

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness of Peer-led and Family-based Education on Self-Care in Diabetic Adolescents

Protocol summary

Study aim

Comparison of the Effectiveness of Peer-led and Family-based Education on Self-Care in Diabetic Adolescents

Design

Classified block randomization, not blinded, sham controlled clinical trial with three groups (family, peer and control) design of 180 diabetic adolescent, enrolled and followed for three months. This study will be conducted at Diabetes clinic in Children's Medical Center and Iranian Diabetes Society in Tehran. All parents and all diabetic adolescents in the two centers will not have any contact together.

Settings and conduct

This study will be conducted at Diabetes clinic in Children's Medical Center and Iranian Diabetes Society in Tehran. First, the conditions for entering the study will be explained for the patient clearly and, if desired, the informed consent form will be completed. This study will be done as not blinded study. To hide the intervention group, the type of intervention will be written on a sheet of paper and will be inserted into opaque and consecutively-numbered envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 12-16 years; Being diabetic type1; Diabetic diagnosis at least for past 1 year; having an active parent Exclusion criteria: The absence of both adolescence and parent in educational class; hospitalization; incidence of Ketoacidosis or diabetic coma during the study period; having hemoglobinopathy, anemia, reticulocytosis and uremia during study

Intervention groups

Intervention group1: (Family education): conducting Six Family educational sessions by the researcher (for 4 groups of 15) with a one-week interval Intervention group2: (Education through peer): conducting Six educational sessions (with a one-week interval) by a peer participant for 4 groups of 15 Diabetic Adolescents Control group: will not receive any interventions Main

Main outcome variables

Self care behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140604017972N13**

Registration date: **2018-06-19, 1397/03/29**

Registration timing: **retrospective**

Last update: **2018-06-19, 1397/03/29**

Update count: **0**

Registration date

2018-06-19, 1397/03/29

Registrant information

Name

Zahra Godarzi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4407

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Peer-led and Family-based Education on Self-Care in Diabetic Adolescents

Public title

Effect of Education by Family and Peer on Self-Care in Diabetic Adolescents

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 12-16 years Being diabetic type 1 Diabetic diagnosis at least for past 1 year Signed the informed consent form Ability to read and write Being single Having an active parent Does not have other medical history

Exclusion criteria:

The absence of both adolescence and parent in educational class Hospitalization during the Study Incidence of Ketoacidosis or diabetic coma during the study period Membership one of a family member in the health team The occurrence of a critical event in the family. Having hemoglobinopathy, anemia, reticulocytosis and uremia during study Unwillingness to continue the study Not fully participating in the conducted sessions for both groups

Age

From **12 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Actual sample size reached: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the classified block randomization will be used. According to the sample size of 180, 30 blocks will be produced using the online site (www.sealedenvelope.com). Then, to hide the intervention group, the type of intervention (peer-led group, family based group, control group) will be written on a sheet of paper and will be inserted into opaque and consecutively-numbered envelopes. Randomizing at the individual level.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

Ethics Committee School of Nursing and Midwifery, Tehran Medical Sciences

Secondary trial Id

IR.TUMS.FNM.REC.1396.2176

Registration date

2017-04-30, 1396/02/10

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, eastern Nosrat St, Tohid square, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-05-01, 1396/02/11

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2176

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Self care behavior

Timepoint

before intervention and 3 months after

Method of measurement

self-care behaviors (SMOD-A) questionnaire

Secondary outcomes

1

Description

HBA1C

Timepoint

before intervention and 3 months after intervention

Method of measurement

Hemotology test by spectrofotometr

Intervention groups

1

Description

Intervention group1: Family education: in the family education group, patient accompanied will receive 6 sessions 120 minutes training.

Category

Lifestyle

2

Description

Intervention group2: Education through peer:In the peer education group, 4 patients will be selected as the peer group leader.The peer group is divided into four groups, and each of these four individuals is randomly assigned to a group of 15 people.Then, with the collaboration of the peer group, the training sessions will be held for intervention groups in 6 sessions of 120 minutes

Category

Lifestyle

3

Description

Control group: receiving no educational intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic in Children's Medical Center

Full name of responsible person

Neda Salimi

Street address

No. 62, Keshavarz Blvd., Street doctor Mohammad Gharib., Children's Medical Center.,Tehran

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2

Recruitment center

Name of recruitment center

Iranian Diabetes Society (IDS)

Full name of responsible person

Neda Salimy

Street address

No. 27, Ramin Malakooti Street., Patris Lomumba-Satarkhan Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

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

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

Tehran University of Medical Sciences

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Position

Master of Pediatric Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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Province

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Postal code

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Phone**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