

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison the effect of conventional and distance training of problem solving on self care and Hg A1C in patients with type 2 diabetes

#### Protocol summary

##### Summary

Diabetes is a chronic illness which needs specific self care behaviors to the end of life. About improvement of metabolic status for which self care education specially with active method (active involvement of diabetic patients) is necessary. Due to the importance of self care, this study aimed to the effective comparison of conventional by problem solving method with and distance training on self care and Hg A1C rate in patients with type 2 diabetes will be done. This interventional quasi-experimental study was performed by choosing 90 diabetic patients randomly divided into three experimental and control groups. Educational programs designed for patients in the intervention group included six sessions. Three months after the educational intervention, the results were evaluated. The second group received indirect education. CDs and pamphlets were provided for them. The control group did not receive intervention. This experimental study was carried out on patients with type 2 diabetes that ages between 30-70 years old and having willingness to participate in the study in Exclusion criteria registered to the Gonabad Diabetes Association. Ninety patients were selected and randomly allocated into three intervention and control groups. Data were gathered using the Summary of Diabetes Self-Care Activities questionnaire and getting a blood test for glycosylated hemoglobin from patients. Data were analyzed using the Chi-squared test, paired t-test and independent t-test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014040817183N1**

Registration date: **2014-09-06, 1393/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-09-06, 1393/06/15

##### Registrant information

###### Name

Ezat Razizadeh shahry

###### Name of organization / entity

Gonabad Univesity of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 53 3723 2918

###### Email address

razizadeh.e@gmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Gonabad Univesity of Medical Sciences

##### Expected recruitment start date

2014-01-05, 1392/10/15

##### Expected recruitment end date

2014-04-04, 1393/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of conventional and distance training of problem solving on self care and Hg A1C in patients with type 2 diabetes

##### Public title

The impact of education on diabetes treatment

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria: 1- patients with type 2 diabetes; 2- at least having the level of primary education; 3- having no acute complications and able to response to questionnaire; 4- having no psychological disease; 5- having willingness to participate in the study; 6- ages between 30-70 years old; Exclusion criteria: 1- no willingness to continue the study, 2- researcher found the exchange of educated information between two intervention and control groups, 3- change in activity, dietary habits and medications, 4- having diabetes complications can be prevented investigation.

## **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: **90**

## **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**

University of Medical Sciences and Health Services  
GONABAD

##### **Street address**

Gonabad-Asian Road Border

##### **City**

Gonabad

##### **Postal code**

9691793718

#### **Approval date**

2014-01-01, 1392/10/11

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

GMU.REC.1392.25

## **Health conditions studied**

### 1

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

diabet

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

E11

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

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

self care

#### **Timepoint**

Before and 3 months after intervention

#### **Method of measurement**

problem solving method from doctor Saif

### 2

#### **Description**

HA1C

#### **Timepoint**

Before and 3 months after intervention

#### **Method of measurement**

blood test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The second group received indirect education. CDs and pamphlets were provided for them. Data were gathered using the Summary of Diabetes Self- Care Activities questionnaire and getting a blood test for glycosylated hemoglobin from patients.

#### **Category**

Lifestyle

### 2

#### **Description**

It is an educational group intervention. Problem solving training on self-care behaviors are performed within 6 sessions.

#### **Category**

Lifestyle

### 3

#### **Description**

The control group did not receive intervention. Data were gathered using the Summary of Diabetes Self- Care Activities questionnaire and getting a blood test for glycosylated hemoglobin from patients.

#### **Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Gonabad Health Center

**Full name of responsible person**

Mrs Zohreh Ahrari

**Street address**

22 Bahman Hospital, Naser khosro Street

**City**

Gonabad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Gonabad Univesity of Medical Sciences

**Full name of responsible person**

Ali Ekrami

**Street address**

Next to Asian Road, Gonabad Univesity of Medical Sciences

**City**

Gonabad

**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, Gonabad Univesity 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**

Gonabad University Of Medical Sciences

**Full name of responsible person**

Ezat razizadeh shahry

**Position**

Bsc. in Nursing- Msc. student in nursing

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

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## **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*