

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of homecare program implementation versus non-homecare on treatment compliance and self-efficacy in patients with type 2 diabetes: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of home care program implementation versus non-homecare on treatment compliance and self-efficacy in patients with type 2 diabetes

##### Design

This is a randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with type 2 diabetes who will refer to the Diabetes Research Center in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 30 to 70 years; Type 2 diabetes; A history of disease for at least 6 months; Literate  
Exclusion criteria: Acute or severe disease; Affecting with diabetes complications; Psychological disorders; Drug or alcohol abuse

##### Intervention groups

Intervention group: Routine treatment plus homecare educational program for 30 to 40 minutes once a week for 2 weeks  
Control group: Just routine care

##### Main outcome variables

Primary outcome: Assessing the treatment compliance  
Assessing the self-efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N263**

Registration date: **2019-02-18, 1397/11/29**

Registration timing: **prospective**

Last update: **2019-02-18, 1397/11/29**

Update count: **0**

##### Registration date

2019-02-18, 1397/11/29

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of homecare program implementation versus non-homecare on treatment compliance and self-efficacy in patients with type 2 diabetes: a randomized clinical trial

##### Public title

Effect of homecare program implementation versus non-

homecare on treatment compliance and self-efficacy in patients with type 2 diabetes

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age of 30 to 70 years; Type 2 diabetes; A history of disease for at least 6 months; Literate

##### **Exclusion criteria:**

Acute or severe disease; Affecting with diabetes complications; Psychological disorders; Drug or alcohol abuse

#### **Age**

From **30 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

#### **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 Hamadan University of Medical Sciences

###### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

###### **City**

Hamadan

#### **Province**

Hamadan

#### **Postal code**

6517838695

#### **Approval date**

2019-01-26, 1397/11/06

#### **Ethics committee reference number**

IR.UMSHA.REC.1397.769

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Diabetes mellitus

##### **ICD-10 code**

E08

##### **ICD-10 code description**

Diabetes mellitus due to underlying condition

### **Primary outcomes**

#### **1**

##### **Description**

Assessing the treatment compliance

##### **Timepoint**

Before the intervention and 2 weeks after the intervention

##### **Method of measurement**

Through history taking

#### **2**

##### **Description**

Assessing the self-efficacy

##### **Timepoint**

Before the intervention and 2 weeks after the intervention

##### **Method of measurement**

By using standard questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Routine treatment plus homecare educational program for 30 to 40 minutes once a week for 2 weeks

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: Just routine care

##### **Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Diabetes Research Center in Hamadan City

**Full name of responsible person**

Hajar Najafi

**Street address**

Diabetes Research Center in Hamadan City, Eram Ave.

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**Province**

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13316najafi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@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**

Hajar Najafi

**Position**

Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Roya Amini

**Position**

MSc in Nursing

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Master

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available