

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)

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+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

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651833147

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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

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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

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emam

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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