Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 beheviors 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

+98 21 2218 0036

Email address

m.azizi@uswr.ac.ir

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

Contact
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Narges Arsalani
Position
Nursing PhD/ Assistant Professor
Other areas of specialty/work
Street address
Kudkyar beadlock , Daneshjoo boulevard, Evin street
City
Tehran
Postal code
Phone
+98 21 2218 0036
Fax
Email
nargesarsalani@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Narges Arsalani
Position
PHD
Other areas of specialty/work
Street address
Kudkyar deadlock , Daneshjoo boulevard, Evin street
City
Tehran
Postal code
Phone
+98 21 2218 0036
Fax
Email
nargesarsalani@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Mahdieh Azizi
Position
Student
Other areas of specialty/work
Street address
Kudkyar deadlock , Daneshjoo boulevard, Evin street
City
Tehran
Postal code
Phone
+98 21 2236 0018
Fax
Email
Mis.azizi1369@gmail.com
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