Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of educational therapy intervention based on the theory of planned behavior on self-care behaviors of people with type 2 diabetes

Protocol summary

Study aim

Determining the effect of educational intervention on self-care behaviors in patients with type 2 diabetes referring to comprehensive health centers in Khorramshahr city based on the theory of planned behavior

Design

This study is a multi-center single-blind cluster randomized controlled trial on 180 patients selected through systematic random sampling.

Settings and conduct

This study is designed as a multi-center cluster randomized controlled trial. The study population consists of patients with type 2 diabetes who attend urban, rural, and urban–rural comprehensive health service centers in Khorramshahr. In this study, comprehensive health service centers are considered as clusters. First, a complete list of all comprehensive health service centers in Khorramshahr will be prepared, and six centers will then be selected using simple random sampling. These centers will be allocated by a statistician to either the intervention group (three centers) or the control group (three centers). A total of 180 participants will be enrolled in the study, with 30 patients with type 2 diabetes selected from each center using systematic random sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria were a confirmed diagnosis of type 2 diabetes, absence of neurological diseases or learning disorders, and informed consent to participate. Exclusion criteria included unwillingness to continue participation, absence from at least half of the educational sessions, change of address or contact number, and death of the participant.

Intervention groups

The intervention group will receive two face-to-face and four virtual educational sessions over four weeks, while the control group will receive routine health care.

Main outcome variables

Knowledge, attitude, abstract norms, perceived behavioral control, behavioral intention, social support, diabetes-related behavior, fasting blood sugar

General information

Reason for update

The information recorded in the IRCT system was revised to resolve certain writing and methodological inconsistencies, clarify intervention details, align the description of the randomization method and study design with the actual conduct of the research (including changing the blinding from double-blind to single-blind), and update the final study status and the number of participants analyzed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250701066313N1**
Registration date: **2025-07-17, 1404/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-02, 1405/04/11**
Update count: **1**

Registration date

2025-07-17, 1404/04/26

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-07, 1404/04/16
Expected recruitment end date
2025-07-17, 1404/04/26
Actual recruitment start date
2025-07-07, 1404/04/16
Actual recruitment end date
2025-08-11, 1404/05/20
Trial completion date
empty

Scientific title
Investigating the effect of educational therapy intervention based on the theory of planned behavior on self-care behaviors of people with type 2 diabetes

Public title
Investigating the effect of educational intervention on self-care behaviors of people with type 2 diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Doctor-confirmed type 2 diabetes No neurological diseases or learning disorders Informed consent to participate in the study
Exclusion criteria:
Unwillingness to continue participating in this research Not attending half of the training sessions Changing the address and contact number where the person cannot be reached. Death
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **180**
Actual sample size reached: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be conducted as a multi-center cluster randomized controlled trial among patients with type 2 diabetes attending urban, rural, and urban-rural comprehensive health service centers in Khorramshahr, Khuzestan Province, Iran. In this study, the comprehensive health service center will be considered the cluster and the unit of randomization. A multistage sampling method will be used. First, a list of all urban, rural, and urban–rural comprehensive health service centers in Khorramshahr will be prepared, and six centers will be selected using simple random sampling. These six centers (clusters) will then be randomly allocated by a statistician to either the intervention group (three centers) or the control group (three centers) using simple random allocation. After the allocation of clusters, the list of patients with type 2 diabetes covered by each center will be obtained and used as the sampling frame. From each center, 30 eligible participants will be selected using systematic random sampling. Additionally, a list of 30 replacement participants will be prepared to substitute individuals who do not meet the inclusion criteria or decline participation. All participants in centers allocated to the intervention group will receive the educational intervention, whereas participants in centers allocated to the control group will receive routine care provided by the health centers. In this design, all patients within each center will be assigned to the same study group according to the cluster allocation in order to prevent contamination between the intervention and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is designed as a single-blind trial. In this study, the data analyst will be blinded to the allocation of participants to the intervention and control groups as well as to the details of the intervention. Due to the educational nature of the intervention, blinding of participants is not feasible.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
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Postal code
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Approval date
2025-01-04, 1403/10/15
Ethics committee reference number
IR.AJUMS.REC.1403.540

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the effect of educational intervention on awareness of self-care behaviors in patients with type 2 diabetes referring to comprehensive health centers in Khorramshahr city
Timepoint
Measuring awareness of self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Awareness questionnaire

2

Description
Determining the effect of educational intervention on attitudes towards self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring attitudes towards self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Attitude questionnaire

3

Description
Determining the effect of educational intervention on abstract norms towards self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring abstract norms towards self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Abstract Norms Questionnaire

4

Description
Determining the effect of educational intervention on perceived behavioral control towards performing self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring perceived behavioral control over self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Perceived Behavioral Control Questionnaire

5

Description
Determining the effect of educational intervention on behavioral intention to perform self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring behavioral intention to perform self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Behavioral Intention Questionnaire

6

Description
Determining the effect of educational intervention on self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring self-care behaviors in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention
Method of measurement
Self-care Behaviors Questionnaire

7

Description
Determining the effect of educational intervention on social support for self-care behaviors in patients with type 2 diabetes
Timepoint
Measuring social support for self-care behaviors in people with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Social support questionnaire

8

Description
Determining fasting blood sugar scores in people with type 2 diabetes
Timepoint
Measurement of fasting blood sugar scores in patients with type 2 diabetes before the start of the intervention and 90 days after the intervention.
Method of measurement
Glucometer device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participants in the control group will receive only the routine health care services provided at the comprehensive health service centers during the study period.

Category

Behavior

2

Description

Intervention group: In the intervention group, a blended educational program consisting of face-to-face and virtual education will be implemented. The face-to-face component will be conducted through lecture sessions accompanied by question-and-answer discussions, while the virtual component will include educational video clips, distribution of pamphlets, and motivational educational text messages sent to the participants' mobile phones. The intervention is designed based on the Theory of Planned Behavior and will be delivered over four weeks, including two one-hour face-to-face educational sessions and four virtual sessions during the same period. After obtaining informed consent from the participants, the questionnaires will be completed and fasting blood sugar (FBS) will be measured in both the intervention and control groups before the start of the intervention. In addition, three months after completion of the educational program, follow-up will be conducted, the questionnaires will be completed again, and fasting blood sugar will be measured by taking blood samples from patients at the comprehensive health service centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Comprehensive Rural Health Services Center

Full name of responsible person

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Recruitment center

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3

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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
Ahvaz 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

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Latest degree
Ph.D.
Other areas of specialty/work
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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
No further information available.

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
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available