Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The impact of home visit-based diabetes self-management education (DSME) on glycemic control in children and adolescents with diabetes

Protocol summary

Study aim

Investigating the impact of home visit-based diabetes self-management education (DSME) on glycemic control in children and adolescents with diabetes

Design

A controlled clinical trial with parallel groups, single-blind, randomized, on 108 school-age children with Type 1 Diabetes. After selecting patients using the convenience sampling method, they will be randomly allocated to the groups using the "Permuted Blocked Randomization Method" by Random Allocation software in 9 blocks of 12 (108 people in total).

Settings and conduct

The intervention is conducted over a period of 3 months, consisting of 3 to 4 home visit sessions for the patients. The implementation method follows diabetes self-management training according to the ADCES7 model. In this single-blind clinical trial, the personnel who measure the patients' metabolic indices and the statistical analyst are unaware of which group the patients belong to.

Participants/Inclusion and exclusion criteria

The most important inclusion criteria: • The patient's age should be between 8 and 16 years. • Have a history of type 1 diabetes for at least one year. • Have a history of poor glycemic control, with glycated hemoglobin (HbA1c) above 8% in the past year. The most important exclusion criteria: • The patient and the caregiver do not attend the sessions. • Any severe physical or emotional crisis occurs for the patient during the study period.

Intervention groups

In addition to routine medical services, patients in the intervention group will receive diabetes self-management training according to the ADCES7 model over 3 months (8 to 10 home visit sessions). Patients in control group will receive routine medical services.

Main outcome variables

Glycosylated hemoglobin؛ lipid profile؛ type 1 diabetes management knowledge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231023059826N1**
Registration date: **2025-04-07, 1404/01/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-07, 1404/01/18**
Update count: **0**

Registration date

2025-04-07, 1404/01/18

Registrant information

Name

amin kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-06, 1403/07/15

Expected recruitment end date

2025-06-05, 1404/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of home visit-based diabetes self-management education (DSME) on glycemic control in children and adolescents with diabetes

Public title

The impact of home visit-based diabetes self-management education (DSME)

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Be willing to participate in the study. Reside in the city where the study is conducted. The patient and the primary caregiver must be able to speak, read, and write in Persian. The patient's age should be between 8 and 16 years. Have a history of type 1 diabetes for at least one year. Have a history of poor glycemic control, with glycated hemoglobin (HbA1c) above 8% in the past year. No family members of the patient should have type 1 diabetes. The patient and the primary caregiver should not have physical disabilities or cognitive, hearing, and visual impairments according to their own statements. Should not have participated in similar studies in the past six months. Should not have other metabolic, chronic, or incurable diseases. The patient and the primary caregiver should not have mental illnesses and should not be taking psychiatric medications. Should not be taking any medications other than those used for diabetes, such as steroids. The primary caregivers should not be employed in health-related professions.

Exclusion criteria:

The death of the patient or the primary caregiver occurs in the family. The patient and the caregiver do not attend the sessions (miss at least two sessions in one month). The patient or the primary caregiver is diagnosed with any incurable physical or mental illness during the study period. Any severe physical or emotional crisis occurs for the patient during the study period. The questionnaires used in the study are completed incompletely. Participates in similar educational sessions. The primary caregiver of the patient in the family is changed for any reason.

Age

From **8 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients enrolled from the pediatric diabetes clinic will be allocated to the intervention and control groups using block randomization with 6-subject blocks. Given the total sample size of 108 participants in this study, 18 blocks of 6 subjects will be utilized. The unit of randomization will be individual patients, and each patient will be randomly assigned to a group based on a sequence generated by Random Allocation Software (RAS). The random sequence generation will follow a sequential process until the completion of sampling. Participants will be allocated to their respective groups in the order of their enrollment into the study, using randomly permuted blocks. Allocation concealment will be implemented via the SNOSE method (Sequentially Numbered, Opaque, Sealed Envelopes). For this purpose, based on the predetermined sample size, envelopes will be prepared. Each randomly generated sequence will be recorded on a card, and these cards will be sealed inside numbered envelopes in sequential order. As patients are enrolled, the envelopes will be opened one by one to reveal their assigned group. Blinding will be applied to the statistical analyst to ensure unbiased outcome assessment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The laboratory personnel or the outcome assessor, who measures the metabolic indicators in question, will be unaware of which patients are in the test or control group (blinding of outcome assessor). Also, the person who performs the data analysis will not know which group the patients are in. Therefore, this study is considered a "Single-Blind Randomised Controlled Trial".

Placebo

Not used

Assignment

Parallel

Other design features

This study will be conducted in two quantitative and qualitative phases. After the completion of the quantitative phase (clinical trial), the qualitative phase of the study will be conducted.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information s

Street address

Faculty of Nursing and Midwifery of Hazrat Fatemeh, entrance of Namazi Hospital, Namazi Square, shiraz

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2024-04-20, 1403/02/01

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1403.014

Health conditions studied

1

Description of health condition studied
type 1 diabetes
ICD-10 code
E10
ICD-10 code description
E10 Type 1 diabetes mellitus

Primary outcomes

1

Description
Glycosylated hemoglobin: comparison of the average "glycosylated hemoglobin percentage value" before and after the intervention, between the two test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
"High performance liquid chromatography" method will be used to measure glycosylated hemoglobin.

2

Description
lipid profile: Comparison of the average "lipid profile" before and after the intervention, between the two test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
In order to measure the "lipid profile" the "enzymatic colorimetry" method will be used.

