

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family centered empowerment model on the treatment regime of diabetes school age children

Protocol summary

Summary

objectives: Diabetes is One of the most common chronic metabolic diseases in the world and our country .it is not curable but it can be controlled. control of diabetes is independing adherence of treatment regime containing medication treatment, dietary regime, sports activities. It is possible with education of children and families. The aim of this study is to determine the effect of family centered empowerment model on the treatment regime of school age children. design: This study is a clinical trial on a 7-12 year old children with type 1 diabetes and their families .siting and conduct A total of 50 patients and their parents, referred to Diabetes Clinic of Golestan Hospital have been chosen to intervention with the ethical standards and criteria. They were divided randomly into two groups.participants including major eligibility criteria: Minimum age 7 years and maximum age 12 years, two months of their diagnosis is past, before no educated, no other acute disease during the study. Inclusion exit: If they would like to be excluded from the study, study dont have no financial loss to them, along with the patient's is the main caregiver.Interventions: The case group educated with family centered empowerment model during four sessions 2 hour. Data were collected with questionnaires, included demographics, physical activity, knowledge, adherence to dietary and medication adherence Before the intervention in the both groups and immediately after the intervention and 2 months after the intervention, the case group were completed and the data evaluated with spss20 software and descriptive and analytical statistical tests .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031710244N2**

Registration date: **2013-06-08, 1392/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-08, 1392/03/18

Registrant information

Name

Farkhondeh Mahmoodi

Name of organization / entity

Jondishapoor University

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8621

Email address

mahmoodifa@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Jondishapoor university of Medical science, University City, Golestan Booolvar, Ahvaz, KHouzeestan, Iran

Expected recruitment start date

2012-10-11, 1391/07/20

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family centered empowerment model on the treatment regime of diabetes school age children

Public title

The effect of family centered empowerment model on the treatment regime of diabetes school age children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Minimum age 7 years and maximum age 12 years, two months of their diagnosis is past, before no educated, no other acute disease during the study.
Inclusion exit: If they would like to be excluded from the study, studydont have no financial loss to them, along with the patient's is the main caregiver

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

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 Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan Boolvar, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2012-10-27, 1391/08/06

Ethics committee reference number

EHT-604

Health conditions studied

1

Description of health condition studied

insulin- dependent diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Parental Knowledge

Timepoint

Before intervention -Immediately intervention- Two months after the intervention

Method of measurement

Knowledge Questionnaire

2

Description

Children Knowledge

Timepoint

Before intervention -Immediately intervention- Two months after the intervention

Method of measurement

Knowledge Questionnaire

3

Description

Medical Regime

Timepoint

Before intervention -Immediately intervention- Two months after the intervention

Method of measurement

Medical Regime Questionnaire

Secondary outcomes

1

Description

Insulin Injection

Timepoint

Before intervention - Immediate after intervention- two months after the intervention

Method of measurement

Practical assessment

2

Description

Dietary Adherence

Timepoint

before intervention - After intervention- Two months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

In the case group during educational meeting 4 meeting, about 2educational meeting about diseases, symptoms, diet, exercise and 2educational meeting practically showing how to inject insulin, glucose check, How to measure insulin,determine the food units perform

Category

Prevention

2

Description

In the control group no intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital Clinic

Full name of responsible person

Farkhondeh Mahmoodi

Street address

Emam Street, NoorAbad, Fars

City

Nnoorabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jundishapur University of Medical Sciences,Golestan Boolvar Ahvaz, Ir

Full name of responsible person

Mostafa Fegghi

Street address

The ground floor, Vice chancellor for research, Jundishapur University of Medical Sciences, Golestan Boolvar,Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Jundishapur University of Medical Sciences,Golestan Boolvar Ahvaz, Ir

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

Jundishapur university of Medical Sciences

Full name of responsible person

Farkhondeh Mahmoodi

Position

Master Nursing Student

Other areas of specialty/work

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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