Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of self-care training on the disease management of people with diabetes in prevention and health promotion clinics affiliated to Hamedan University of Medical Sciences in 2024

Protocol summary

Study aim
The effect of self-care training on disease management of people with diabetes

Design
A clinical trial with a control group, with parallel groups, not blinded, non-randomized

Settings and conduct
The place of the project is in prevention and health promotion clinics. The method of data collection is that in the initial phase and before diabetes self-care training, both intervention and control groups will complete questionnaires, then in the second phase of the study and three months after receiving self-care training in the intervention group, questionnaires will be distributed again and will be completed.

Participants/Inclusion and exclusion criteria
Confirmation of diabetes by a doctor (type one or type two); At least 6 months have passed since the diagnosis of diabetes; Being literate in reading and writing in the patient; Age over ten years

Intervention groups
The intervention group will undergo diabetes self-care training by social medical specialists, and the control group will only be monitored for three months.

Main outcome variables
Quality of Life; foot care status; adherence to the Mediterranean diet; physical activity; Medication compliance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141027019694N2**
Registration date: **2024-01-03, 1402/10/13**
Registration timing: **prospective**
Last update: **2024-01-03, 1402/10/13**
Update count: **0**

Registration date
2024-01-03, 1402/10/13

Registrant information

Name
Azar Pirdehghan

Name of organization / entity
Hamadan university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0572

Email address
a.pirdehghan@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-31, 1402/11/11

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of self-care training on the disease management of people with diabetes in prevention and health promotion clinics affiliated to Hamedan University of Medical Sciences in 2024

Public title
The effect of diabetes self-care education on diabetes

management

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of diabetes by a doctor (type 1 or type 2 diabetes) At least 6 months have passed since the diagnosis of diabetes Being literate in reading and writing in the patient Age over ten years Willingness to participate in the study

Exclusion criteria:

Having a cognitive problem Suffering from serious and debilitating complications caused by diabetes, such as severe kidney failure, heart failure, blindness, etc Having concurrent diseases (comorbidity) Use of immunosuppressive drugs and corticosteroids

Age

From **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Hamedan University of Medical Sciences

Street address

address: Hamadan University of Medical Sciences Headquarters, Shahid Fahmideh St. zip code: 6517838736

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-11-05, 1402/08/14

Ethics committee reference number

IR.UMSHA.REC.1402.564

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

The self-care score in the diabetes self-care questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and 3 months after the self-care training

Method of measurement

Diabetic self-care questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

At the beginning of the study and three months after the self-care training

Method of measurement

Quality of life questionnaire

2

Description

Foot care status

Timepoint

At the beginning of the study and three months after the self-care training

Method of measurement

Foot care status questionnaire

3

Description

Adherence to the Mediterranean diet

Timepoint

At the beginning of the study and three months after the self-care training

Method of measurement

Mediterranean diet compliance questionnaire

4

Description

Physical activity status

Timepoint

At the beginning of the study and three months after the self-care training

Method of measurement

Physical activity questionnaire

5

Description

Medication adherence

Timepoint

At the beginning of the study and three months after the self-care training

Method of measurement

Medication compliance questionnaire

Intervention groups

1

Description

Intervention group: In the prevention and health promotion clinics, the specialists of the social medicine group provide face-to-face training for diabetic patients who refer to the centers after taking a comprehensive history, complete examinations and completing a comprehensive health file. The self-care education of patients in this study is direct and indirect. In direct education, social medical specialists teach patients the basic principles and how to self-care for diabetes in person and for one hour. Educational axes in the DSME approach with the aim of improving blood sugar control include reducing glycosylated hemoglobin and fasting blood sugar, as well as increasing patients' compliance in the correct use of medications and lifestyle modification in order to reduce complications and increase quality of life, and include the definition of the disease, a summary of the disease process, Complications of diabetes, ways to prevent complications, nutrition in diabetes, the need to exercise, how to perform physical activities, how and when to measure blood sugar by a diabetic person, medications and how to take them correctly and regularly, how to inject insulin and medication side effects, self-management of change Behavior and control of stress and quitting unhealthy behaviors from before such as smoking and alcohol consumption and the time and intervals of referrals to check eye, heart and kidney complications. Risk assessment is done for patients and preventive measures are recommended at different levels based on age and sex and risk level. Necessary screenings are also performed. In indirect education, manuals and pamphlets and approved online sites are introduced to patients with various subjects of self-care education to study at home (study duration is about 2.5-3 hours). The duration of teaching patients is about four hours in total.

Category

Behavior

2

Description

Control group: This group is only monitored for three months without receiving self-care training by social medical specialists.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Be'sat Hospital

Full name of responsible person

Azar Pirdehghan

Street address

Hamadan University of Medical Sciences Headquarters, Shahid Fahmideh St. - zip code: 6517838736

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3131 0000

Email

webda@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

Street address

Hamadan University of Medical Sciences Headquarters, Shahid Fahmideh St.

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3131 0000

Email

webda@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Erfan Rajabi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Number 35, Ghadir dead end, Sheghaiq Alley, Sanati St, Resalat Square
City
Hamedan
Province
Hamadan
Postal code
6515798737
Phone
+98 81 3822 1862
Email
erfanrajabi542@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Azar Pirdehghan
Position
Community medicine assistant proffessor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Community medicine department, Medical school, Hamadan University of medical sciences, Hamadan, Iran.
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۷۳۶
Phone
+98 81 3838 0572
Fax
Email
a.pirdehghan@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Azar Pirdehghan
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Community medicine department, Medical school, Hamadan University of medical sciences, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۷۳۶
Phone
+98 81 3838 0572
Fax
+98 81 3838 0208
Email
a.pirdehghan@umsha.ac.ir

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
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to compare with similar studies and perform meta-analysis

From where data/document is obtainable

Azar PirDehghan, email: a.pirdehghan@umsha.ac.ir Erfan Rajabi, email: erfanrajabi542@gmail.com

What processes are involved for a request to access data/document

The requester will send a message to the email and a response will be given within one month.

Comments