Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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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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 ≥ from the Amon Summary Mental Assessment (MMSE) Score 7 ≤ for the Depression and Anxiety and Stress Scale (DASS) score 12% for the Depression, Anxiety and Stress Scale Score 16≤ 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 Committe
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
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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
Street address
Tehran University of Rehabilitation Sciences and Social Health, Evin, Daneshjoo Blvd., Koodkiar dead end
City
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1985713834
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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

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nasim Pirzadeh

Position
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+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