

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of Team education on HbA1c levels in patients with diabetes type 2

#### Protocol summary

##### Study aim

Determine the effect of teamwork on HbA1c in patients with type 2 diabetes

##### Design

To determine the sample size, the guide study and the mean comparison formula with 95% confidence interval and 80% test power were used, 35 of which were estimated in each group (23). Considering the probable loss of samples, 40 people were estimated for each group. Therefore, 80 patients with type 2 diabetes in the diabetes unit of Bahar in 1395 would be eligible for a simple random sampling in two intervention and control groups.

##### Settings and conduct

The present study is an interventional study with the aim of evaluating the effect of teamwork on HbA1c in patients with type 2 diabetes in diabetes mellitus in Bahar in 1396. The population under study in this study is type 2 diabetes patients living in Bahar, Hamadan province, who are referred to the diabetes department. The main tool of the research is a questionnaire containing personal information and patient's laboratory and educational records.

##### Participants/Inclusion and exclusion criteria

Admission criteria for inclusion in the study include: aged 30 years and above, at least one year after diagnosis of type 2 diabetes, patients treated with oral pill, patients treated with insulin injections, and patients treated with both methods Treatment, having at least literacy, reading and writing, and having. Exclusion criteria include discontinuation of entry into the study, the occurrence of gestational diabetes, complications of diabetes mellitus such as kidney stroke, blindness, etc., of severe illnesses such as various cancers and other chronic and debilitating illnesses. The need for home care is the occurrence of a variety of diseases that affect the level of HbA1c, such as the occurrence of anemia, hemoglobinopathy, uremia, kidney failure, etc., the types of diseases that affect the understanding or receipt of

patient support The family is affected, such as having a mental illness or having an addiction.

##### Intervention groups

The number of training sessions in the intervention group was performed by the diabetes team of the diabetes community in Bahar city, consisting of 3 people (internist, nurse and nutrition expert); 12 sessions of maximum 3 hours (4 sessions each month). The intervention group was randomly divided into four groups: 13-12 They will receive a training session each month (in the whole intervention group they will attend 3 times in the training sessions). In each session, each member of the trainer will provide at least 0.5 hours of relevant training to the intervention team and their attendants, and then answer 0.5 hours to the questions and answers of the patients.

##### Main outcome variables

Reduce complications of diabetes, increase patient quality of life, self-care in patients, counseling and team training on disease improvement, lifestyle changes in patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171202037702N1**

Registration date: **2018-01-09, 1396/10/19**

Registration timing: **prospective**

Last update: **2018-01-09, 1396/10/19**

Update count: **0**

##### Registration date

2018-01-09, 1396/10/19

##### Registrant information

##### Name

Alireza Moradi

##### Name of organization / entity

**Country**  
Iran (Islamic Republic of)

**Phone**  
+98 81 3450 9994

**Email address**  
ali.moradi@umsha.ac.ir

**Recruitment status**  
**Recruitment complete**

**Funding source**

**Expected recruitment start date**  
2018-01-20, 1396/10/30

**Expected recruitment end date**  
2018-02-04, 1396/11/15

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of Team education on HbA1c levels in patients with diabetes type 2

**Public title**  
The effect of Team education on HbA1c levels in patients with diabetes type 2

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age of 30 years and older, at least one year after diagnosis of type 2 diabetes, patients treated with oral contraceptives, patients treated with insulin injections, and patients treated with both methods of treatment, having at least reading and writing skills  
**Exclusion criteria:**  
Dissatisfaction with entering the study, having diabetes, pregnancy complications, diabetes mellitus such as kidney stroke, blindness, etc., serious illnesses such as various cancers and other chronic and debilitating diseases that require home care Have a variety of diseases that affect HbA1c levels, such as all types of anemia, hemoglobinopathies, uremia, kidney failure, and the like of a variety of diseases that affect the understanding or support of the patient's family support, such as Having a mental illness or having an addiction

**Age**  
From **30 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**

They were randomly divided into two intervention and control groups(Use the random numbers table)

**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

Shariati Street

##### City

hamadan

##### Province

Hamadan

##### Postal code

65178838678

#### Approval date

2017-11-25, 1396/09/04

#### Ethics committee reference number

IR.UMSHA.REC.1396.567

## Health conditions studied

### 1

#### Description of health condition studied

Team education

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Reducing HbA1c

#### Timepoint

Prior to entering the study, the patient performed the relevant test within the last 2-4 weeks at the selected central lab of the city or will be requested by a specialist physician. As well as the results of the HbA1c test in two intervention and control groups after the study, which the patient will undergo the relevant test 8-12weeks after training in the selected central lab of the city.

#### Method of measurement

With the Hiccard Marker HbA1C (NYCOCARD)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The number of training sessions in the intervention group was performed by the diabetes team of the diabetes community in Bahar city, consisting of 3 people (internist, nurse and nutrition expert); 12 sessions of maximum 3 hours (4 sessions each month). The intervention group was randomly divided into four groups: 13-12 They will receive a training session each month (in the whole intervention group they will attend 3 times in the training sessions). In each session, each member of the trainer will provide at least 0.5 hours of relevant training to the intervention team and their attendants, and then answer 0.5 hours to the questions and answers of the patients.

#### Category

Prevention

### 2

#### Description

The control group receives routine training and treatment according to the routine diabetes plan. In routine training, the patient is trained by a nurse, doctor or counselor, and only the steps that the patient needs to follow is provided to him at each visit (if he has time) by a member of the diabetes team. In some cases, due to the busy unit of diabetes, a person may not have normal training.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

diabetes unit of bahar

##### Full name of responsible person

mahdi rezvan

##### Street address

Imam street

##### City

bahar

##### Province

Hamadan

##### Postal code

651833147

##### Phone

+98 81 3451 1340

##### Fax

+98 81 3450 9994

##### Email

moradi783@yahoo.com

#### Web page address

<http://shb.umsha.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Saeed Bashirian

##### Street address

Shariati

##### City

hamadan

##### Province

Hamadan

##### Postal code

6517838678

##### Phone

+98 81 3838 0572

##### Email

bashiri\_3@yahoo.com

##### Web page address

<http://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

alireza moradi

##### Position

Employee

##### Latest degree

Master

##### Other areas of specialty/work

Public Health

##### Street address

emam

##### City

bahar

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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

Not applicable

### Informed Consent Form

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

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable