

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the effect of healthy lifestyle education through peer education and virtual education (based on Interactive virtual classroom and applications) on indicators of lifestyle that promotes health, self-esteem and self-efficacy of diabetics referred to military hospitals

Protocol summary

Study aim

Comparison of the effect of healthy lifestyle education through peer education and virtual education on indicators of lifestyle that promotes health, self-esteem and self-efficacy of diabetics referred to military hospitals

Design

Clinical trial with control group, with parallel groups, without blinding, by Convenience Sampling, on 135 patients.

Settings and conduct

In three groups of peer education, virtual education and control will be done in the medical centers of the Army University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at least six months of diagnosis of uncontrolled type 2 diabetes, 21 to 75 years of age, no history of participation in diabetes education programs in the last six months, the possibility of installing software in the mobile phone and Internet access, lack of cognitive problems, physical disabilities, hearing or vision impairment. Exclusion criteria: the new physical problem resulting disability, Reluctance to participate, no ability to use the software.

Intervention groups

Peer training group: Peer training, through trained peers in the form of face-to-face training with classes, lectures, and questions and answers through 4, 35 minutes sessions. Virtual education group: The prepared educational program including clip, image, audio, text, and application will be provided to patients in three sessions every other day for two months in a virtual education group. Control group: no intervention.

Main outcome variables

Health-promoting lifestyle; Self-esteem; Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052115N1**

Registration date: **2021-10-06, 1400/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-06, 1400/07/14**

Update count: **0**

Registration date

2021-10-06, 1400/07/14

Registrant information

Name

Azad Fatahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4629 5184

Email address

azad8271@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-05, 1400/06/14

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	group A, and so on blockchain is continued until so many blocks are selected It is possible to obtain the required sample size.
Scientific title	Blinding (investigator's opinion)
Comparison of the effect of healthy lifestyle education through peer education and virtual education (based on Interactive virtual classroom and applications) on indicators of lifestyle that promotes health, self-esteem and self-efficacy of diabetics referred to military hospitals	Not blinded
Public title	Blinding description
The effect of healthy lifestyle education through peer education and virtual education (based on Interactive virtual classroom and applications) on indicators of lifestyle that promotes health, self-esteem and self-efficacy of diabetics	Placebo
Purpose	Not used
Education/Guidance	Assignment
Inclusion/Exclusion criteria	Parallel
Inclusion criteria:	Other design features
At least six months have passed since the diagnosis of uncontrolled type 2 diabetes based on the fasting blood sugar index above 126 mg / dL. Have an age range between 21 and 75 years Have no history of participating in diabetes education programs during the past six months. Willingness to participate in the present study. Be literate and use a smartphone. Be able to speak Persian. Mobile access and the ability to use it Ability to install software on mobile phones and Internet access Do not have cognitive problems, physical disabilities, need for diabetic foot surgery, No medical or related education Absence of hearing or vision impairment Not be a part of treatment staff Possibility to make direct telephone calls to the patient and his active family member.	Secondary Ids
Exclusion criteria:	empty
The patient develops new physical problems that make them lose the ability to take care of themselves. Reluctance to cooperate the study Do not use software	Ethics committees
Age	1
From 21 years old to 75 years old	Ethics committee
Gender	Name of ethics committee
Both	AJA University of Medical Sciences
Phase	Street address
N/A	Tehran, Ghods Town (West), between South Flamek and Zarafshan, Iran TV St. - Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor
Groups that have been masked	City
No information	Tehran
Sample size	Province
Target sample size: 135	Tehran
Randomization (investigator's opinion)	Postal code
Randomized	6797168353
Randomization description	Approval date
The allocation clause will be used. To randomly assign patients to three groups of peer education, virtual education and control, the six-random block method is used as follows. Groups will be assigned letters A, B and C randomly (BCACAB, BACCAB, ABCBAC, CBAACB blocks). In this method, blocking is based on the week and possible blocks are selected randomly. For example, patients who visit the Armed Forces Hospital in the endocrine ward in the first week enter control group B. Patients in the second week are in the peer education group C in the third week are in the virtual education	2021-09-08, 1400/06/17
	Ethics committee reference number
	IR.AJAUMS.REC.1400.131
	Health conditions studied
	1
	Description of health condition studied
	diabetes mellitus
	ICD-10 code
	E11.9
	ICD-10 code description
	Type 2 diabetes mellitus without complications
	Primary outcomes
	1
	Description
	Health Promoting Lifestyle Indicators
	Timepoint
	Before the intervention and two months later, patients in all three groups are assessed using a questionnaire promoting health
	Method of measurement
	Walker Health Promoting Lifestyle Questionnaire (HPLPII)

2

Description

Self-Esteem

Timepoint

Before the intervention and two months later, patients in all three groups are assessed using a questionnaire self-esteem

Method of measurement

Rosenberg Self-Esteem Questionnaire

3

Description

Self-Efficacy

Timepoint

Before the intervention and two months later, patients in all three groups are assessed using a self-efficacy of diabetic patients questionnaire .

Method of measurement

Type 2 Diabetic Self-Efficacy Questionnaire (DMSSES)

Secondary outcomes

empty

Intervention groups

1

Description

Peer Education Intervention group: In the present study, the purpose of peer education is to provide face-to-face training through trained peers by holding classes, lectures and questions and answers for 4 sessions of 35 minutes.

Category

Lifestyle

2

Description

Virtual education intervention group (based on interactive virtual classroom and application): A virtual education program designed by the researcher that includes how to take care of themselves such as diet and activity, etc. The researcher implemented a training program. The training program includes a clip, image, audio, text and application are provided to patients in three sessions every other day for two months in a virtual training group.

Category

Lifestyle

3

Description

Control group: without any intervention by researchers

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

AJA Medical Sciences Hospitals

Full name of responsible person

Azad Fatahi

Street address

AJA University of Medical Sciences - - West Fatemi St.
End of Etemadzadeh St. Tehran

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Web page address

<https://www.ajaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Seyede Azam Sajadi

Street address

Shahid Etemadzadeh St., West Fatemi St., Tehran

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Province

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Artesh 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Azad Fatahi

Position

master of medical surgical nursing. non-faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

Master

Other areas of specialty/work

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City

javanrood

Province

Kermanshah

Postal code

6797168353

Phone**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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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