

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The Effect of mobile-learning on stress and self-efficacy among diabetes patients with covid-19

Protocol summary

Study aim

Determining the effect of mobile learning on stress and self-efficacy in people with covid-19 diabetes

Design

A randomized clinical trial, single blinded, with a parallel group design of 70 patients

Settings and conduct

After receiving ethic code & IRCT code; a master list will be provided from Tehran university affiliated hospitals with the most admission of patient with covid-19. Patients will be divided into control and intervention groups by blocking randomization method. This intervention is a single blind one. Informed consent to participate in the study & questionnaires (demographic questionnaire, perceived Stress questionnaire & self-efficacy in diabetes questionnaire) will be completed by telephone call. Intervention ends in 3 months.

Participants/Inclusion and exclusion criteria

1. Diagnosis of type one or type two diabetes by specialist 2. Detection of covid-19 based on positive PCR test 3. Age range 18-65 year old 4. Basic literacy (able to read and write) 5. Having mobile phone 6. Living in Tehran; 1. Having any disease that interferes with the research process like psychological problems, stroke, heart attack, ketoacidosis 2. Re-infection by covid-19

Intervention groups

During three months, each week between 8 and 12 AM, three educational content including motivational items, daily care, healthy lifestyle, warning signs or complications about covid-19 and diabetes will be provided based on the preferred method (SMS or Call). Control group will not receive any educational content, except for the welcome SMS, and they will receive a phone call once a month just not to lose samples. At the end of the intervention, in order to observe the ethics in the research, the presented content will be provided to the control group in the form of a CD.

Main outcome variables

1. stress 2. self-efficacy in diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210302050555N1**

Registration date: **2021-03-28, 1400/01/08**

Registration timing: **prospective**

Last update: **2021-03-28, 1400/01/08**

Update count: **0**

Registration date

2021-03-28, 1400/01/08

Registrant information

Name

Sara Abbasian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 3661

Email address

s-abbasian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of mobile-learning on stress and self-efficacy among diabetes patients with covid-19

Public title

The Effect of mobile-learning on stress and self-efficacy among diabetes patients with covid-19

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type one or type two diabetes by a specialist. Detection of covid-19 based on positive PCR test. Age range 18-65 year old. Basic literacy(able to read and write). Having mobile phone. Living in Tehran.

Exclusion criteria:

Having any disease that interfere with the research process like psychological problems, stroke, heart attack, ketoacidosis. Re-infection by covid-19.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking randomization First, I go to the hospitals with an official introduction letter. A master list of all eligible people will be prepared and will be placed in the intervention and control group by blocking randomization method. Based on the results of studies, the number of required samples in each group is equal to 31 people in each group; taking into account of the 10% drop, the final number of required samples in each group is equal to 35. Total of 70 diabetic people with Covid-19 are determined are allocated by block randomization method into intervention and control groups. In the present study, the number of blocks will be 4 blocks. The adequacy of the number of samples in the early stages of this study is re-evaluated.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single blind research. After explanation and clarification all steps to participants and obtaining written consent; the study will be started.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Nursing and midwifery department of Tehran University of Medical Science, Nosrat St., Enqelab Sq., Tehran,

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.TUMS.FNM.REC.1399.230

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07.2

ICD-10 code description

COVID19, virus not identified

2

Description of health condition studied

diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

stress.

Timepoint

measuring stress level will be done before the intervention & 3 months after beginning of the intervention.

Method of measurement

Cohen's perceived stress questionnaire

2

Description

Self-efficacy in diabetes

Timepoint

measuring self-efficacy level will be done before the

intervention & 3 months after beginning of the intervention.

Method of measurement

Diabetes self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the informed consent form to participate in the study and completing the desired questionnaires (demographic information questionnaire, perceived stress questionnaire and diabetes self-efficacy questionnaire) by phone call; During three months, three educational contents per week between 8 and 12 AM, including motivational items, daily care, healthy lifestyle, nutrition, exercise, warning signs or complications about covid-19 and diabetes will be provided based on the preferred method of each (Phone call or text message). At the end of the intervention, the questionnaires will be completed again by phone call.

Category

Rehabilitation

2

Description

Control group: After completing the informed consent form to participate in the study and completing the desired questionnaires (demographic information questionnaire, perceived stress questionnaire and diabetes self-efficacy questionnaire) by phone call; Welcome and study entry SMS will send to control group. During three months, in the first week of each month, they receive phone call in order to greet and not to lose samples. At the end of the intervention, in order to observe the ethics in the research, the presented content will be provided to the control group in the form of a CD.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Sara Abbasian

Street address

Baharloo hospital, Behdari Ave., Rahahan Sq., Tehran

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2

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

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Shariati hospital, North kargar Ave., Tehran

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3

Recruitment center

Name of recruitment center

Imam Khomeini Hospital complex

Full name of responsible person

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4

Recruitment center

Name of recruitment center

Yas hospital complex

Full name of responsible person

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Name of recruitment center
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Full name of responsible person
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Recruitment center

Name of recruitment center
Amiralam Hospital complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Doctor.mohammadali sahraian
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Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital
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Phone
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Email
Sahraian1350@yahoo.com

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
Sara Abbasian
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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