

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Invastage Effect of Family Psychoeducation on the burden of family care and self-care behaviors in adolescents with type 1 diabetes

Protocol summary

Summary

The study aimed to determine the effect of family psychoeducation on family burden and self-care behaviors of adolescence with type 1 diabetes. Design: This study is a clinical trial with two groups of participants, include diabetic adolescents ages 12 to 18 years of age and accompanied by a member of the family. Setting and conduct: family psychoeducation for eight two-hour sessions for a month by lecture and discussion procedure will be provided for family members and adolescents. Major Inclusion and Exclusion criteria: The participants included adolescents with type 1 diabetes and a member of their family, who have the conditions of entering and exiting to the study. Interventions: Interventions will be for mental training to diabetic adolescents and their family members. Educational content based on material contained in the questionnaires is intended. glycolysis hemoglobin blood samples will be taken before the intervention. The questionnaire of the burden of care and self-care behaviors will be completed by adolescents and their family members, and three months later blood samples will be taken and questionnaires will be completed again. The main outcome variable: burden of care and self-care behaviors in adolescents with type 1 diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121525532N1**

Registration date: **2016-03-01, 1394/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-01, 1394/12/11

Registrant information

Name

Behnam Frahmandnia

Name of organization / entity

Joundi Shapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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arvaneh.y@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur university of medical sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Invastage Effect of Family Psychoeducation on the burden of family care and self-care behaviors in adolescents with type 1 diabetes

Public title

Effect of Family Psychoeducation on the burden of family care and self-care behaviors in adolescents with type 1 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria; non-risk adolescent patients to long-

term complications of diabetes (retinopathy, nephropathy, neuropathy) spent at least one year of patient medical diagnostic Declaration willingness to participate in training programs; Exclusion criteria; the occurrence of any social crisis, the family during the study - hospitalization or acute illness-absenteeism at meetings of more than 2 times

Age

From **82 years** old to **94 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

based on teenagers attending in golestan diabetes clinic creating the list of people and grouping randomize based on odd and even numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur Ahvaz University of Medical Sciences

Street address

Department of Development Ahvaz Jundishapur University of Medical Sciences, Highway Golstan, Ahvaz

City

Ahvaz

Postal code

15794-61357

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.AJUMS.REC.1394 .457

Health conditions studied

1

Description of health condition studied

type 1 diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Family psychoeducation

Timepoint

Before the intervention, three months after the intervention and six months after intervention

Method of measurement

Diabetes Family Impact - Scale(DfI-S)

Secondary outcomes

1

Description

family burden

Timepoint

Before the intervention, three months after the intervention and six months after intervention

Method of measurement

Diabetes Family Impact - Scale(DFI-S)

2

Description

Self - care behaviors of adolescence

Timepoint

Before the intervention, three months after the intervention and six months after intervention

Method of measurement

Self- report Measure Of type 1 Diabetes for adolescents(SMOD-A)

Intervention groups

1

Description

Intervention group: Family psychoeducation for 8 sessions, each session lasting 90 minutes and will run twice a week for groups. Training sessions include members with one another, as is the process of working group sessions and topics include speech problems in the treatment of diabetes, the role of patients and their families in disease management, diet, exercise, monitoring blood glucose and oral health, diabetes and psychological issues, etc. during each session, the topic of the meeting will be reviewed before. At the end of the training burden of care and self-care questionnaires will be completed by both groups. The HbA1C blood sugar test done during the three and six months for groups.

Category
Lifestyle

2

Description

Control group: no intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital diabetic clinic

Full name of responsible person

Frahmandnia behnam

Street address

Golestain hospital, Golestain, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research JondiShapour University of Medical Sciences

Full name of responsible person

Saki Nader

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ground floor, Vice chancellor for research Joundishapur Ahvaz, university of medical sciences

City

Ahvaz

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research JondiShapour 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

JondiShapour University of Medical Sciences

Full name of responsible person

Frahmandnia behnam

Position

nursing post graduat

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