

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

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

#### Protocol summary

2013-08-02, 1392/05/11

##### 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

##### 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 Mirhaghjoo

**Position**

Vice chancellor for education

**Other areas of specialty/work****Street address**

Shahid Beheshti Nursing and Midwifery College,  
Daneshjoo Boulevard, Shahid Beheshti Highway,  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*