Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of peer education compared to Common Education on the children's blood glucose management and self-efficacy of mothers having preschool children with type 1 diabetes

Protocol summary

Study aim

Determining the effect of peer education on blood sugar management and self-efficacy of mothers with a young child with type 1 diabetes

Design

The clinical trial has a control group, with parallel groups, without blinding, Random allocation has been used for randomization.

Settings and conduct

The study site is the Diabetes Clinic of Imam Hussein Hospital in Isfahan; The study population is mothers having a young child with type 1 diabetes; There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetes diagnosis is definitely by a pediatric endocrinologist; the Child is in the age range of 3 to 6 years; absence of an evolutionary disorder or other chronic illnesses in child; The ability to read and write by parents; Passing at least three days and a maximum of one month of diagnosis of diabetes; not participation of parents in other educational programs related to child care with diabetes; Parents' awareness of child's type 1 diabetes. Non-inclusion criteria: Involvement of parents in other processes that require child care, such as hospitalization of the child or parent; The parents' discontent to participate in the study

Intervention groups

Control group: receiving routine training. Intervention group 1: receiving education from a peer who has a child with type 1 diabetes. Intervention group 2: receiving education from a peer with type 1 diabetes.

Main outcome variables

Child's Blood Glucose Management Score; Mother's Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200207046403N2**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name

Fatemeh Joonbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-09, 1402/03/19

Expected recruitment end date

2023-10-11, 1402/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of peer education compared to Common Education on the children's blood glucose management and self-efficacy of mothers having preschool children with type 1 diabetes

Public title
Investigating the effect of peer education on blood glucose management and self-efficacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Definite diabetes diagnosis by a pediatric endocrinologist Being the Child in the age range of 3 to 6 years Absence of an evolutionary disorder or other chronic illnesses in child The ability to read and write by parents Passing at least three days and a maximum of one month of diagnosis of diabetes Not participation of parents in other educational programs related to child care with diabetes Parents' awareness of child's disease (type 1 diabetes)

Exclusion criteria:
Parents are involved in other processes that require child care, such as hospitalization of the child or parent The parents' discontent to participate in the study

Age
From **21 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a simple random sampling method: In this way, a number will be assigned to all the names of the people in the prepared list. The number assigned to each person is written on a piece of paper. All the sheets are mixed together in a container. The first number that is randomly selected from all the numbers will be placed in the control group and the next numbers will be placed is in the peer group with a child with diabetes and the peer group with diabetes, respectively.

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 Faculty of Nursing, Management and Rehabilitation, Isfahan University of Medical

Street address
Hazar Jarib St., Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

City
Isfahan

Province
Isfehan

Postal code
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Approval date
2023-05-22, 1402/03/01

Ethics committee reference number
IR.MUI.NUREMA.REC.1402.027

Health conditions studied

1

Description of health condition studied
diabetes

ICD-10 code
E10.9

ICD-10 code description
Type 1 diabetes mellitus without complications

Primary outcomes

1

Description
Self-efficacy score based on researcher-made questionnaire

Timepoint
At the beginning of the study, one and three months after the intervention

Method of measurement
Self-efficacy questionnaire developed by the researcher

2

Description
The blood sugar management score is based on the researcher's checklist

Timepoint
At the beginning of the study, one and three months after the intervention

Method of measurement
Checklist made by the researcher

3

Description
HBA1C value based on experiment

Timepoint

Before starting the intervention and three months after the intervention

Method of measurement

Using the A1C Clover device

Secondary outcomes

empty

Intervention groups

1

Description

Control Group receives the usual hospital training which is held by a diabetes education expert. Research samples in the control group in accordance with the routine of the hospital will visit on Tuesday for training, which includes a 4 -hour session with titles: diabetes, blood glucose control method, insulin injection, and dietary control necessities, the methods of control the complications of the disease. All mothers participating in this group are added to one of the virtual messengers formed by the hospital education expert to keep in mind the conditions of the child and the mother and the lack of child or parent diseases.

