

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Stress Management Workshop for Mothers of Children With Type 1 Diabetes on Their Children's Blood Sugar

Protocol summary

Study aim

Evaluation the effect of maternal stress management on blood sugar in children with diabetes

Design

Clinical Trial with a Control group, with Parallel, non-blind, Simple Randomized groups, on 48 mothers and their children. The Orib Coin model was used for randomization.

Settings and conduct

Location: Amirkabir Teaching Hospital, Arak. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with diabetic children, ability to read and write. Non inclusion criteria: dissatisfaction of participants, being a single supervisor.

Intervention groups

Intervention group: Mothers of children with type 1 diabetes for whom a stress management training workshop is held. Control group: Mothers of children with type 1 diabetes for whom no stress management workshop is held.

Main outcome variables

Baby Blood Sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049988N1**

Registration date: **2021-06-24, 1400/04/03**

Registration timing: **retrospective**

Last update: **2021-06-24, 1400/04/03**

Update count: **0**

Registration date

2021-06-24, 1400/04/03

Registrant information

Name

Masoomeh Adavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3413 3061

Email address

daneshkadeha@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Stress Management Workshop for Mothers of Children With Type 1 Diabetes on Their Children's Blood Sugar

Public title

The Effect of Stress Management on Blood Sugar

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers' inclusion criteria: Having a child with type 1 diabetes who is at least three months old at the time of diagnosis, willingness to participate in reading, literacy. Inclusion criteria for children: Having type 1 diabetes that is at least three months after diagnosis.

Exclusion criteria:

Criteria for non-inclusion of mothers: acute and chronic disorders (with emphasis on psychiatric disorders); Being a single parent, the existence of another crisis in the family. Criteria for non-inclusion of children: history of other acute and chronic diseases in the past, co-occurrence of other acute and chronic diseases at the same time, presence of congenital or chromosomal disorders

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization - Easy sampling of diabetic children, type 1 diabetes referred to Amirkabir Hospital in Arak and doctor's office (Dr. Mohammad Ahangar Davoodi) in 2021, 48 people were randomly selected and divided into two groups using the Orib Coin method. In the Orib Coin method, a dice and a coin are required. To place people in the control and intervention groups, first a coin is thrown, if it is a line, a dice is thrown, and if it is 1 to 3, the person is placed in the control group. For the second time in the intervention group, the dice that were thrown must be between 3 and 4 in order for the person to be in the intervention group. In the same way, 48 people will be divided until the end.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Arak University of Medical Sciences

Street address

Shahid Shiroodi

City

arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.ARAKMU.REC.1399.341

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

Type 1 diabetes

ICD-10 code

E10.9

ICD-10 code description

Type 1 diabetes mellitus without complications

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

Baby blood sugar

Timepoint

3 months Before starting the study. After completing the stress management classes and a month later.

Method of measurement

Glucometer

Secondary outcomes**1****Description**

Mothers' stress

Timepoint

Before the start of the study, after completing the stress management classes, and a month later

Method of measurement

Cohen Perceived Stress Questionnaire

Intervention groups**1****Description**

Intervention group: Mothers with diabetic children, stress management workshop, during 8 face-to-face sessions, PowerPoint presentation and educational video

Category

Rehabilitation

2**Description**

Control group: Control group: Mothers with diabetic children, without stress management workshop

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Kabir Hospital, Arak

Full name of responsible person

Masoumeh Adavi

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Shahid Shiroodi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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Alam al-Huda street; Shahid Shiroodi street

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Masoumeh Adavi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Ganja

Position

science Committee

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Latest degree

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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

Information such as age, mean blood sugar in children before and after educational interventions and the effect of stress management workshop on stress and blood sugar in children

When the data will become available and for how long

Access period starts from 1400

To whom data/document is available

Researchers working in academic institutions and hospitals

Under which criteria data/document could be used

Provided with proper and ethical use to reduce the stress of mothers with children with diabetes and referral to information is free access.

From where data/document is obtainable

Masoumeh Adavi, 09189596008

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

Send first and last name, field of study, university of study, type of requested data, via SMS

Comments