Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment the effect of virtual self-care education on COVID-19 anxiety, among the community dwelling elderly

Protocol summary

Study aim
Determined the effect of virtual self-care education on COVID-19 anxiety, among the community dwelling elderly

Design
This study is a randomized clinical trial with two groups of intervention and control, which are divided into two parallel groups of 61 people by block random allocation. This study is a blinded and phase 3 study that is performed on 122 elderly people.

Settings and conduct
The research environment is the community center covered by the municipality of District 6 of Tehran. After accessing the elderly and introducing the research objectives to them through WhatsApp messengers, the researcher sends the informed consent form and the study questionnaire for the research samples. The intervention includes training in physical, mental and social self-care related to Covid-19 in the form of podcasts and videocasts, which are recorded by the researcher in approximately 20 to 30 minutes and delivered to the participants within 6 weeks. The source of the files is the tutorials provided on the site (WHO) and (CDC).

Participants/Inclusion and exclusion criteria
Admission: Seniors 60 to 74 years old, with the ability to use a mobile phone, read, write, see and hear. Have an Internet access, ability to perform daily activities and satisfaction of participating in the study. Absence: Suffering from generalized anxiety disorder

Intervention groups
For the experimental group, the intervention included training in physical, mental and social self-care related to Covid-19 in the form of podcasts and videocasts for 6 consecutive sessions. For the control group, no intervention will be performed and only pre-test and post-test will be taken by using research tools.

Main outcome variables
Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210427051101N1**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**
Update count: **0**

Registration date
2021-06-19, 1400/03/29

Registrant information

Name
Maryam Amirzadegan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-21, 1400/03/31

Expected recruitment end date
2021-07-22, 1400/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Assessment the effect of virtual self-care education on COVID-19 anxiety, among the community dwelling elderly

Public title

Assessment the effect of virtual self-care education on COVID-19 anxiety, among the community dwelling elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

age between 60-74 years Having and being able to use a smart phone Internet access Be literate Ability to see and hear Ability to perform their daily activities (score 13 and above based on ADL tools) Satisfaction with participating in the study

Exclusion criteria:

Score 16 or more in the Generalized Anxiety Disorder Questionnaire (GAD-7)

Age

From **60 years** old to **74 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is by block random sampling method and participants are divided into two groups of intervention and control. Given the sample size, n blocks of 4 are required for random block allocation. The intervention group will be displayed with A and the control group with B. Blocks of size 4 can be six modes 1-AABB 2-ABAB 3-ABBA 4- BBAA 5- BABA 6-BAAB. Then we roll the dice, for example 4 comes to BBAA, we roll the dice again, for example 5 comes to BABA, and so on, we repeat and roll the dice until all the samples are allocated. In order to hide the random allocation from the researcher, a dark envelope sample size is prepared and each of the random sequences created is recorded on a card and placed inside the envelope and finally the envelope lid is pasted. At the time of enrollment in the study, according to the order of entry of samples, one of the envelopes is opened in order and the group of the sample is specified.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants are randomly divided into control and intervention groups. Then the trainings are provided to the intervention group and every three weeks the participants in the control and intervention group are followed up through WhatsApp messenger. Therefore, participants are unaware of their position in the group and the type of intervention performed. Due to the use of dark envelopes and English letters for random assignment of participants, the researcher is unaware of the location of participants and a name is determined for each person based on computer coding, and the researcher follows people through this and during the call. Due to the coding of individuals, it is unaware of their random allocation. The outcome assessor and data analyst reviews and announces the results using data encoding.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Joint Organizational Ethics Committee of the School of Nursing and Midwifery with the Faculty of Reh

Street address

No. 8, Unit 5, 7/35 Alley, Simetri Niroohavayie St, Damavand St.

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Province

Tehran

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Approval date

2021-04-25, 1400/02/05

Ethics committee reference number

IR.TUMS.FNM.REC.1400.017

Health conditions studied

1

Description of health condition studied

COVID-19 anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

Anxiety Score Based on Coronavirus Pandemic Anxiety Scale

Timepoint

Measurement of anxiety level at the beginning of the study and two weeks after the end of the intervention (8 weeks after the start of the study)

Method of measurement

Coronavirus Pandemic Anxiety Scale (CPAS-11)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention includes physical, psychological and social self-care training related to Covid-19, which is in the form of podcasts and videocasts and is recorded in approximately 20 to 30 minutes and is designed according to their level of understanding; Participants are uploaded to WhatsApp messengers and given Covid-19 self-care tutorials for 6 consecutive sessions. Then, once every three weeks, in order to prevent the participants from leaving the research according to the exit criteria, the elderly are followed up through video calls in WhatsApp messengers. The trainings are in three dimensions: physical, mental and social and are presented to the participants during 5 educational parts and 1 review of previous trainings. Thus, the educational content of each session of the intervention will be based on the dimensions of self-care according to the following text: 1.Covid-19 and how to transmit it, disease prevention, how to use masks, gloves, alcohol, food hygiene, environmental health and clothing 2. Common and uncommon symptoms in Covid-19 disease, how to check the symptoms, time of test, necessary health and care measures at the time of symptoms 3. Quarantine and the ability to adapt to psychological and social stress 4. Food recommendations in quarantine, sports activities in quarantine, social activities in quarantine 5. Care recommendations for using public transportation and travel 6. Review of the mentioned topics

Category

Other

2

Description

Control group: For the control group, no intervention will be done, only once every three weeks to prevent the participants in the study to leave according to the exit criteria, follow-up of the elderly is done through video call in WhatsApp messengers. At the end of the intervention, training files will be provided to the participants of the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Community Center in the Sixth District of Tehran Municipality

Full name of responsible person

Najmeh Esmaeili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Maryam Amirzadegan

Position
Master student

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Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Considering that the present study is an academic dissertation and a copy of it will be provided to Tehran University of Medical Sciences; Therefore, all data is potentially shareable after identifying individuals.

When the data will become available and for how long
The time period for accessing the documents of this study is 3 months after the publication of the results.

To whom data/document is available
The data and documents of this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
All researchers working in scientific and academic centers, including professors, students of all medical, nursing and paramedical degrees, nurses working in hospitals and community health centers, physicians,

psychologists and other paramedical disciplines, request permission to receive unidentified data of this study. The use of the documents of this study can be used for all the mentioned groups only by mentioning the source and without any interference in its texts.

From where data/document is obtainable

Considering that a copy of the dissertation will be provided to the library of the School of Nursing and Midwifery of Tehran University of Medical Sciences; Therefore, clients can visit the library of this center in person at the address: Tohid Square, Dr. Mirkhani St. (Eastern Nusrat), School of Nursing and Midwifery, Tehran University of Medical Sciences; Phone number: +982166927171; Or visit the library site of Tehran University of Medical Sciences in absentia at http://lib.tums.ac.ir/ to benefit from the documents of this study.

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

If the client visit the library of the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences in person, he can read the research documents in the library by introducing himself to the librarian and presenting a valid ID card. It should be noted that the client will not be allowed to take the document out of the library and take a photo of it. If the client visit the library site of Tehran University of Medical Sciences in absentia, the client will enter a part of the study title in the search box and a summary of the present study will be displayed for him.

Comments