

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effect of Patient Education Through Social Media on COVID-19-Related Fear, Anxiety, and Self-care in Diabetes Patients

Protocol summary

Study aim

Determining the effect of patient education through social media on COVID-19-related fear, anxiety, and self-care in diabetes patients

Design

. This is a double-blinded randomized controlled trial, in which a total of 120 patients with diabetes will be recruited using convenience sampling and then randomly allocated to two groups of intervention and control.

Settings and conduct

This study will be conducted in Vali-E-Asr and Ayatollah Mousavi Hospitals, Zanjan, Iran, both of which are known as the centers for metabolic diseases. Eligible patients will be selected from internal wards and specialized clinics. In this study, participants will be randomly assigned to two groups of intervention and control. Moreover, participants, data analysts, and clinical caregivers will not be informed of patient allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Exact diagnosis of diabetes by a physician according to laboratory and clinical tests 2- Being literate 3- Having the ability to use a smartphone, tablet, or laptop 4- Not being infected by COVID-19 5- Granting written informed consent to participate in the study 6- Being in the age range of 18-60 years Exclusion criteria: 1- Having a mental health disorder

Intervention groups

Patients in the intervention group will receive educational intervention through social messaging apps. Educational content consists of data on the COVID-19 nature, causes, and symptoms of the disease, pharmacological treatment and correct use of drugs, diet, isolation, personal hygiene, and mental health. It should be noted that the control group will not receive any educational intervention by the research team.

Main outcome variables

In this study, the effect of patient education through social media on the COVID-19-related fear, anxiety, and self-care in diabetes patients will be evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210515051303N1**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

mohammad zirak

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-19, 1400/03/29

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Patient Education Through Social Media on COVID-19-Related Fear, Anxiety, and Self-care in Diabetes Patients Public title The Effect of Patient Education Through Social Media on COVID-19-Related Fear, Anxiety, and Self-care in Diabetes Patients Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: exact diagnosis of diabetes by a physician according to laboratory and clinical tests Being literate Having the ability to use a smartphone, tablet, or laptop Not being infected by COVID-19 Granting written informed consent to participate in the study Being in the age range of 18-60 years Exclusion criteria: Having a mental health disorder (Panic disorders, Major depressive disorder, Post traumatic stress disorder) Age From 18 years old to 50 years old Gender Both Phase N/A Groups that have been masked • Participant • Care provider • Data analyser Sample size Target sample size: 120 Randomization (investigator's opinion) Randomized Randomization description Block randomization will be used to assign patients to the control and intervention groups, so that 6 blocks with size of 4 will be used in this regard. The letter A and B will be considered for sampling patients in the intervention and the control group, respectively. The following blocks will be written on pieces of paper with numbers from 1 to 6. We will then randomly pick up the pieces of paper through rolling a dice. Sampling will then begin according to the order achieved in the above procedures. 1. AABB 2. BBAA 3. ABBA 4. BAAB 5. ABAB 6. BABA According to the order of the letters in the blocks, patients will be assigned to the intervention or control group. Then the next blocks will be selected through rolling the dice again. For example, we roll the dice 6 times for the first time and the following numbers are given by chance: 514362 → ABAB AABB BAAB ABBA BABA BBAA Blinding (investigator's opinion) Double blinded Blinding description In this study, participants will not be informed of their allocation to the intervention or control group. Clinical caregivers and statistical analyzers will also not be aware of patient allocation. Placebo	Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Zanjan University of Medical Sciences Street address Zanjan University of Medical Sciences, Dr.Sobouti Blvd. Zanjan,Iran City Zanjan Province Zanjan Postal code 4513956184 Approval date 2021-04-04, 1400/01/15 Ethics committee reference number IR.ZUMS.REC.1400.009 Health conditions studied 1 Description of health condition studied COVID-19-related fear, anxiety, and self-care in diabetes patients ICD-10 code E08 ICD-10 code description Diabetes mellitus due to underlying condition Primary outcomes 1 Description COVID-19-related fear, anxiety, and self-care Timepoint before and immediately after the intervention Method of measurement Fear of COVID-19 Scale (FC-19S), COVID-19 Anxiety scale (CDAS), and Self-care in COVID-19 Scale (SCOID) Secondary outcomes empty Intervention groups
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Description

Intervention group: Training will be provided to the patients in the intervention group during two weeks. On each day of this period, content of an educational topic will be uploaded in specified order for the patients in the intervention group using whatsapp messenger in file formats including audio, photo or video. To ensure the receipt of training by the patients in the intervention group, the researcher will give them a call during the intervention period. Training content includes data on the COVID-19 nature, causes, symptoms, disease transmission, medication, diet, how to quarantine the patient and family, how to observe hygiene, principles of hand washing and personal hygiene, how to dilute and use disinfectants for frequently touched surfaces and used areas, such as bathrooms and toilets.

Category

Other

2

Description

Control group: Patients in this group will not provided with any intervention so that they only received routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Dr. Ahmad Jalilvand

Street address

Dr. Sobouti (Gavazang) Blvd- Ayatollah Mousavi Hospital

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2

Recruitment center

Name of recruitment center

Vali-E-Asr Hospital

Full name of responsible person

Dr. Mohammad Hasan Rostamkhani

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Valiasr Square - Dr. Shariati St. - Vali-E-Asr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Parviz Ghezelbash

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Dr. Sabouti Blvd., Zanjan 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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Zirak

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

After the completion of the study, researchers will publish the required information based on the ethical considerations in the text of the thesis. Therefore, the required demographic information as well as the mean scores of the dependent variables will be published in the thesis and the article or articles derived from this research project.

When the data will become available and for how long

The thesis resulting from this research project will probably be available in late August 2021. The researchers can access the text of the thesis in the dissertation database of the central library of Zanjan University of Medical Sciences. The article resulting from this thesis will be submitted in one of the prestigious international journals within 6 months after the approval

of the thesis.

To whom data/document is available

Data and documentation will be available to medical researchers.

Under which criteria data/document could be used

The data can be used to study, give citation, create new ideas, and practically apply in medical centers.

From where data/document is obtainable

To receive the data, the researchers can refer to the thesis database of the central library of Zanjan University of Medical Sciences or send an email to the first author

of the project (Ali Sadeghian). Email: alisadeghian75@yahoo.com

What processes are involved for a request to access data/document

Researchers can get access to the data by providing reasons and guaranteeing citation to the article(s) resulting from the thesis project. They should send an email to the first author of the research project (Ali Sadeghian). Email: alisadeghian75@yahoo.com

Comments