randomization list will be based on randomization and random allocation and will be provided by the software for the two groups A and B, and the block sizes are quadruple and the numbers 1 and 6 will be reversed. Different will be assigned. 1.AABB 2.ABAB 3.ABBA 4.BBAA 5.BABA 6.BAAB

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 Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Avenue, Shiraz

City

Shiraz

Province

Fars

Postal code

713451978

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.SUMS.REC.1397.324

Health conditions studied

1

Description of health condition studied

Diabete

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

mean of glycosylated hemoglobin

Timepoint

At the beginning of the study and three months after the study

Method of measurement

The method of measuring glycosylated hemoglobin in this study is a calorimetric method using a Dirui auto-analyzer, which is calibrated daily.

2

Description

Mean score of self-care behaviors

Timepoint

At the beginning of the study and three months after the study

Method of measurement

Self-care questionnaire in adolescents with type 1 diabetes

Secondary outcomes

empty

Intervention groups

1

Description
After dividing the intervention group into 6 groups of 8, and assigning peers, each peer intervention group will be assigned a random number table. Peer-to-peer patients will be trained by their group on a weekly basis over 4 90-minute sessions. Face-to-face meetings will be grouped with questions and answers.
Category
Behavior

2

Description
Control group: The control group received routine training (training by the clinical staff).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (AS) Clinic of diabetes in Shiraz
Full name of responsible person
Rezaie Attar
Street address
Namazi Square, Zand Avenue, Shiraz
City
شیرلز
Province
Fars
Postal code
7134814734
Phone
+98 71 3231 9362
Email
bonyaddiabet.az13@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyyed Basir Hashmi
Street address
Central Building of Shiraz University of Medical Sciences, Zand Avenue, Shiraz
City
Shiraz
Province
Fars
Postal code
713451978
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mitra Edraki
Position
Structor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
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Person responsible for updating data

Contact
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Position
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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
Only part of the information, such as information on the main outcome or the like, can be shared.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions, people working in the industry
Under which criteria data/document could be used
Any copying is grateful. Observance of the principles of compilation is obligatory.
From where data/document is obtainable
Referring to the academic staff member, Ms. Mitra Edraki address to School of Nursing Midwifery, University of Medical Sciences Shiraz, Namazi Square, Zand Avenue, Shiraz Contact with Academic Officer Mrs. Mitra Edraki contact person: 0098 9177008428 By email: edrakim@sums.ac.ir
What processes are involved for a request to access data/document
Applicants requesting the use of documents and data files can be contacted by email or by contact or by referring to the academic officer. The listing of the hive can be obtained by email in PDF format five days after the application is submitted.
Comments