

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of implementing an intervention based on Peplau's theory on blood sugar control and self-care of adolescents with type 1 diabetes

Protocol summary

Study aim

We intend to investigate the effect of designing and implementing an intervention based on Peplau's theory on blood sugar control and self-care in type 1 diabetes in adolescents.

Design

The clinical trial has two intervention and control groups with 20 people each. The researcher divides the samples into two equal intervention and control groups by simple random method using SPSS software. Blinding is not possible.

Settings and conduct

Place of study: Diabetes Association of Arak city; Study population: 40 teenagers with type 1 diabetes who are equally divided into two intervention and control groups; Type of blinding: No blinding was done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of type 1 diabetes by a specialist doctor and recorded in the patient's medical record; At least three months have passed since the patient being diagnosed with type 1 diabetes; Willingness and ability of adolescents and parents to participate in the study; Adolescents must be between 12 and 18 years old. Exclusion criteria: Adolescents suffering from diseases other than diabetes.

Intervention groups

In the control group, no action is taken and this group only fills the three-part questionnaire of demographic information, Tobert's self-care and blood sugar checklist with an interval of 8 weeks. In the intervention group, the mentioned questionnaires are filled first, then, according to the self-care needs of teenagers with type 1 diabetes, several theoretical and practical training sessions are held in relation to diabetes self-care with the help of lectures, videos, etc., and finally After 8 weeks, the questionnaires must be filled again.

Main outcome variables

diabetes self-care score on Tobert questionnaire scale;
Average blood sugar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230924059498N1**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **prospective**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Sara Samie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3435 1361

Email address

s.samiei@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-08-06, 1403/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing an intervention based on Peplau's theory on blood sugar control and self-care of adolescents with type 1 diabetes		Street address Faculty of Nursing, Payambar-e-Azam university complex, Sardasht, Arak	
Public title The effect of Peplau's theory on blood sugar control and self-care in type 1 diabetes		City Arak	
Purpose Education/Guidance		Province Markazi	
Inclusion/Exclusion criteria Inclusion criteria: Type 1 diabetes diagnosis by a specialist doctor and recorded in the patient's medical record At least three months have passed since the diagnosis of type 1 diabetes in the patient Willingness and ability of adolescents and parents to participate in the study Adolescents must be between 12 and 18 years old Exclusion criteria: Adolescents suffering from diseases other than diabetes		Postal code 3848176941	
Age From 12 years old to 18 years old		Approval date 2023-10-14, 1402/07/22	
Gender Both		Ethics committee reference number IR.ARAKMU.REC.1402.143	
Phase N/A		Health conditions studied	
Groups that have been masked <i>No information</i>		1	
Sample size Target sample size: 40		Description of health condition studied Diabetes Type 1	
Randomization (investigator's opinion) Randomized		ICD-10 code E10.9	
Randomization description The researcher will talk to the teenagers and their parents and explain the purpose of the research and the method of implementation to them and get their consent to participate in the research. If they agree to participate in the research, their names will be registered in the list of research samples. Then, the researcher will code the specified names and assign them to two equal intervention and control groups by simple random method using SPSS software.		ICD-10 code description Type 1 diabetes mellitus without complications	
Blinding (investigator's opinion) Not blinded		Primary outcomes	
Blinding description		1	
Placebo Not used		Description Diabetes self-care score in Tobert questionnaire	
Assignment Parallel		Timepoint The effect of designing and implementing an (educational) intervention based on Peplau's theory on the self-care of adolescents with type 1 diabetes, before the intervention and 8 weeks after the intervention.	
Other design features		Method of measurement Tobert diabetes self-care questionnaire	
Secondary Ids empty		Secondary outcomes	
Ethics committees		1	
Ethics committee Name of ethics committee Ethics Committee of Arak University of Medical Sciences		Description Average fasting blood sugar score	
		Timepoint The effect of implementing of the intervention based on Peplau's theory on the average fasting blood sugar score before the intervention and 8 weeks after the end of the intervention.	
		Method of measurement Glucometer device (to complete the fasting blood sugar monitoring checklist)	
		2	
		Description Average blood sugar score two hours after a meal	
		Timepoint The effect of the implementation of the intervention based on the Peplau theory on the average blood sugar score two hours after the meal, before the intervention	

and 8 weeks after the end of the intervention.

