Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 (SCOVID)

Secondary outcomes

empty

Intervention groups

1

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

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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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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
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Person responsible for scientific inquiries

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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 fromthis 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