

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of education on mental health and self-care in type II diabetic patients.

#### Protocol summary

##### Summary

objective: Determine the effect of self-care education program on mental health and self-esteem in patients with type 2 diabetes. Designing : This is a non-randomized clinical trial study with pre-test and post-test will be done with the control group. Among the 78 patients with type 2 diabetes are selected as the sample are considered. procedure: This will be the all of the samples (control and test), questionnaire of mental health and self-esteem In the first meeting with the investigator, will be completed. Type II diabetes self-management training programs through face-to-face intervention, speech and question and answer, In three one-hour sessions over three weeks (three weeks will be consecutive.) For the experimental group, will be held. During the intervention control group, the intervention will be taken. Self-esteem and mental health of patients and control groups, one month after the training, By Goldberg mental health questionnaire and Rosenberg self-esteem questionnaire, measured And mental health and self-esteem at the end of the two groups will be studied and analyzed. Inclusion criteria: 1. whether people with type 2 diabetes, according to the treating physician; 2. 40-60 years of age; 3 - the ability to perform self-care company continued exclusion criteria: 1. Lack of patient consent to participate in research continue 2 absence In a training session interventions: type II diabetes self-management education program .The primary outcome variable: mental health and self-esteem. No secondary outcome.

#### General information

##### Acronym

not

##### IRCT registration information

IRCT registration number: **IRCT2017030932511N1**

Registration date: **2017-03-09, 1395/12/19**

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

Last update:

Update count: **0**

##### Registration date

2017-03-09, 1395/12/19

##### Registrant information

###### Name

mahnaz shabani

###### Name of organization / entity

Iran University of Medical Sciences. nursing school

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8888 2885

###### Email address

mahnaz.shabani2013@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences Nursing school

##### Expected recruitment start date

2017-02-19, 1395/12/01

##### Expected recruitment end date

2017-04-14, 1396/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of education on mental health and self-care in type II diabetic patients.

##### Public title

The effect of self-care education on mental health and self-esteem

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

.Inclusion criteria:1 infected subjects with type 2 diabetes, according to the treating physician; 2. 40-60 years of age; 3. monthly referral of patients to the health center city of Amol;4. Sign in cases of mental illnesses 5. The ability to self care(Lack of upper limb disabilities or lack of disease, orthopedic (musculoskeletal) and Rheumatology upper limb ...).Exclusion criteriaLack of patient consent to participate in the continuing investigation 2. sudden withdrawal of one or more persons Of subjects during the study and to participate in training programs, for reasons such as relocating Location of the city of Amol 3 The incidence of some side issues, family etc. or pleasant consequences for one or more subjects 4 do not Participate in a training session.

## **Age**

From **40 years** old to **60 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **78**

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

Randomized

## **Randomization description**

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

Not blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

not

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

iran medical science university

##### **Street address**

tehran.hemmat free way.side of milad tower

##### **City**

tehran

##### **Postal code**

IR.IUMS.REC.1395.921

##### **Approval date**

2016-05-17, 1395/02/28

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

IR.IUMS.REC 9211196244.1395

### 2

#### **Ethics committee**

##### **Name of ethics committee**

iran medical science university

##### **Street address**

tehran.hemmat free way.side of milad tower

##### **City**

tehran

##### **Postal code**

1449614535

##### **Approval date**

2016-02-28, 1394/12/09

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

IR.IUMS.REC 9211196244.1395

## **Health conditions studied**

### 1

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

Type 2 of diabetes mellitus

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

E 14

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

Unspecified diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

self steem

#### **Timepoint**

before and 1 month after of intervention

#### **Method of measurement**

RSES questionair

### 2

#### **Description**

sanity

#### **Timepoint**

before and 1 mount after of intervention

#### **Method of measurement**

GHQ -28- questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The control group was not performed and only at the end will receive a training manual.

#### **Category**

Other

## 2

### Description

Type II diabetes self-management training programs through face-to-face intervention, speech and question and answer, in three one-hour sessions over three weeks (three weeks will be consecutive.) For the experimental group, will be held.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

mofatteh clinic

**Full name of responsible person**

maryam qobadi raad

**Street address**

mazandaran.amol.28th aftar.mofatteh clinic

**City**

amol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

the assistance of research of University of Medical Sciences

**Full name of responsible person**

seyyed ali javad moosavi

**Street address**

Besides Milad Tower proper task of promoting martyr Hemmat Highway of Medical Sciences

**City**

tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

the assistance of research of 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**

School of Nursing and Midwifery, Iran University of Medical Sciences

**Full name of responsible person**

fariba nasiri ziba

**Position**

Master of nursing

**Other areas of specialty/work****Street address**

Tehran Nursing and Midwifery Iran .vlysr St. martyr Yassami .danshkdh

**City**

tehran

**Postal code**

1449614535

**Phone**

+98 21 8888 2885

**Fax**

+98 21 8888 2885

**Email**

fariba\_nz@yahoo.com

**Web page address**

www.iums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of Nursing and Midwifery in Iran

**Full name of responsible person**

fariba nasiri ziba

**Position**

Master of nursing

**Other areas of specialty/work****Street address**

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www.iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

School of Nursing and Midwifery in Iran

**Full name of responsible person**

mahnaz shabani

**Position**

Masters student

**Other areas of specialty/work**

**Street address**

Age .kh martyr Yassami .danskdh Nursing Iran

**City**

tehran

**Postal code**

1449614535

**Phone**

+98 21 8888 2885

**Fax**

+98 21 8888 2885

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mahnaz.shabani2013@gmail.com

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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*