Method of measurement

Glucometer device (to complete the blood sugar monitoring checklist two hours after meals)

Intervention groups

1

Description

Intervention group: the researcher calls the participants to the diabetes association and introduces himself and the objectives of the study to them, and after receiving informed consent, to each of the participants a three-part questionnaire, demographic information questionnaire, Tobert diabetes self-care questionnaire and delivers the blood sugar monitoring checklist. Regarding the blood sugar monitoring checklist, the researcher explains to the patients that they should write down their fasting and two-hour post-breakfast blood sugar levels for 7 days. In the same way, it is explained to the participants that they should start filling the desired sheet from the day after the meeting and finally deliver it to the researcher next week. It is explained to the participants that they should bring the questionnaires with them in the next meeting which will be held next week. At this stage, after gathering the participants, the beginning of the training sessions and the days of the class are explained to the teenagers and it is stated that two training sessions will be held every week. Blood sugar control sheets are collected from patients and their blood sugar management status is checked. Training sessions will be held according to the third stage of Peplav's theory (exploitation stage). Teaching teenagers will be done using lectures, group discussions, pictures and educational videos. Also, based on the determined self-care needs, several sessions of practical training classes are organized. The training program will be implemented in one-hour sessions and the number of sessions depends on the prioritization of needs. At the end, a booklet containing the content of the training will be provided to all samples (intervention and control groups). The fourth stage is called dissolution, which ends the training process. The participants are prepared for this stage from the previous two sessions. If there is any ambiguity or question, it will be answered in this meeting. Two months (8 weeks) after the completion of the training sessions, the participants will be contacted again and the two-part Tobert diabetes self-care questionnaire and blood sugar monitoring will be delivered to them. Finally, the researcher coordinates with the samples and receives the questionnaire from them.

Category

Other

2

Description

Control group: In order to prevent the occurrence of possible biases due to the meeting of intervention and control group people in the diabetes association and to

inform the control group people about the training sessions of the intervention group and the effect on them, the research was first on the participants of the control group and then It will be done on the intervention group. The researcher calls the participants to the Diabetes Association and obtains the informed consent form from them and their parents and then asks the teenagers to complete the questionnaires that are given to them. The questionnaires have three parts and are filled according to the mentioned instructions. After a week, they will be contacted and asked to hand over the questionnaires. In order to prevent errors in the research and to create coordination between the intervention and control groups, an 8-week interval is considered from the moment of delivery of the questionnaire, and then the questionnaires are filled again. No special action is taken in this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Diabetes Association

Full name of responsible person

Sara Samie

Street address

Phase 1; Pardis Town; Qa'em Maqam street

City

Arak

Province

Markazi

Postal code

3816985776

Phone

+98 86 3435 1361

Email

s.samiei@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

Street address

Faculty of Nursing, Payambar-e-Azam University complex, Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3524

Email

s.samiei@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Sara Samie

Position

Nurse, Master's degree in pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Etehad 1 Alley, Etehad Ave., Hamid Town

City

Arak

Province

Markazi

Postal code

3816985776

Phone

+98 86 3435 1361

Fax**Email**

s.samiei@arakmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Somaye Sayahi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing, Payambar-e-Azam University complex, Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3524

Email

s.sayahi@arakmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Sara Samie

Position

Nurse, Master's degree in pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Etihad Ave., Hamid Town, Arak

City

Arak

Province

Markazi

Postal code

3816985776

Phone

+98 86 3435 1361

Fax**Email**

s.samiei@arakmu.ac.ir

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information such as age of teenagers, education of parents, duration of type 1 diabetes in teenagers (in years), body mass index of teenagers, types of insulin used by teenagers, diabetes self-care score of teenagers

with type 1 diabetes before and after intervention in each group (control and intervention), the average fasting blood sugar score and 2 hours after the meal before and after the intervention in each group in teenagers with type 1 diabetes. The information will be published without mentioning names and individual characteristics.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only researchers working in academic institutions and hospitals

Under which criteria data/document could be used

Free access is provided on the condition of correct and ethical use in order to improve self-care and blood sugar control of adolescents with type 1 diabetes and referring to the information of this research and preserving the rights of the researchers of this project.

From where data/document is obtainable

Sara Samie sarasamie81@gmail.com

What processes are involved for a request to access data/document

Send name and surname; field of study; university of study; reason for needing said information; type of requested data; only via email

Comments