Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of self-care education based on the family-centered empowerment model on self-management, self-care, and readmission rates of patients with diabetic ketoacidosis

Protocol summary

Study aim

The aim of this study was to determine the effect of self-care education with a family-centered approach on self-management, self-care, and readmission rates of patients with diabetic ketoacidosis admitted to Seyed al-Shohaday Hospital in Jahrom in 2026.

Design

This study is a clinical trial and has a control group and is for 136 patients, 68 in each group. The sampling method in this study will be a random block method, in which samples that are similar in terms of one or more specific characteristics are placed in a block, which controls the effects of these factors.

Settings and conduct

This study is to be conducted at Seyed al-Shohaday Hospital in Jahrom city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of diabetes according to the opinion of an internist or endocrinologist Having an active companion and a relative of the patient to participate in the implementation of the intervention who is fully aware of his disease and is concerned about his treatment. Having a minimum level of literacy, to the point of being able to read and understand the content in the uploaded clips. Aware of time and place, able to understand Persian Exclusion criteria: Having advanced malignant diseases such as types of cancer, chronic kidney disease, and advanced heart disease Failure to attend the training session Failing to feel unwell during the training period Unwillingness to continue cooperation Patient death

Intervention groups

Educational sessions will begin for the families of patients in the intervention group. The researcher will provide three days of face-to-face education to the companions of patients in the intervention group about diabetes and its important complication, ketoacidosis, and strategies for preventing and dealing with it. Each session will last approximately half an hour.

Main outcome variables

Self-management, self-care, readmission rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210114050037N4**
Registration date: **2026-03-26, 1405/01/06**
Registration timing: **prospective**

Last update: **2026-03-26, 1405/01/06**
Update count: **0**

Registration date

2026-03-26, 1405/01/06

Registrant information

Name

Ali asghar Rahmanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 3628

Email address

lynurse8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of self-care education based on the family-centered empowerment model on self-management, self-care, and readmission rates of patients with diabetic ketoacidosis

Public title

Investigating the effect of self-care education based on the family-centered empowerment model on self-management, self-care, and readmission rates of patients with diabetic keto acidosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of diabetes according to the opinion of an internist or endocrinologist Having an active companion and a close relative of the patient to participate in the implementation of the intervention, who is fully aware of her illness and is concerned about her treatment. Having a minimum level of literacy to be able to read and understand the content in the uploaded clips. Aware of time and place, able to understand Persian

Exclusion criteria:

Having advanced malignant diseases such as various types of cancer, chronic kidney disease, and advanced heart disease Failure to attend training session His/her feeling unwell during the training period Unwillingness to continue cooperation death of the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the sample size, since patients enter the study gradually, the block randomization method will be used to assign participants to the control or intervention groups. In this method, considering the sample size of 136participants and 22 participants per block, we will need 6 blocks. All possible block permutations include AABB, ABAB, ABBA, BAAB, BABA, and BBAA. Then, a number from 1 to 6 will be randomly selected, and allocation will begin with that block. The subsequent blocks will also be selected and completed in the same manner.

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 the Faculty of Medical Sciences, Garash

Street address

Gerash City, Imam Hussein Blvd., Daneshjoo Blvd., Gerash Faculty of Medical Sciences

City

Gerash

Province

Fars

Postal code

7441758666

Approval date

2026-02-25, 1404/12/06

Ethics committee reference number

IR.GERUMS.REC.1404.023

Health conditions studied

1

Description of health condition studied

Diabetic Keto Acidosis

ICD-10 code

E10.10

ICD-10 code description

Type 1 diabetes mellitus with ketoacidosis without coma

Primary outcomes

1

Description

The effect of self-care training based on the family-centered empowerment model

Timepoint

Measuring the level of self-management before the start of the intervention and one month after the intervention.

Method of measurement

Diabetes self-management questionnaire

2

Description

Measuring self-care

Timepoint

Before the start of the intervention and one month after

the intervention

Method of measurement

Self-care Activities Summary Questionnaire

3

Description

Readmission rate

Timepoint

Before and one month after the intervention

Method of measurement

Demographic information questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Families and patients in this group are impacted by self-care education regarding diabetic ketoacidosis.In this way, the researcher provides face-to-face education for the companions of patients in the intervention group for three days about diabetes and its important complication, ketoacidosis, and strategies for preventing and dealing with it, with each session lasting approximately half an hour. After each session, the researcher asks the patient's companion to give his or her feedback on the information provided and to clarify any ambiguity. In addition, the patient's companion is asked to convey the information to the patient when he or she has enough energy and patience.The educational content of these three sessions is as follows: Session 1: Introduction to diabetes, its types, and proper diet adherence Session 2: How to use and store insulin (with an educational video) and, if taking oral diabetes medications, related training Session 3: Self-monitoring of blood sugar and familiarization with the symptoms of low or high blood sugar and strategies for dealing with it It should be noted that the content of the educational sessions will be collected from the book by Bruner and Suddarth, reputable websites and articles related to diabetes. After the intervention, patients and family members were given three months to take care of themselves and keep their disease under control based on the skills acquired in the educational sessions.

Category

Other

2

Description

Control group: Patients in this group will only undergo routine ward training.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohaday Hospital, Jahrom City

Full name of responsible person

Ali asghar Rahmanian kushkaki

Street address

Dr. Abdolreza Rahmanian Street, Ostad Motahari Blvd., Jahrom, Fars

City

Jahrom

Province

Fars

Postal code

7415854139

Phone

+98 71 5414 2000

Email

info@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gerash University of Medical Sciences

Full name of responsible person

Mohammad Jafari

Street address

Imam Hossein (AS) Blvd., Daneshjoo Blvd., Garash Faculty of Medical Sciences

City

Gerash

Province

Fars

Postal code

7441758666

Phone

+98 71 5244 8101

Email

info@gerums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gerash 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
Gerash University of Medical Sciences
Full name of responsible person
Ali asghar Rahmanian Kushkaki
Position
Instractor
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
Imam Hossein (AS) Blvd., Daneshjoo Blvd., Garash Faculty of Medical Sciences
City
Gerash
Province
Fars
Postal code
7441758666
Phone
+98 71 5244 8101
Email
info@gerums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Ali asghar Rahmanian Kushkaki
Position
Instractor
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
Imam Hossein (AS) Blvd., Daneshjoo Blvd., Garash Faculty of Medical Sciences
City
Gerash
Province
Fars
Postal code
7441758666
Phone
+98 71 5244 8101
Email
Lynurse8@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Aliasghar Rahmanian Kushkaki
Position
Instractor
Latest degree
Master
Other areas of specialty/work
Health Promotion
Street address
Imam Hossein (AS) Blvd., Daneshjoo Blvd., Garash Faculty of Medical Sciences
City
Gerash
Province
Fars
Postal code
7441758666
Phone
+98 71 5244 8101
Email
Lynurse8@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
There is no further 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available