# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

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

## Protocol summary

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

## 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**

+98 28 3365 1678

**Email address**

m.mansori@tak.iums.ac.ir

**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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1365775

**Phone**
+98 28 3365 1678

**Email**
m.mansouri@gmail.com

**Web page address**

## 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

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۱۴۴۹۶۱۴۵۳۵

**Phone**
+98 17 2336 2621

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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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## Person responsible for scientific inquiries

**Contact**

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**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

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**Full name of responsible person**

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**Web page address**

## 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@g mail.com

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

6 months after printing results

**Comments**

no