

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

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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 aftab.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

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Person responsible for updating data

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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