

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Assessment of the effectiveness of psychoeducation for mothers of children aged 8 to 12 years with type 1 diabetes on HbA1c, self-management, quality of life and social support of children.

Protocol summary

Study aim

The purpose of this research is to investigate the effectiveness of psychological education of mothers of children with type 1 diabetes on HbA1c, self-management, quality of life and social support of children, so that if this intervention and the useful protocol found in foreign articles are effective in helping Children with type 1 diabetes in our country benefit.

Design

The current research is a clinical trial (RCT) that is conducted with pre-test, post-test and control group and randomization.

Settings and conduct

Both experimental and control groups were provided with a set of educational pamphlets, which were taught and reviewed during eight face-to-face briefings. The protocol, which is based on foreign articles, will receive training at the center of endocrinology and metabolism of Sedge Tahereh, Isfahan.

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study include children with type 1 diabetes with an age range of 8 to 12 years, and 6 months have passed since the diagnosis of their disease, the absence of accompanying psychiatric disorders in children, and having minimal literacy in mothers, as well as willingness to cooperate. Exclusion criteria include failure to complete questionnaires correctly or failure to regularly participate in psychological training sessions.

Intervention groups

Psychoeducation is the process of educating clients about the nature of illness, including its cause, progression, consequences, prognosis, treatment, and alternatives.

Main outcome variables

The score of the diabetes self-management questionnaire, the score of the quality of life questionnaire for children aged 8 to 12 years, the score

of the children's social support scale questionnaire, the score of the children's behavioral questionnaire, the HbA1C score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056942N2**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

Registrant information

Name

Mahdi Mirpourian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effectiveness of psychoeducation for mothers of children aged 8 to 12 years with type 1 diabetes on HbA1c, self-management, quality of life and social support of children.

Public title

Assessment of the effectiveness of psychoeducation for mothers of children aged 8 to 12 years with type 1 diabetes on HbA1c, self-management, quality of life and social support of children.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with type 1 diabetes aged 8 to 12 years 6 months have passed since the diagnosis of their disease
Absence of concomitant psychiatric disorder in children having minimum reading and writing literacy in mothers
Willingness to cooperate

Exclusion criteria:

Failure to complete questionnaires correctly
Lack of regular participation in psychological training sessions

Age

From **8 years** old to **12 years** old

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

The sampling method is random, and in the first stage, the sampling method was consecutive, and then in the random sampling method, double blocks were used for random allocation. Then the members of each block of two were sorted according to the national code and the table of random numbers was used in such a way that for numbers 0 to 4 the first person was moved to group 1 and the second person to group 2 and for numbers 5 to 9 people The second person was transferred to group 1 and the first person was transferred to group 2, and this work continued until the sample size was sufficient, and after that, the table of random numbers was used again to determine groups 1 and 2, in such a way that for numbers 0 to 4 groups of psychological training group 1 and control group group 2 were determined and for numbers 5 to 9 psychological training group group 2 and control group group 1 were selected

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

EthicS Committee of Isfahan University of Medical Sciences

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Isfahan University of Medical Sciences, Hazar Jerib Street, Isfahan

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Postal code

8174673461

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.MUI.MED.REC.1402.239

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

type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

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

Diabetes self-management questionnaire score

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Diabetes self-management questionnaire

2**Description**

Questionnaire of the quality of life of children aged 8 to 12 years

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Questionnaire of the quality of life of children aged 8 to 12 years score

3

Description

Child and adolescent social support scale score

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Child and adolescent social support scale

4

Description

Child behavior questionnaire score

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

Child behavior questionnaire

5

Description

hba1c level

Timepoint

Before the intervention, immediately after the intervention and 3 months after the intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: A series of educational pamphlets with the content of the importance of blood sugar regulation and the warning signs of hypoglycemia and hyperglycemia have been provided, and during eight face-to-face orientation sessions, the contents of these pamphlets have been taught and reviewed, as well as the daily experiences and challenges of these mothers regarding their children's diabetes in the presence of the therapist. And without providing specific training, a group discussion will take place.

Category

Placebo

2

Description

Intervention group: Intervention group: in the experimental group of mothers of diabetic children, in addition to the cases mentioned in the control group, in two psychological training groups of 12 people during 8

weekly one-hour sessions according to the protocol that was used based on foreign articles, in the Siddigeh Endocrine and Metabolism Center Tahereh Isfahan received training. The general content of the training sessions includes: first session: introduction to diabetes and the type of intervention - second session: teamwork and family communication - third session: blood sugar monitoring and medication use - fourth session: problem solving skills - The fifth session: Avoiding perfectionism and setting realistic goals - The sixth session: The importance of weight management - The seventh session: Reducing the feeling of exhaustion and gaining social support - The eighth session: Ways to stay motivated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Sedigeh Tahereh Endocrine and Metabolism Research Center

Full name of responsible person

Dr Mansoor Siavash

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

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

Reza Bagherian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available