3

Description
knowledge scores: Comparison of the average "Diabetes Self-Management Knowledge Scores" before and after the intervention, between the two test and control groups.
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
Knowledge assessment questionnaire for children/adolescents with diabetes (M-WIKAD)

Secondary outcomes

1

Description
Frequency of self-monitoring of blood sugar: Comparison of the average frequency of "self-monitoring of blood sugar" before and after the intervention, between the test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis.

2

Description
Quality of life: comparing the average scores of "quality of life" before and after the intervention, between the two test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
PedsQL™ 4.0 Pediatric Quality of Life Inventory

3

Description
missed dose of insulin frequency : Comparison of the average frequency of "missed dose of insulin" before and after the intervention between the test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis.

4

Description
The average duration of exercise per week: comparison of the average "duration of exercise per week" before and after the intervention between the two test and control groups
Timepoint
Before the start of the intervention, after the intervention, 3 and 6 months after the intervention
Method of measurement
time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis.

5

Description

The average frequency of hypoglycemia in the week before and after the intervention between the two test and control groups

Timepoint

Before the start of the intervention, after the intervention, 3 and 6 months after the intervention

Method of measurement

time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis.

6

Description

The average frequency of daily hyperglycemia before and after the intervention between the two test and control groups

Timepoint

Before the start of the intervention, after the intervention, 3 and 6 months after the intervention

Method of measurement

time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis.

7

Description

The average number of hospitalizations due to diabetic ketoacidosis, before and after the intervention between the two experimental and control groups

Timepoint

Before the start of the intervention, after the intervention, 3 and 6 months after the intervention

Method of measurement

time diary : The tool for recording activity time and events, this tool includes tables about the frequency of self-monitoring of blood sugar, the duration of exercise and events such as the number of missed doses of insulin, the frequency of hypoglycemia ānd hyperglycemia, which are recorded on a daily basis. Also, events such as hospitalization due to diabetic ketoacidosis can be recorded.

Intervention groups

1

Description

Intervention group: In this study, the intervention for each patient will be conducted over a period of 3 months, comprising 3 to 4 home visit sessions, along with daily follow-up through phone calls and WhatsApp messaging platform.The implementation method will be in accordance with the ADCES7 model, which encompasses the seven key behavioral guidelines established by the American Association of Diabetes Care & Education Specialists (ADCES) and includes the areas of healthy coping, healthy eating, being active, taking medication, monitoring, problem solving, and reducing risks.Thus, in the first training session held at the home of each patient, the patient's condition will be examined based on each of the seven areas, the patient's weaknesses and strengths will be identified in each of the areas, and After determining the educational needs of each patient, the necessary training will be provided according to the relevant instructions (according to the guidelines). For example, in the field of healthy eating, the nutritional pattern of the patient and family, the knowledge and skills of the patient (and the main caregiver) about food groups, the effect of different foods on blood sugar, sources of carbohydrates, amounts of carbohydrates in foods, how to count carbohydrates, nutritional information labels of different foods, food substitutes, deciding on food choices in the outdoor environment and many other things will be examined according to the relevant guidelines in the field of healthy eating, Then, the necessary training will be provided based on the patient's needs in that area, according to the relevant instructions (Adces7 self care behaviour).In the field of taking medication, the patient's knowledge and skills about the name of the drug (insulin), the mechanism of action, the peak effect, the best time of use, possible side effects, missed dose, how to store the drug, how to properly inject insulin, the best places for Injections, side effects of unprincipled injections, maintaining safety points and many other cases will be examined and the necessary training will be provided based on the patient's needs in that area, according to the relevant instructions.This educational process will continue in the next sessions and until the completion of training in all areas of being active, monitoring, problem solving, reducing risks and healthy coping. In this way, trainings will be completed in all seven areas of diabetes self-management, according to the instructions of the Association of Diabetes Care and Education Specialists.

Category

Behavior

2

Description

Control Group: Patients in the control group will receive routine services within the healthcare delivery system. In this clinic, patients are typically visited every three months by a pediatric endocrinologist, and when necessary, they are referred to the nutritionists and psychologists stationed at the clinic for further training. In contrast, patients in the intervention group will receive diabetes self-management education for a duration of 3 months, consisting of 1 session per week or biweekly, totaling 3 to 4 personalized sessions conducted exclusively in the patient's home, In accordance with the guidelines of the American Association of Diabetes Care and Education Specialists (ADCES).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
بخش دیابت اطفال واقع در درمانگاه تخصصی و فوق تخصصی امام رضا - دانشگاه علوم پزشکی شیراز - ایران

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
Shiraz University of Medical Sciences

Grant code / Reference number
29738

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Information regarding the primary and secondary outcomes of the participants will be provided upon the researchers' request.
When the data will become available and for how long
Access to the data will begin after the publication of the articles resulting from the present project.
To whom data/document is available
The data will be made available to researchers in scientific and academic institutions upon request.
Under which criteria data/document could be used
If a valid confirmation from a scientific or academic institution is provided, along with a statement indicating that the data will be used solely for scientific research, the data will be made available to the researchers.
From where data/document is obtainable
Applicants can request the data through the email of the article's authors. torabik@sums.ac.ir kianiam@sums.ac.ir
What processes are involved for a request to access data/document
If the confidentiality of the participants' information in the study is ensured, the data will be immediately provided to the researchers via email.
Comments