Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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

Public title
The effect of Peplau's theory on blood sugar control and self-care in type 1 diabetes
Purpose
Education/Guidance
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
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: **40**
Randomization (investigator's opinion)
Randomized
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.
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 Arak University of Medical Sciences
Street address
Faculty of Nursing, Payambar-e-Azam university complex, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2023-10-14, 1402/07/22
Ethics committee reference number
IR.ARAKMU.REC.1402.143

Health conditions studied

1

Description of health condition studied
Diabetes Type 1
ICD-10 code
E10.9
ICD-10 code description
Type 1 diabetes mellitus without complications

Primary outcomes

1

Description
Diabetes self-care score in Tobert questionnaire
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.
Method of measurement
Tobert diabetes self-care questionnaire

Secondary outcomes

1

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Arak University of Medical Sciences
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Sara Samie
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Nurse, Master's degree in pediatric nursing
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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