

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of educational intervention based on self-regulation theory to increase medication adherence in Type 2 diabetic patients

#### Protocol summary

##### Summary

The aim of this study was to determine the effect of educational program based on the theory of self-regulation in increasing medication adherence in type II diabetic patients. Methods: This is an interventional study with two groups, pre-test and post-test will be performed on 120 patients with type II diabetes aged between 30 and 65 years, who meet in the home health records, consent to participate in the study and be able to participate Meetings and understanding, they will be carried out. Samples will be randomly drawn. Intervention (education based on the theory of self-regulation) will be conducted on case groups. A self-made questionnaire which its validity and reliability study to be checked before and 8 weeks after treatment, all samples will be answered.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015121425518N1**

Registration date: **2015-12-29, 1394/10/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-29, 1394/10/08

##### Registrant information

##### Name

Behzad Gholamaliei

##### Name of organization / entity

Hamadan University of Medical Sciences, School of Public Health

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3493 6012

##### Email address

b.gholamaliei@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellor for Research and Technology of the Hamadan University of Medical Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of educational intervention based on self-regulation theory to increase medication adherence in Type 2 diabetic patients

##### Public title

The effect of education on medication adherence in patients with type II diabetes

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: having health records in health center for control and treatment of diabetes, satisfaction from the study, diabetic patients are able to participate in training sessions and understand the training offered and aged between 30 to 65 years Exclusion criteria: patients with diabetes who does not wish to continue participating in the study, Patients with diabetes who are not attending regular training sessions, Age less than 30 years and more than 65 years

**Age**

From **30 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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 the Hamadan University of  
Medical Sciences

**Street address**

Hamadan, Martyr Fahmideh Street, Hamadan  
University of Medical Sciences, School of Public  
Health

**City**

Hamadan

**Postal code**

65178

**Approval date**

2015-07-25, 1394/05/03

**Ethics committee reference number**

IR.UMSHA.REC.1394.198

**Health conditions studied****1****Description of health condition studied**

Type 2 diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

**Primary outcomes****1****Description**

Medication Adherence

**Timepoint**

Before and one month after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control: no intervention

**Category**

N/A

**2****Description**

Intervention: medication adherence education based on  
self-regulation theory and the method Teach Back and  
Pictorial for 4 sessions for patients with type 2 diabetes.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Health center of Tuyserkan

**Full name of responsible person**

Behzad Gholamaliee

**Street address**

Hamadan, Martyr Fahmideh Street, Hamadan  
University of Medical Sciences, School of Public  
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**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research and Technology of the  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeed Bashirian

**Street address**

Hamadan, Martyr Fahmideh Street, Hamadan  
University of Medical Sciences, Vice-Chancellor for  
Research and Technology

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-Chancellor for Research and Technology of the  
Hamadan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Hamadan University of Medical Sciences, School of  
Public Health

**Full name of responsible person**

Behzad Gholamaliei

**Position**

MSc student in Health Education

**Other areas of specialty/work**

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Dr Akram Karimi-Shahanjarin

**Position**

Phd in Health education

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**Web page address**

**Sharing plan**

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

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty