

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigation of the Effect of an Empowerment Program on Mothers' Knowledge and Metabolic Control of Pre-school Children with type 1 Diabetes

Protocol summary

Increasing the knowledge of mothers about diabetes
Better metabolic control in preschool children

Study aim

Determination of the effect of empowerment program on Mothers' Knowledge And metabolic control of preschool children with type 1 diabetes

Design

Clinical trial without control group Community based and pragmatic With a single-party design, , randomized strain

Settings and conduct

This is a semi-experimental study contains a single-group pretest-post test plan. The purpose is to empower mothers who have pre-school children with type 1 diabetes. It will be held on five sessions in the classroom of hospital, for investigation the effect of program on mothers knowledge and the metabolic control of their children.

Participants/Inclusion and exclusion criteria

Inclusion criteria for mothers: 1. Mothers who have pre-school children with type -1 diabetes, according to their physician's diagnosis 2. There is no chronic illness other than diabetes, in pre-school children (according to the medical records). 3. Minimum abilities of mothers in reading and writing skills. 4. Non-participation of mothers in similar training courses. 5. There is no other children with chronic disease in the family. Inclusion criteria for children : 1. Pre-school children who have diabetes with range of 3 to 6 years old. 2. There is no chronic disease other than type 1 diabetes Based on medical reports on their case. 3-At least one month has passed since the children had been diagnosed with diabetes Exclusion criteria: 1.Cancellation of samples for continuing the study. 2. Hospitalization of children. 3. More than one absence of mothers in session.

Intervention groups

Mothers who have pre-school children with type 1 diabetes

Main outcome variables

Increasing the sense of empowerment of mothers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039196N1**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **prospective**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

Name

Maryam Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the Effect of an Empowerment Program on Mothers' Knowledge and Metabolic Control of Pre-school Children with type I Diabetes

Public title
The Impact of Empowerment Program on Children's Diabetes Control

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Mothers Entry Criteria Mothers of preschool children with type 1 diabetes according to their physician's diagnosis Having at least reading and writing skills in mothers Child entry criteria: Preschool children with diabetes aged 3 to 6 years old At least one month from the onset of diabetes.
Exclusion criteria:
Cases of any chronic disease other than diabetes in preschool children (according to medical records) Mother companies participate in similar training courses There is another child in the family with chronic disease

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **33**
More than 1 sample in each individual
Number of samples in each individual: **2**
Measurement of knowledge in mothers once before intervention and once immediately after intervention and 3 months after intervention and in children with diabetes, HbA1c levels were measured before and after intervention.measured before and after intervention.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of medical science

Street address

Hemat Highway, University of Iran

City

Tehran

Province

Tehran

Postal code

12458769

Approval date

2018-02-04, 1396/11/15

Ethics committee reference number

IR.IUMS.FMD.REC1396.9311687008

Health conditions studied

1

Description of health condition studied

Dont have

ICD-10 code

ندارد

ICD-10 code description

ندارد

Primary outcomes

1

Description

HbA1C levels in preschool children with type 1 diabetes, measured by HbA1C.

Timepoint

Before intervention and 3 months after intervention.

Method of measurement

It will be done with an experienced person in the lab of hospital by measuring level of HBA1C taking venous blood as a sample and using a Nakokard device (calibrated)

2

Description

Measuring diabetic knowledge of mothers of preschool children with type 1 diabetes

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Through Michigan Knowledge Assessment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A five-session empowerment program will be held in a lecture-lesson for mothers with preschool children with diabetes to measure the effect of this program on raising the knowledge of mothers and as a result of metabolic control in their children.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods Children's Hospital

Full name of responsible person

Maryam Mansory

Street address

Valiasr St., Ghods Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

morteza naserbakht

Street address

Hemmat Highway Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

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PR@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Mansory

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After completing the plan, the result of this study and the outcome of the study will be discussed publicly

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Use the results of this research

From where data/document is obtainable

m.1990mansouri@gmail.com

What processes are involved for a request to access data/document

6 months after printing results

Comments

no