Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effectiveness of self-efficacy-based intervention on self-care level in diabetic adolescents

Protocol summary

Summary

The aim of this randomized controlled trial was to examine the effectiveness of self-efficacy- based intervention on self-care level among diabetic adolescents. The study was conducted in the Children's Hospital of Rasht. The study population,aged between 11 and 20, consisted of 50 eligible adolescents suffering from Type I Diabetes and referred to the clinic. Using a Randomized Block Design, which consisted of both genders who assigned into the experimental and control groups. After signing an informed consent , the participants filled out questionnaires specifically designed for these adolescents regarding demographic data, self-efficacy and self-care . Before the implementation of the desired intervention, the researcher determined the mean score of self-efficacy and self-care. The participants in the experimental group received intervention designed to enhance self-efficacy based on Bandura's theory. The intervention consisted of 6 sessions (2 hours) each week, for two weeks in addition to the routine care. In two episodes, immediately after the completion of the intervention and three months later, all participants filled out the questionnaire again. Additionally, the researcher measured and recorded glycosylated hemoglobin (HbA1c) before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201055499N2**
Registration date: **2013-08-02, 1392/05/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-02, 1392/05/11

Registrant information

Name

Seyedeh Noushaz MirHaghjou

Name of organization / entity

Nursing and Midwifery Faculty, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 6046

Email address

n_haghjou@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Office of the Vice Chancellor for Research , Guilan University of Medical Sciences

Expected recruitment start date

2012-01-02, 1390/10/12

Expected recruitment end date

2012-08-10, 1391/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of self-efficacy-based intervention on self-care level in diabetic adolescents

Public title

The effectiveness of self-efficacy-based intervention on self-care level in diabetic adolescents

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 11 and 20 ; being single; diabetic diagnosis at least for past two months. Exclusion criteria: having hemoglobinopathy, anemia, reticulocytosis and uremia during study

Age

From **11 years** old to **20 years** old

Gender

Both

Phase

1

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 vice chancellor for research , Guilan University of Medical Sciences

Street address

Vice chancellor for research , Opposite of Alzahra hospital, Shahid Siadati street, Namjoo Avenue, Rasht Rasht Guilan Iran, Islamic Republic Of 68164-41446

City

Rasht

Postal code

68164-41446

Approval date

2012-01-11, 1390/10/21

Ethics committee reference number

2901130506

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E10, E 11,

ICD-10 code description

E10 Insulin-dependent diabetes mellitus, E11 Non-insulin-dependent diabetes mellitus, E12 Malnutrition-related diabetes mellitus, E13 Other specified diabetes mellitus, E14 Unspecified diabetes mellitus

Primary outcomes

1

Description

Self-care

Timepoint

Prior to the intervention,Immediately and after the intervention and after three months

Method of measurement

Diabetic adolescents self-care questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Case group: After signing an informed consent, the participants filled out questionnaires specifically designed for these adolescents regarding demographic data, self-efficacy and self-care in relation to their diagnoses, in the presence of the researcher. Before the implementation of the desired intervention, the researcher determined the mean score of self-efficacy and self-care. The participants in the experimental group received intervention designed to enhance self-efficacy based on Bandura’s theory. The intervention involved three sessions each week-each session lasting 2 hours-for the total duration of two weeks, in addition to the routine care. Intervention was directed at self-efficacy enhancement according to Bandura's theory. The intervention involved preparing the appropriate practice conditions, using other patients' successful experiences, and getting and building on feedback. In two episodes, immediately after the completion of the intervention and three months later, all participants filled out the questionnaire again. Additionally, the researcher measured and recorded glycosylated hemoglobin (HbA1c) before and after the intervention.

Category

Other

2

Description

Control group: researcher did not any intervention in this group. Both groups received routine care.

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Hospital
Full name of responsible person
Seyedeh Noshaz Mirhaghjoo
Street address
Children’s Hospital, Across from the Azodi Stadium, Namjoo Avenue, Rasht
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Office of the Vice chancellor for research, Guilan University of Medical Sciences
Full name of responsible person
Dr Abdolrasol Sobhani
Street address
Alzahra Hospital, Shahid Siadati Street, Namjoo Avenue, Rasht, Guilan, The Islamic Republic of Iran
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Office of the Vice chancellor for research, Guilan 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
Shahid Beheshti Nursing and Midwifery College
Full name of responsible person
Seyedeh Noshaz Mirhaghjou
Position
Vice chancellor for education
Other areas of specialty/work
Street address
Shahid Beheshti Nursing and Midwifery College, Daneshjoo Boulevard, Shahid Beheshti Highway, Rasht, Guilan, The Islamic Republic of Iran
City
Rasht
Postal code
41469-39814
Phone
+98 13 1555 6046
Fax
Email
n_haghjou@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti Nursing and Midwifery College
Full name of responsible person
Seyedeh Noshaz Mirhaghjou
Position
Vice chancellor for education
Other areas of specialty/work
Street address
Shahid Beheshti Nursing and Midwifery College, Daneshjoo Boulevard, Shahid Beheshti Highway, Rasht, Guilan, The Islamic Republic of Iran
City
Rasht
Postal code
39814-41469
Phone
+98 13 1555 6046
Fax
+98 13 1555 0097
Email
n_haghjou@gums.ac.ir; n.haghjou@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti Nursing and Midwifery College
Full name of responsible person
Seyedeh Noshaz Mirhaghjou
Position
Vice chancellor for education
Other areas of specialty/work
Street address
Shahid Beheshti Nursing and Midwifery College, Daneshjoo Boulevard, Shahid Beheshti Highway, Rasht, Guilan, The Islamic Republic of Iran
City
Rasht
Postal code
39814-41469
Phone
+98 13 1555 6046
Fax
+98 13 1555 0097
Email
n_haghjou@gums.ac.ir; n.haghjou@yahoo.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