

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Survey the Impact of Orem's Self-Care Model on the Quality of Life in Adolescent with Diabetes Type 1

Protocol summary

Study aim

The aim of this study was to investigate the effect of self-care program based on Orem's self-care model on quality of life in adolescents with type 1 diabetes referred to the 17 Shahrivar Hospital in Rasht.

Design

The present study is a quasi-experimental research with a control group and sampling will be done by convenience method.

Settings and conduct

The present study will be carried out in 17 Shahrivar hospital of Rasht. In this study, adolescents will be allocated into two groups of intervention and control and the intervention group will be provided with an educational program, while the control group will not receive. The quality of life in both groups will be measured after the intervention.

Participants/Inclusion and exclusion criteria

The inclusion criteria: all adolescents aged 11 to 18 years old admitted to 17 Shahrivar Hospital in Rasht. Exclusion criteria: existence of any psychological disorders in adolescents.

Intervention groups

There are two groups of intervention and control. In intervention group educational training base on Orem's theory provide and in control group educational training do not provide.

Main outcome variables

Quality of life in adolescents

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171008036651N3**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **prospective**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

Registration date

2019-03-05, 1397/12/14

Registrant information

Name

Yasaman Yaghobi

Name of organization / entity

Guilan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 6046

Email address

yasamanyaghobi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-20, 1398/01/31

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the Impact of Orem's Self-Care Model on the Quality of Life in Adolescent with Diabetes Type 1

Public title

Survey the Impact of Orem's Self-Care Model on the Quality of Life in Adolescent with Diabetes Type 1

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic adolescents aged 11 to 18 years old who will be hospitalized in the 17-Shahrivar hospital of Rasht.

Exclusion criteria:

Psychological disorders in adolescents

Age

From **11 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)

N/A

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**

Ethica committee of Guilan University of Medical Sciences

Street address

Guilan University Of Medical Sciences, Iran Radiator Building, Imam Khomeini Blv, Rasht

City

Rasht

Province

Guilan

Postal code

3984141469

Approval date

2019-01-14, 1397/10/24

Ethics committee reference number

IR.GUMS.REC.1397.403

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E08.10

ICD-10 code description

Diabetes mellitus due to underlying condition with ketoacidosis without coma

Primary outcomes**1****Description**

Quality of life score in adolescents

Timepoint

The quality of life in adolescents will be measured immediately and two months after the intervention in the two groups.

Method of measurement

The quality of life in adolescents will be measured by the Weber quality of life questionnaire.

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group, the Orem-based educational program will be presented by the researcher in six sessions and at the end of the training sessions and two months later, the quality of life will be measured.

Category

Lifestyle

2**Description**

In the control group, the educational program will not be provided and the quality of life will be measured in the same way as the intervention group at the end of the training sessions and two months later.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

17 Shahrivar Medical and Education Center

Full name of responsible person

Somaye Pouy

Street address

Yakhsazi Square, Hamidian Town, Rasht

City

Rasht

Province

Guilan

Postal code

4148835132

Phone

+98 13 3323 8307

Email

somayepouy@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Doctor Shadman Nemati

Street address

Guilan University Of Medical Sciences, Iran Radiator
Building, Imam Khomeini Blv, Rasht

City

Rasht

Province

Guilan

Postal code

416351873

Phone

+98 13 3333 6394

Email

nemati@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Somaye Pouy

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yakhsazi Square, Hamidian Town, Rasht

City

Rasht

Province

Guilan

Postal code

4148835132

Phone

+98 13 3355 5056

Email

somayepouy@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Doctor Yasaman Yaghobi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Nursing and Midwifery Faculty,
Yakhsazi Square, Rasht

City

Rasht

Province

Guilan

Postal code

4148835132

Phone

+98 13 3355 5056

Email

yasamanyaghobi@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Somaye Pouy

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Yakhsazi Square, Hamidian Town, Rasht.

City

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Province

Guilan

Postal code

4148835132

Phone

+98 13 3355 5056

Email

somayepouy@gmail.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the information of the participants and do not starting sampling, we do not currently decide on the release of individual information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available