

# 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)

##### Phone

+98 71 3824 8333

##### Email address

bahadori\_farzaneh@yahoo.com

##### 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

Street, 10th Alley, in front of the police station

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

6656371357

##### **Phone**

+98 71 3823 3890

##### **Email**

bahadori\_farzaneh@yahoo.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

University of social welfare and rehabilitation sciences

##### **Full name of responsible person**

Dr.Hamidreza khankeh

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985713834

##### **Phone**

+98 21 7173 2000

##### **Email**

bahadori\_farzaneh@yahoo.com

#### **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**  
Geriatrics  
**Street address**  
Department of Health Promotion, School of Health,  
Shiraz university of Medical Sciences. Razi Ave  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7153675541  
**Phone**  
+98 71 5367 5541  
**Email**  
N.pirzadeh7238@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
University of social welfare and rehabilitation sciences  
**Full name of responsible person**  
Farzaneh Bahadori  
**Position**  
student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Geriatrics  
**Street address**  
Tehran University of Rehabilitation Sciences and  
Social Health, Evin, Daneshjoo Blvd., Koodkiar dead  
end  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1985713834  
**Phone**  
+98 917 813 6507  
**Email**  
bahadori\_farzaneh@yahoo.com

## Person responsible for updating data

### 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**  
Geriatrics  
**Street address**  
Department of Health Promotion, School of Health,  
Shiraz university of Medical Sciences. Razi Ave  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7153675541  
**Phone**  
+98 71 5367 5541  
**Email**  
N.pirzadeh7238@gmail.com

## 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