Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of the Collaborative Care Model on Quality of Life and Self-Efficacy Among Students with Type 1 Diabetes: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the impact of implementing a Collaborative Care Model on the quality of life and self-efficacy of students with Type 1 Diabetes.

Design
A double-blind, randomized controlled clinical trial with parallel groups involving 58 diabetic students, utilizing the Sealed Envelope website for randomization.

Settings and conduct
This study will use convenience sampling to recruit participants and employ block random assignment for 58 students with Type 1 Diabetes visiting the educational and medical center of Dezful Big Hospital (Ganjoyan) who meet the inclusion criteria. Participants will be divided into two double-blinded groups of 29.

Participants/Inclusion and exclusion criteria
Students with type 1 diabetes

Intervention groups
The participatory care model in this study consists of four stages: motivation, preparation, engagement, and evaluation. 1.Motivation Stage: Patients will be educated about Type 1 Diabetes and its complications by a multidisciplinary team, including specialists and a family member, aiming to empower them with knowledge for managing their condition. 2.Preparation Stage: Specific educational goals will be set, including program timing and follow-up methods, ensuring patients know what to expect. 3.Engagement Stage: This phase includes five training sessions for the intervention group, focusing on practical skills related to diabetes management to enhance self-efficacy. 4.Evaluation Stage: After the intervention, an evaluation will assess the model's effectiveness by measuring changes in participants' quality of life and self-efficacy.

Main outcome variables
This model can be implemented in educational and treatment centers to improve the quality of life and self-efficacy of students with Type 1 Diabetes, while preventing long-term complications for patients and families and reducing additional costs for healthcare systems.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241130063895N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date
2025-01-08, 1403/10/19

Registrant information

Name
Simin Aghaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 916 098 7668

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Impact of the Collaborative Care Model on Quality of Life and Self-Efficacy Among Students with Type 1 Diabetes: A Randomized Clinical Trial

Public title
Exploring the Collaborative Care Approach for Students with Type 1 Diabetes

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Participants must be between 12 and 18 years old at the time of enrollment. Participants must be currently enrolled as students in a primary or secondary school. Participants must have a caregiver involved in their care and support. The student and their caregiver must be mentally healthy and free from significant mental illnesses. Participants must have a confirmed diagnosis of Type 1 diabetes made by a pediatrician. Participants must have a confirmed diagnosis of Type 1 diabetes made by a pediatrician. Participants must provide informed consent to participate in the study.

Exclusion criteria:
Individuals who do not meet the inclusion criteria will be excluded. Individuals with any other chronic illness will be excluded. If either the child or the caregiver develops a mental illness during the study, they will be excluded.

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants will be sampled using a convenience method. Subsequently, they will be allocated to two groups through a block randomization technique.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this method, considering the total number of 58 samples and the number of 2 study groups, the block size will be considered as a multiple of 2. Therefore, blocks of 2, 4, and 6 will be selected. Then, based on the online random assignment site, patients will be assigned to the test and comparison groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences

Street address
Motahari Boulevard, Yasouj University of Medical Sciences, Education, Research and Technology Department

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Approval date
2024-12-04, 1403/09/14

Ethics committee reference number
IR.YUMS.REC.1403.115

Health conditions studied

1

Description of health condition studied
Type 1 Diabetes

ICD-10 code
E10

ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Quality of Life Questionnaire Score (DQOLY)

Timepoint
Measurement of quality of life score at the beginning of the study (before the intervention) and at the end of the fifth intervention session (sixth session).

Method of measurement
Type 1 Diabetic Adolescent Quality of Life Questionnaire (DQOLY)

2

Description
Self-efficacy questionnaire for diabetic patients

Timepoint
Measuring self-efficacy scores at the beginning of the

study (before the intervention) and at the end of the fifth intervention session (sixth session).

Method of measurement

Self-efficacy questionnaire for diabetic patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participatory care model is implemented with researcher management for the intervention group. The participatory care model in this study consists of four stages: motivation, preparation, engagement, and evaluation. Training in the motivation stage is carried out by informing patients about the disease and its dangerous consequences and outcomes with the cooperation of all team members and the client. In the next step, preparation, educational goals and the timing of the education programs and the method of follow-up are determined. Engagement is also implemented by holding 5 training sessions for the intervention group, and then evaluation is carried out after the intervention.

Category

Lifestyle

2

Description

Control group: The control group does not receive any intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dezful Grand Hospital (Ganjovian)

Full name of responsible person

Simin aghaee

Street address

Rana Building, Corner of Hafez 12 Street, Hafez District, Dezful, Khuzestan

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siminaghaee97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hosseini Motlagh

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Research Deputy, Yasuj University of Medical Sciences, Shahid Motahari Boulevard, Yasuj, Kohgiluyeh and Boyer-Ahmad Province

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Simin Aghaee

Position

Master's student in Pediatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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
The only part of the data that can be shared is information related to the main outcome or similar aspects.
When the data will become available and for how long
Access begins 6 months after the publication of the results
To whom data/document is available
For researchers working in academic and scientific institutions, as well as in private and public clinics and hospitals.
Under which criteria data/document could be used
Any use of published documents is permitted, provided that proper referencing is given.
From where data/document is obtainable
Researcher: Simin Aghaei Email: siminaghaee97@gmail.com Address: Hazrat Zainab School of Nursing, Yasuj University of Medical Sciences, Yasuj, Iran
What processes are involved for a request to access data/document
Any correspondence and requests will be addressed exclusively through the researcher's email and will be responded to within a maximum of two weeks.
Comments