

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of family centered care on management of diabetic children's blood glucose control in Research Center for Diabetes of Hamadan - Iran

Protocol summary

Summary

The purpose of this study was determination the effects of family centered care for the management of glucose control in children with insulin-dependent diabetes attending to the Diabetes Research Center of Hamadan. Methods and materials: Quasi-Experimental one-group pretest-post test design. The study population: Children with insulin-dependent diabetes attending to the Diabetes Research Center of Hamadan with their main caregivers. Inclusion criteria: 1) Child has 10- 14 years old; 2) Child has not any other chronic diseases; 3) Child and his/her main caregiver have not any mental or cognitive illness ; 4) Main caregivers be literate. Exclusion criteria: 1) One member of the family has a position in health teams; 2) Child and his/her significant caregiver be absent in more than one session. Sample size: 40 diabetic children and their main caregivers. Interventions: Four sessions will be conducted for each group consist of 10 diabetic children with their main caregivers. Therefore, 16 education sessions will be done. The time of each session will be 30 to 40 minutes. The methods of teaching will be lecture, group discussion, questions and answers and the role playing. Outcome: using questionnaires which will be filled by the child and his/her main caregiver, one week before and one month after intervention, bounding to the diet, bounding to the principles of insulin therapy, how to measure blood glucose, and physical activity programs will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013033112879N1**

Registration date: **2013-05-26, 1392/03/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-26, 1392/03/05

Registrant information

Name

Seyedeh Zohreh Mortazavi

Name of organization / entity

Faculty of nursing and midwifery, Hamadan University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0527

Email address

z.mortazavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family centered care on management of diabetic children's blood glucose control in Research Center for Diabetes of Hamadan - Iran

Public title

Family-centered care in the management of diabetes

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: 1) At least six months passed of the child's diabetes diagnosis; 2) Child has 10-14 years old; 3) Child has not any other chronic diseases; 4) The child's family must live in Hamadan; 5)) Child and his/her significant caregiver have not any mental or cognitive illness; 6) Main caregivers be literate; 7) The child and his/her significant caregiver did not participate in other formal training programs about diabetes within the last month; 8) Parents do not have experience of diabetes in own or previous child. Exclusion criteria: 1) One member of the family has a position in health teams; 2) Child and his/her significant caregiver be absent in more than one session

Age
 From **10 years** old to **14 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **40**

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

Local Human Review Board, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh st, Hamadan

City

Hamadan

Postal code

65178

Approval date

2013-04-15, 1392/01/26

Ethics committee reference number

16/35/9/78/د/پ

Health conditions studied

1

Description of health condition studied

Diabetes of type1

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

observance diet

Timepoint

a week before and one month after intervention

Method of measurement

questionnaire managing blood glucose control

2

Description

observance principles of insulin therapy

Timepoint

a week before and one month after intervention

Method of measurement

questionnaire managing blood glucose control

3

Description

how measure blood glucose

Timepoint

a week before and one month after intervention

Method of measurement

questionnaire managing blood glucose control

4

Description

physical activity programs

Timepoint

a week before and one month after intervention

Method of measurement

questionnaire managing blood glucose control

Secondary outcomes

1

Description

blood glucose

Timepoint

a week before and one month after intervention

Method of measurement

form of blood glucose levels

Intervention groups

1

Description

Four sessions will be conducted for each groups consisted of 10 diabetic children with their significant caregivers. Therefore 16 education sessions will be done. The time of each session will be 30 to 40 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for Diabetes

Full name of responsible person

Seyedeh Zohreh Mortazavi, Msc student of pediatric nursing

Street address

Myrzad Eshghi st, Hamadan

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Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Haidar Tavalani

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave, Hamadan

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Hamadan

Grant name

از محل یک درصد بودجه ی طرح های تحقیقاتی دانشگاه

Grant code / Reference number

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

Yes

Title of funding source

Vic-Chancellor for research, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of nursing and midwifery, Hamadan University of Medical Sciences

Full name of responsible person

Seyedeh Zohreh Mortazavi

Position

MSC student of pediatric nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Faculty of nursing and Midwifery, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Cheraghi

Position

PhD in Nursing

Other areas of specialty/work

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Person responsible for updating data

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty