

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of teaching mother and child together using the teach-back method with the multimedia method, on self-care behaviors in children with type 1 diabetes.

Protocol summary

Study aim

Comparison of the effect of mother and child education using teachback and multimedia methods on the average score of self-care behaviors in children with type 1 diabetes

Design

A clinical trial with a control group, with 2 parallel groups, without blinding, randomized on 45 patients.

Settings and conduct

This research will be conducted on children with type 1 diabetes and their mothers. Patients are selected according to the sample size by simple random sampling and according to the entry criteria and obtaining a score of less than 47 from Tobert and Glasgow's diabetes self-care questionnaire (2002), then the patients are divided into three groups (two intervention groups and one control group). Placed. Due to the uncertainty of the list of patients and the gradual admission of DKA patients in the PICU department, the first patient who meets the entry criteria will be placed in the control group, the second patient in the teachback group, and the third patient in the multimedia group, and this arrangement will continue until the end of sampling. he does

Participants/Inclusion and exclusion criteria

Inclusion criteria Child age 6-12 Obtaining a score less than 47 of Tobert Voglasko's diabetes self-care questionnaire (2002) Exclusion criteria Unwillingness to participate in the study or Death

Intervention groups

Teachback instruction method as the intervention
Multimedia teaching method as the control

Main outcome variables

Self-care behaviors in type 1 diabetic children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231128060208N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

Rahimeh Zelhagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 033 0375

Email address

rahime.zelhagh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of teaching mother and child

together using the teach-back method with the multimedia method, on self-care behaviors in children with type 1 diabetes.	
Public title	Comparing the effect of teaching mother and child together using the teach-back method with the multimedia method, on self-care behaviors in children with type 1 diabetes.
Purpose	Education/Guidance
Inclusion/Exclusion criteria	Inclusion criteria: 3. 6 months to a year have passed since the diagnosis of diabetes Getting a score less than 47 from Tobert and Glasgow's diabetes self-care questionnaire (2002) Diagnosing type 1 diabetes in a child by a doctor Not teaching the child about diabetes during the last month Absence of the child's parents in the medical science group Access and ability of the child or a family member. to electronic devices such as phones or laptops Child age 6-12 The child's absence of physical and mental illness other than diabetes (by examining the doctor's case and medical history) Consciousness level should be based on Glasgow 15 criteria Having a desire to participate in research The mother should not be responsible for taking care of any patient other than diabetes in the family The possibility of calling the child's mother Mother's literacy The absence of the mother suffering from mental, nervous or other known chronic diseases (according to the history taken) Having a mother's phone or laptop and the ability to work with it Exclusion criteria: Creating physical problems in the mother or child that prevents self-care Withdrawal of mother and child from participating in the study Non-cooperation of the client Participation in self-care training sessions of other workshops or researches Death of mother or child
Age	From 6 years old to 12 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	By simple random method In order to randomly assign the groups, 45 sheets of the same shape and size are cut and written on 15 sheets of the control group, 15 sheets of the teachback group and 15 sheets of the multimedia group, and the sheets are folded and put in a container and mixed. to be Upon admission of each patient, a sheet is removed from the container to determine the group and the patient's group is determined based on the writing on the sheet
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Zabol University of Medical Sciences
Street address	Zabol, Jihad Square, Shahid Bagheri St., Zabol University of Medical Sciences Headquarters
City	Zabol
Province	Sistan-va-Balouchestan
Postal code	9861663335
Approval date	2023-10-14, 1402/07/22
Ethics committee reference number	IR.ZBMU.REC.1402.079
Health conditions studied	
<u>1</u>	
Description of health condition studied	diabetes type 1
ICD-10 code	E08
ICD-10 code description	Diabetes mellitus due to underlying condition
Primary outcomes	
<u>1</u>	
Description	Self care behaviors
Timepoint	Before the start of the intervention and 3 months later
Method of measurement	Toberth and Glasgow 2002 questionnaire measurement of HBA1C
Secondary outcomes	
<u>1</u>	
Description	Toberth and Glasgow 2002 questionnaire score

Timepoint

Before the intervention and one month later

Method of measurement

The average scores ranged from 0-70 and it was divided into three parts, and a general compliance score was obtained by summing the scores of each question.

2

Description

HbA1C

Timepoint

Before the intervention and 3 months later

Method of measurement

Metabolic tests (HbA1C) in children are all done in the same laboratory. The reliability of the laboratory instrument will be checked by checking the calibration of the device every time the device is used. Also, all the tests will be performed in the same environment and by a specific person and device.

Intervention groups

1

Description

Control group: Receive routine hospital training

Category

N/A

2

Description

Intervention group: Teaching self-care behaviors by the teachback method The first session provides explanations about diabetes and its causes and complications, ways to prevent complications • The second session provides necessary training on the type of diet, meal times and snacks • The third session teaches how to inject insulin and injection sites • The fourth session Training on how to check blood sugar and its hours and foot care. At the end of each session, to ensure that the client learns the said items, open questions are asked so that the topics can be repeated if necessary. This process continues until the client learns completely. In addition, at the beginning of each session, the training items of the previous session are asked in the form of open questions so that the training items of the previous session can be repeated if necessary. At the end of the session, the taught items are provided to the client in the form of an educational pamphlet.

Category

Behavior

3

Description

Intervention group: Teaching self-care behaviors by multimedia method • In the first session, explanations are given about diabetes and its causes and complications, ways to prevent complications • The second session of necessary training about the type of diet, the frequency of meals and snacks • The third

training session on how to inject insulin and injection sites • The fourth training session on how to check blood sugar and its hours and take care of the feet In the multimedia training group, the same content is used, but it is not presented face-to-face, instead, patients receive training videos through CDs, DVDs, and mobile device files. The content of these videos includes all the content that is taught face-to-face in the teaching group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirul Mominin Zabol Hospital

Full name of responsible person

Mehdi Khosravi

Street address

3rd km of Zabol Zahedan road, Amir al-Mominin Hospital, Zabol

City

Zabol

Province

Sistan-va-Balouchestan

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9861979917

Phone

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Email

amirhospital@zbm.ac.ir

Web page address

<https://amir.zbm.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

هادی میرزایی

Street address

Zabol, Jihad Square, Shahid Bagheri St., Central Headquarters of the University of Medical Sciences

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zabol

Province

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Email

info@zbmu.ac.ir

Web page address

<https://zbmu.ac.ir>

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

Yes

Title of funding source
Zabol University of Medical Sciences
Proportion provided by this source

1

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
Zabol University of Medical Sciences

Full name of responsible person
rahimeh zelhagh

Position
Special care senior student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Title and more details about the data/document

Information about illness and family conditions without identifying the client Only part of the data, such as information related to the main outcome, can be shared

When the data will become available and for how long

The access period starts one month after the publication of the article

To whom data/document is available

The opinion of researchers working in academic and scientific institutions

Under which criteria data/document could be used

All necessary analyzes are allowed for use in research related to children's diabetes

From where data/document is obtainable

gmail RAHIME ZELHAGH RAHIME.ZELHAGH@GMAIL.COM

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

Send a request to Gmail

Comments