

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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**