Category

Other

2

Description

Intervention group 1: The recipient of the training by the parent with a child with type 1 diabetes. The second number that is randomly taken out from the numbers inside the container is placed in the second intervention group. They come to class on Monday to avoid leakage of information. When parents come to the clinic, written consent is obtained from the parent at first. Then they participate in the classes held by a peer who has a child with type 1 diabetes who met the criteria for entering the study as a peer educator (having a young child with type 1 diabetes; having a diploma or higher; Iranian and resident of Isfahan; ability to conduct meetings and provide training; having the ability and interest in group training). The peer educator will also receive training from the research team (Three two-hour sessions including the definition of the peer and the purpose of doing the work - the principles of diabetes education, answering the questions of the peers - expressing the peer's experiences in each case, checking the ability to practically do each case). In addition, she/he must get a higher score according to the questionnaire of peer coaches made by the researcher, the opinion of the endocrinologist and based on the evidence in the documents such as the results of the tests and periodical examinations of the diabetes specialist in terms of the occurrence of diabetes complications and keeping the child's blood sugar within the normal range and being successful in managing the disease. The second group receives training provided by the peer who has a child with type 1 diabetes which will be held in three two-hour sessions, including the blood sugar check method, insulin injection, diet, disease complications, the practical implementation of the above things and the experiences of peer trainers in each of the above cases. The researcher will be present in all the meetings in order to provide the possibility of holding and monitoring the implementation of the meetings. Also, if this research method is effective for the intervention groups, after the completion of the study, meetings with the same method will be held for the control group. All mothers participating in this group are added to one of the virtual messengers formed by the peer educator who has a young diabetic child to follow up the conditions of the child and the mother.

Category

Other

3

Description

Intervention group 2: The recipient of education by a peer suffering from type 1 diabetes. The third number that is randomly taken from the numbers inside the container is placed in the third intervention group. They visit on Wednesdays to prevent information leakage. At the time of referral, a written consent obtained from the parent first, then participate In the classes held by a peer has type 1 diabetes who met the criteria for entering the study as a peer educator (having type 1 diabetes; having a diploma or higher; Iranian and resident of Isfahan; Ability to conduct meetings and provide training; Having the ability and interest in group training) She has also received training from the research team(Three two-hour sessions including the definition of the peer and the purpose of doing the work - the principles of diabetes education, answering the questions of the peers - expressing the peer's experiences in each case, checking the ability to practically do each case) and According to the questionnaire of peer coaches made by the researcher, they got a higher score Also, according to the opinion of the endocrinologist and based on the evidence in the file, such as: the results of the tests and periodical examinations of the diabetes specialist in terms of the occurrence of diabetes complications and keeping their child's blood sugar within the normal range, they have been successful in managing the disease. The third group receives training provided by a peer who has type 1 diabetes these trainings are held in three two-hour sessions, including the blood sugar check method, insulin injection, diet, disease complications, the practical implementation of the above, and the experiences of peer trainers in each of the above cases. The researcher will be present in all the meetings in order to provide the possibility of holding and monitoring the implementation of the meetings. Also, if this research is effective for the intervention groups, after the completion of the study, meetings with the same method will be held for the control group. All mothers participating in this group are added to one of the virtual messengers formed by the peer educator who had type 1 diabetes to keep in mind the conditions of the child and the mother and the lack of child or parent diseases.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Emam Hossein specialized pediatrics hospital

Full name of responsible person
Fatemeh Joonbakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Fatemeh Joonbakhsh

Position
faculty member

Latest degree
Master

Other areas of specialty/work
Pediatrics

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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
Total individual data after de-identification and parental self-efficacy and glycemic management data
When the data will become available and for how long
The start of the 6-month access period after the results are published
To whom data/document is available
Researchers working in scientific institutions
Under which criteria data/document could be used
There are no special conditions
From where data/document is obtainable
Email to this email address f.joonbakhsh@nm.mui.ac.ir
What processes are involved for a request to access data/document
First, she/he sends the request email and after checking the request, the answer and data will be provided to her/him
Comments