Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of a Family-Centered Empowerment Model on Self-Management in Adolescents with Type 1 Diabetes

Protocol summary

Study aim
To determine the effect of the family-centered empowerment model on self-management among adolescents with type 1 diabetes.

Design
Randomized controlled clinical trial, parallel group, open-label, multicenter, on 90 patients. Block randomization with block size of four and allocation concealment using sequentially numbered, opaque, sealed envelopes are conducted.

Settings and conduct
The study is conducted in outpatient clinics and wards of Qods, Velayat, and Rahimian hospitals in Qazvin province. Participants are allocated to intervention and control groups. The intervention includes education based on the four steps of the family-centered empowerment model for adolescents and parents, while controls receive routine care. The study is open-label.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 12 to 18 years; insulin-treated type 1 diabetes; accompanied by a parent; no other chronic illness; basic literacy; informed consent and assent. Exclusion criteria: Acute diabetic complications or prolonged hospitalization; absence from over one third of sessions; withdrawal; loss to follow-up at post-test.

Intervention groups
Intervention group: Implementation of the family-centered empowerment model in four stages including perceived threat, self-efficacy, self-esteem, and process and final evaluation with follow-up. Control group: Receiving routine standard diabetes care and education.

Main outcome variables
Diabetes self-management score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260929071238N1**
Registration date: **2026-10-05, 1405/07/13**
Registration timing: **prospective**

Last update: **2026-10-05, 1405/07/13**
Update count: **0**

Registration date
2026-10-05, 1405/07/13

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of a Family-Centered Empowerment Model on Self-Management in Adolescents with Type 1 Diabetes

Public title
Effect of family empowerment on self-management in

adolescents with type 1 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 12 and 18 years at the time of entry into the study. Definitive diagnosis of type 1 diabetes mellitus by a pediatric endocrinologist based on standard diagnostic criteria. At least 6 months of documented history of type 1 diabetes to ensure familiarity of the adolescent and family with disease management principles. Receiving insulin therapy as the primary treatment regimen. Regular follow-up at the diabetes clinic or pediatric endocrinology center during the study period. Having at least one parent or primary caregiver (mother, father, or legal guardian) willing and able to participate in the family-centered empowerment program. Absence of acute or chronic comorbid conditions that could affect diabetes self-management ability, participation in educational sessions, or outcome evaluations. Ability of both the adolescent and parent/caregiver to communicate effectively and comprehend the educational content provided in the intervention sessions. Ability to read, write, and comprehend educational materials and complete the study questionnaires. No participation in similar structured diabetes education, self-management promotion programs, or family-centered empowerment interventions within the past 6 months. Providing written informed consent by parents or legal guardians along with written informed assent from the adolescent prior to study enrollment.

Exclusion criteria:

Occurrence of acute medical complications: Development of acute diabetes complications (such as severe diabetic ketoacidosis or hypoglycemia requiring emergency intervention) or any other acute underlying illness leading to prolonged hospitalization that prevents active participation in the study. Non-adherence to the intervention protocol: Absence from more than one-third (or more than two sessions) of the educational intervention sessions or failure to perform the activities and follow-ups specified in the empowerment model. Voluntary withdrawal: The desire of the parent or adolescent to withdraw from the study at any stage of the research process. Major changes in the treatment regimen: Implementation of significant and unusual changes in the adolescent's medication/treatment protocol outside of the routine clinic plan during the intervention period. Migration or loss to follow-up: Change of residence, lack of response to follow-ups, or inability to establish communication for post-test evaluations.

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible adolescents, following screening based on inclusion and exclusion criteria, were allocated into intervention (family-centered empowerment model) and control groups in a 1:1 ratio using permuted block randomization with a block size of 4. The random allocation sequence was generated using a table of random numbers. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) were utilized; each participant's envelope was opened sequentially only after obtaining written informed consent and confirming enrollment by an individual independent of the intervention team.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The study is a randomized controlled trial (RCT), parallel-group, open-label design. Participants are allocated to either the intervention or control group using block randomization (block size of 4). Allocation concealment is ensured using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Educational Block 1, Science and Research Branch, Islamic Azad University, Shohada-ye Hesarak Blvd, Daneshgah Sq, End of Shahid Sattari Expressway, Tehran, Iran

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Approval date

2026-04-20, 1405/01/31

Ethics committee reference number

IR.IAU.TMU.REC.1405.029

Health conditions studied

1

Description of health condition studied
Type 1 Diabetes Mellitus
ICD-10 code
E10
ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Diabetes self-management score measured by the standardized Diabetes Self-Management Questionnaire (comprising 27 items across 4 domains: glucose monitoring, diet, physical activity, and healthcare contact, scored on a 5-point Likert scale with total score ranging from 27 to 135)
Timepoint
At baseline (prior to intervention) and 3 months after completion of the intervention
Method of measurement
Self-reporting completion of the standardized Diabetes Self-Management Questionnaire by the adolescent

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group along with one of their parents will participate in an educational program based on the Family-Centered Empowerment Model (FCEM). The program consists of six 90-minute educational sessions conducted bi-weekly over 3 months (in-person and in small groups) at the hospital diabetes clinic. The intervention follows four steps: 1) Enhancing perceived threat (knowledge about diabetes nature, complications, and consequences of poor control), 2) Improving self-efficacy through problem-solving and practical skills (hands-on blood glucose monitoring, insulin injection technique, dietary and physical activity management, and handling emergencies), 3) Increasing self-esteem through educational participation (reinforcing the adolescent's role as an educational ambassador to share learning with family members and peer discussions), and 4) Formative and summative evaluation (assessing knowledge retention, addressing questions, and treatment adherence). An educational booklet will also be provided at the end of the intervention.
Category
Behavior

2

Description
Control group: Participants in the control group will only receive routine care and standard education provided at the hospital diabetes clinic (including periodic physician visits and standard advice from healthcare providers), with no structured empowerment program. To comply with research ethics, an educational summary booklet of the empowerment model will be provided to the control group participants and their families after completion of the study and post-test assessments.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
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2

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Qods hospital
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3

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Name of recruitment center
Rahimian hospital
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Sponsors / Funding sources

1

Sponsor
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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
Islamic Azad University
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
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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
Due to the necessity of maintaining strict confidentiality regarding the personal and identity-related information of the participants (children and adolescents), in accordance with biomedical ethics codes, and given that written informed consent was not obtained from parents or participants for the public disclosure of raw data in open-access databases, there is no plan to share the Individual Participant Data (IPD). However, the aggregated results and statistical analyses of this study will be published in the form of a thesis and scientific manuscripts.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable