

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluating of an educational-supportive virtual intervention on treatment adherence among patients with Type 2 diabetes with limited health literacy

Protocol summary

Study aim

Evaluating of a virtual educational-supportive intervention based on empowerment model on promoting treatment among patients with type 2 diabetes with limited health literacy

Design

This study will be conducted as a randomized controlled trial with parallel groups. At this stage, 264 participants will be randomly assigned to two intervention and comparison groups (132 people in each group) through random allocation by random quadruple block method from different centers. In this study, blinding has not been considered.

Settings and conduct

Study location will be governmental diabetes clinics in Kerman city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 30 years, limited health literacy, low adherence to treatment, at least 6 months have passed since diabetes diagnosis, willingness to participate in the study, the absence of approved psychological problems. Exclusion criteria: Pregnant women with gestational diabetes, type 1 diabetes; underlying diseases not related to type 2 diabetes (such as cancers and autoimmune patients, etc.)

Intervention groups

Intervention group: Virtual educational supportive intervention based on an Empowerment Model. Control group: only the routine training of the centers.

Main outcome variables

Adherence to treatment and HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210601051465N1**

Registration date: **2021-06-27, 1400/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**

Update count: **0**

Registration date

2021-06-27, 1400/04/06

Registrant information

Name

Nasrin Pourhabibi Zarandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating of an educational-supportive virtual intervention on treatment adherence among patients with Type 2 diabetes with limited health literacy

Public title
Evaluating of an educational intervention on Treatment adherence among patients with Type2 diabetes

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 30 yrs. Limited health literacy Low treatment adherence Type 2 diagnosis confirmed at least 6 months before Willingness to participate in the study

Exclusion criteria:

Pregnant women with gestational diabetes Type 1 diabetes Comorbidities not related to type 2 diabetes (such as types of cancers and autoimmune system diseases, etc.) Approved psychological problems

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **264**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted using random permuted blocks method by R software R(<https://www.r-project.org/>). It will make six possible sequences; these are AABB, ABAB, ABBA, BAAB, BABA, BBAA. The different diabetic centers will be alphabetically coded (e.g. A, B, C, D and so on) and a participant will attach to each diabetic center will be given numerical codes (e.g. participants in diabetic center Y were numbered A001, A002, A003 and so on).It is noted that patients with type 2 diabetes has medical records in each diabetes center.

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, School of Public Health, Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Poursina St., School of Public Health,

Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14155-6446

Approval date

2021-01-16, 1399/10/27

Ethics committee reference number

IR.TUMS.SPH.REC.1399.250

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Health literacy

ICD-10 code

Z41

ICD-10 code description

Encounter for procedures for purposes other than remedying health state

3

Description of health condition studied

Treatment adherence

ICD-10 code

Z71

ICD-10 code description

Persons encountering health services for other counseling and medical advice, not elsewhere classified

Primary outcomes

1

Description

Health literacy

Timepoint

Before and three months after intervention

Method of measurement

Health literacy questionnaire

Secondary outcomes

1

Description

Adherence to treatment

Timepoint

Before and six months after intervention

Method of measurement

Modanloo Questionnaire

2**Description**

HbA1c

Timepoint

Before, three and six months after intervention

Method of measurement

Patient medical records (Blood test)

Intervention groups**1****Description**

Intervention group: Participants will be invited to complete the questionnaires at the baseline, three and six months after the end of intervention. Both intervention and control groups will be attended the regular diabetes education in the diabetes center. In addition, the intervention group will be received virtual educational program based on Empowerment Model constructs in eight episodes lasting 45–60 minutes in every week for two months. The constructs include perceived threats, participation, evaluation and follow up. These constructs will be considered regarding improvement of adherence to treatment among patients with type 2 diabetes. Moreover, text messages will be sent as a boosting after intervention that serves as a quick reference to the education. The content of educational programs will be included information about treatment adherence based on proper health literacy strategies and diabetes complications about not adherence to treatment. The trainers will be followed an approved lesson plan to provide educational information regarding adherence to treatment. The trainers will be skilled health providers who have at least bachelor degree. The theoretical framework of the study will be based on Empowerment Model to provide an opportunity to improve health literacy to achieve better treatment adherence for participants.

Category

Prevention

2**Description**

Control group: This group will be received only the routine diabetes education in centers. There will be no more intervention for control group.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Erfan Health Diabetes Clinic

Full name of responsible person

Ali Asghar Abbasi

Street address

Jahad Ave.

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Kerman

Province

Kerman

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Email

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2**Recruitment center****Name of recruitment center**

Bahonar Hospital Diabetes Clinic

Full name of responsible person

Mahdi Ahmadinejad

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Gharani Ave.

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Kerman

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7613747181

Phone

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m.ahmadinejad@kmu.ac.ir

3**Recruitment center****Name of recruitment center**

Shafa Hospital Diabetes Clinic

Full name of responsible person

Mahmoud Nekouei Moghaddam

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Kowsar Blvd.

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Province

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Keshavarz Blvd, Poursinia Street ,vice chancellor for research of Tehran University of Medical Sciences

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Roya Sadeghi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Other areas of specialty/work

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable