

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of self-care education based on family-center empowerment model on self-care behaviors and HbA1C in patients with Type 1 Diabetes

Protocol summary

Summary

purpose: the Determination of effect of self care education based on family-center empowerment model on self care behaviors and hemoglobin A1C in type 1 diabetes patient. Design:Quasi-experimental, randomized , Single-center The study population: Patients with type 1 diabetes, 12 to 18 years old, Referred to Iranian Diabetes Association whodivided into two groups Randomly . The experimental group received self-care education and The control group did not receive any training . The sample size: 80 intervention: self care education in In three areas: Nutrition, exercise and physical activity , and use of insulin and control Complications based on four steps (perceived threat , problem solving , educational participation and evaluation) family-centered empowerment model in 5 sessions of 90 minutes time of study: 1394

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051322258N1**

Registration date: **2015-08-07, 1394/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-07, 1394/05/16

Registrant information

Name

Mahdieh Azizi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education based on family-center empowerment model on self-care behaviors and HbA1C in patients with Type 1 Diabetes

Public title

the effect of self care in diabetes

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:1. definitive diagnosis of type I diabetes by a physician , 2.Are in the age range 18-12, 3. having tendency to participate in study Exclusion criteria: 1. Have no desire to continue participating in the study

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

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
University of Social Welfare and Rehabilitation Sciences

Street address
Kudkyar deadlock, Daneshjoo boulevard, Evin street

City
Tehran

Postal code

Approval date
2015-03-11, 1393/12/20

Ethics committee reference number
IR.USWR.REC.1394.37

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
Self care

Timepoint
Before the intervention and 1/5 month after intervention

Method of measurement
Self-care behaviors questionnaire

2

Description
Hemoglobin A1C

Timepoint
Before and 3 months after intervention

Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Self-care education in the areas of nutrition, exercise and physical activity and control of Complications and drug use based on step of (Perceived threat , problem solving , educational partnership and Evaluation) family-center empowerment model, In five sessions 90 minutes

Category
Lifestyle

2

Description
control group: did not receive any training.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Diabetes Association

Full name of responsible person
Mahdieh Azizi

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Narges Arsalani

Street address
Kudkyar deadlock , Daneshjoo boulevard, Evin street

City
Tehran

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 University of Social Welfare and Rehabilitation 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

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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