

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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)

##### Phone

+98 24 3318 6344

##### Email address

mohammadzirak@zums.ac.ir

##### 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

## 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

##### Street address

Dr. Sobouti (Gavazang) Blvd- Ayatollah Mousavi Hospital

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956183

##### Phone

+98 24 3313 0000

##### Fax

+98 24 3313 1203

##### Email

mousavihospital@zums.ac.ir

##### Web page address

<https://mousavi.zums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Vali-E-Asr Hospital

##### Full name of responsible person

Dr. Mohammad Hasan Rostamkhani

##### Street address

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

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4515777978

##### Phone

+98 24 3377 0801

##### Fax

+98 24 3377 0751

##### Email

valiasr@zums.ac.ir

##### Web page address

<https://valiasr.zums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr. Parviz Ghezelbash

##### Street address

Dr. Sabouti Blvd., Zanjan University of Medical Sciences

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

##### Phone

+98 24 3314 8318

##### Email

info@zums.ac.ir

##### Web page address

<https://zums.ac.ir/>

##### 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

**Street address**

Dr. Sabouti Blvd., Zanjan University of Medical Sciences, Zanjan School of Nursing and Midwifery

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956113

**Phone**

+98 24 3314 8318

**Fax**

+98 24 3314 8319

**Email**

mohammadzirak@zums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

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4513956113

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+98 24 3314 8318

**Fax**

+98 24 3314 8319

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mohammadzirak@zums.ac.ir

## Person responsible for updating data

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Zanjan University of Medical Sciences

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**Phone**

+98 24 3314 8318

**Fax**

+98 24 3314 8319

**Email**

mohammadzirak@zums.ac.ir

## 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**