

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effectiveness of various virtual education methods on the mental health of the elderly during the corona disease epidemic, Shiraz, 2021

Protocol summary

Study aim

Determining and comparing the mean score of stress, anxiety and sleep quality tests in the elderly in text message-based virtual education group, voice virtual education group and multimedia message-based virtual education group before and after the intervention

Design

Clinical trial with three intervention groups, with parallel, non-random groups, on 90 elderly people referred to Shiraz health centers (each group of 30 clients of one center)

Settings and conduct

This intervention will include relaxation techniques, positive mental imagery, muscle relaxation, meditation exercises, meaning therapy, sleep, sleep hygiene, and stimulus control. 90 elderly people (30 people from each center) will be selected from the clients participating in the educational programs of Shiraz health centers using the purpose-based method. At the beginning of the study, the researcher will form three groups in WhatsApp cyberspace, the first intervention group will receive all the educational content in cyberspace in the form of text message, the second group will receive all the educational content in the form of voice and the third intervention group will receive all the educational content in the form of multimedia messages (clips).

Participants/Inclusion and exclusion criteria

Age 60 to 74 years old; have a minimum literacy; history of severe mental disorders.

Intervention groups

At the beginning of the study, the researcher will form three groups in WhatsApp cyberspace, the first intervention group will receive all the educational content in cyberspace in the form of text message, the second group will receive all the educational content in the form of voice and the third intervention group will receive all the educational content in the form of

multimedia messages (clips).

Main outcome variables

Stress; anxiety; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180730040644N2**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

Farzaneh Bahadori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3824 8333

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-30, 1400/11/10

Expected recruitment end date

2022-05-10, 1401/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of various virtual education methods on the mental health of the elderly during the corona disease epidemic, Shiraz, 2021

Public title

The effect of different e-learning methods on the mental health of the elderly during corona disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum literacy Having a smartphone Active users in cyberspace (membership in virtual groups and approval of activity in groups by the group manager) earning a score of $24 \geq$ from the Amon Summary Mental Assessment (MMSE) Score $7 \leq$ for the Depression and Anxiety and Stress Scale (DASS) score 12% for the Depression, Anxiety and Stress Scale Score $16 \leq$ from the Pittsburgh Sleep Quality Questionnaire

Exclusion criteria:

Withdrawal from cooperation after entering the intervention No active participation in the group (no daily viewing of messages, no answering calls and no participation in virtual discussions that take place in the group) Under pharmacological and non-pharmacological treatments for mental and sleep disorders History of attending e-learning classes on stress, anxiety and sleep disorders history of severe mental disorders Untreated vision and hearing disorders (do not wear glasses for vision problems and do not use hearing aids for severe hearing impairments) Loss of a close relative during the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Rehabilitation Sciences and Social Health, Student Research Committee

Street address

University of Science and Rehabilitation and Social Health, Koodakiar End, Daneshjoo Blvd. Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.USWR.REC.1400.193

Health conditions studied**1****Description of health condition studied**

-

ICD-10 code**ICD-10 code description**

-

Primary outcomes**1****Description**

Stress score in Kessler Distress Questionnaire and Yield Standard Questionnaire

Timepoint

Before the intervention and after the last intervention session

Method of measurement

Kessler Distress Questionnaire and Yield Standard Questionnaire

2**Description**

Anxiety score in Kessler Distress Questionnaire and Yield Standard Questionnaire

Timepoint

Before the intervention and after the last intervention session

Method of measurement

Kessler Distress Questionnaire and Yield Standard Questionnaire

3

Description

Sleep quality score on the Pittsburgh questionnaire

Timepoint

Before the intervention and after the last intervention session

Method of measurement

Pittsburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: sending a text message. The intervention is offered three sessions a week for a period of two months -This intervention will include relaxation techniques, positive mental imagery, muscle relaxation, meditation exercises, meaning therapy, sleep, sleep hygiene, stimulus control.

Category

Other

2

Description

Second Intervention group: sending an audio message. The intervention is offered three sessions a week for a period of two months -This intervention will include relaxation techniques, positive mental imagery, muscle relaxation, meditation exercises, meaning therapy, sleep, sleep hygiene, stimulus control.

Category

Other

3

Description

Third Intervention group: sending a multimedia clip. The intervention is offered three sessions a week for a period of two months -This intervention will include relaxation techniques, positive mental imagery, muscle relaxation, meditation exercises, meaning therapy, sleep, sleep hygiene, stimulus control.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz city health center of Valfajr martyrs

Full name of responsible person

Dr. Ahmad Rezazadeh

Street address

Shiraz, South Motahhari Boulevard, West Golchin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr.Hamidreza khankeh

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Tehran University of Rehabilitation Sciences and Social Health, Evin, Daneshjoo Blvd., Koodkiar dead end

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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

University of social welfare and rehabilitation 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

Shiraz University of Medical Sciences

Full name of responsible person

Nasim Pirzadeh

Position

student
Latest degree
Bachelor
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

No - There is not 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

Not applicable

Title and more details about the data/document

Results of pre-test and post-test data analysis

When the data will become available and for how long

After the publication of articles extracted from the
research project

To whom data/document is available

University professors - staff of health centers

Under which criteria data/document could be used

To evaluate the effectiveness of e-learning methods

From where data/document is obtainable

Farzaneh Bahadori

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

by Email bahadori_farzaneh@yahoo.com

Comments