

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-centered education on anxiety and stress of parents with a child with diabetes

Protocol summary

Study aim

The effect of family-centered education on anxiety and stress of parents with a child with diabetes

Design

Clinical trial with control and intervention group on 100 people

Settings and conduct

Research environment of nephrology ward of Hazrat Ali Asghar Hospital

Participants/Inclusion and exclusion criteria

Admission requirements: Parents of children 6 to 15 years old with diabetes Knowledge of the type of child disease Absence of any stressful event other than the child's illness during the past year Absence from attending similar training sessions and classes No entry conditions: Lack of parental cooperation

Intervention groups

First, by obtaining the necessary permits, the experimental and control groups are randomly selected. A number of 100 parents of children with diabetes are selected. While the control group receives routine care, after the training, the anxiety and stress questionnaires are distributed to the experimental and control groups and one month later. Finally, the data obtained from the questionnaires are collected and analyzed

Main outcome variables

Anxiety and stress

General information

Reason for update

Acronym

دیابت

IRCT registration information

IRCT registration number: **IRCT20141216020344N8**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered education on anxiety and stress of parents with a child with diabetes

Public title

The effect of family-centered education on anxiety and stress of parents

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
 Parents of children 6 to 15 years old with diabetes
 Awareness of the type of child's disease
 No stressful event other than the child's illness during the past year
 Absence from attending similar training sessions and classes

Exclusion criteria:
 Lack of parental cooperation

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **100**

Randomization (investigator's opinion)
 Not randomized

Randomization description

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
 University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.IUMS.REC.1400.1020

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and immediately after intervention
 and one month after intervention

Method of measurement

Beck Anxiety Questionnaire

Secondary outcomes

1

Description

Stress

Timepoint

Before intervention and immediately after intervention
 and one month after intervention

Method of measurement

Life Stress Questionnaire (LDI)

Intervention groups

1

Description

Intervention group: The family-centered model is implemented in four stages of perceived threat, self-efficacy, educational participation and evaluation during four sessions of 20 to 40 minutes for the intervention group; The control group receives only routine ward care. According to this model, the first step in the intervention phase is to understand the threat, which in this phase increases the knowledge and awareness of the parents. The use of drugs and the spirit and follow-up of tests and treatment is done. The second step is the problem-solving stage, which is done to increase self-esteem and self-control. In this stage, when parents' knowledge and attitude about the disease increase, they should participate in care programs. The third step is educational participation. The fourth step is evaluation, which is measured in two stages, one at the end of the intervention and one month later. Parents are first asked to complete the parent questionnaire. Then four 40-minute sessions are performed in four consecutive weeks (one session per week, every day). Before each session with the parents, the meeting time is set and the sessions are held for their convenience in the ward study class. In the first session (40 minutes), the researcher uses face-to-face training with parents about childhood diabetes, common signs and symptoms, diagnostic methods. And treatment programs, depending on the

stage and condition of the child's illness; Then, these parents are given basic training in this field. It should be noted that this session is provided separately and to all parents in the intervention group. To implement the second stage of the empowerment model, parents are placed in groups of 6 to 3 people. Second, 40 minutes, they are asked to discuss ways to communicate and exchange ideas with the hospital treatment team. In this session, they share their experiences and information about treatment, evaluation and control of treatment side effects. Other topics discussed in this session include proper nutrition, hygiene and how to inject insulin, side effects of medications, improving self-control in the face of sick children and their problems, as well as ways to support other family members. During this session, the researcher tries to lead the discussion indirectly. During the third session, and in order to implement the third stage of the empowerment model, each participant is asked to go to one of his / her family members, who is responsible for caring for the child. , To teach about what they have learned in the last two sessions. , And answer the researcher's questions under his / her indirect supervision. During this session, any possible problems, such as forgetting the material or passing on incorrect information by the trained parents, will be corrected immediately by the researcher. In the fourth session or the final evaluation session, the researcher evaluates all the questions of the participants in the intervention group by asking questions about the whole content taught and the items that were discussed in the second and third sessions. Eventually removes the remaining ambiguities. It is important to note that the subject of the previous session is evaluated by the researcher and at the beginning of each session by asking one or two questions. For one person and the absence of a family member in the third training session, leads to their removal from the entire study.

Category

N/A

2

Description

Control group: In the control group, routine care is performed and family-centered interventions are not performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital in Tehran

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 912 622 3904

Email

khoshnezhad.hr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hossein Keyvani

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

admins@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

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Tehran, Modares Highway, after Mirdamad Bridge,
Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar
Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2045

Email

khoshnezhad.hr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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+98 21 2222 2045

Email

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

Data is encrypted in order to make the identity of
individuals unidentifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr Hamidreza Khoshnezhad Ebrahimi Email
address:khoshnezhad.hr@iums.ac.ir

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

After submitting the application via academic email, we
will provide the information files to the individuals within
a maximum of one week.

Comments