

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of online Floor-seated Exercise training on depression, anxiety and stress of older adults in COVID-19 epidemy

Protocol summary

Study aim

Determining the effect of virtual sitting exercises on depression, anxiety and stress in the elderly in the Covid 19 epidemy

Design

Random clinical trial with control and test group, community-based and pragmatic, randomized, Excel software rand function is used for randomization.

Settings and conduct

Obtaining confirmation from the university and the code of ethics - referring to the comprehensive center of health services in Karaj - explanation about Executive plan, purpose and research process - Admission of people to the study in an accessible manner according to the inclusion criteria and sample size - Assignment of a code to each sample and based on randomly assigned blocking to the volume of 4 blocks, individuals as Equal to two groups of control and test - participants complete online demographic questionnaire and dass-21- Perform sports exercises online through the Skype application by a sports coach, for 12 weeks, three days a week, 30-45 minutes - Send sport video for the control group in WhatsApp - Take the dass-21 post-test from the two groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 79-60 years- Tending to attend online seated exercise classes - Have the physical ability to attend classes.- Be able to use the facilities needed to participate in classes. Criteria for not entering: Any psychological disorder reported by the individual- History of participating in any virtual sports activity that is similar to the activity in the present study. Use of psychiatric medications before the study

Intervention groups

For the experimental group, doing sports exercises virtually through the Skype application, for 12 weeks, three days a week, time: 30-45 minutes. control group: sending videos through whatsapp (they are voluntarily, not supervised and not seated exercises)

Main outcome variables

variables: Depression, Anxiety and Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220107053651N1**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **retrospective**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Shadi Ghadiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3253 3478

Email address

shadikio95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-01-25, 1400/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of online Floor-seated Exercise training on depression, anxiety and stress of older adults in COVID-19 epidemic

Public title

The effect of online Floor-seated Exercise training on depression, anxiety and stress of older adults during COVID-19 epidemic

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 79-60 years Willingness to attend online sitting sport classes Have the physical ability to attend sitting sports classes at a distance. Have the ability to use the tools and facilities needed to participate in online sitting sport classes

Exclusion criteria:

Any psychological disorder reported by the individual History of participation in any virtual sports activities that are similar to the activities intervened in the present study. Use of psychiatric drugs before the study

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Quadruple blocking. Explanation of the method: Each sample is assigned a code and these codes are given to a person other than the researcher without the names of the samples and based on randomly assigned block allocation to the volume of 4 blocks (two assignments to the control group and two Assignment to the test group) - in such a way that the letter A will be considered for the test group and the letter B will be considered for the control group. Possible modes in the four blocks of six modes include AABB, BBAA, ABAB, BABA, ABBA, BAAB, each mode will be written on a card and the cards will be assigned the number one to six, then using the dice of the six modes One may be selected and the selected seniors will be divided into two groups based on that. This process will continue until the sample size is completed. block randomization is performed in practice using SAS statistical software. Concealment is done through the SNOSE (Sequentially Numbered, Opaque, Sealed Envelopes) method: based on the size of the research sample, a number of envelopes with aluminum wrappers (in order not to clarify the contents of the envelopes), are prepared and each of the random sequences created is

recorded on a card and the cards are inside. Letter envelopes are placed in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. At the time of registration, based on the order in which eligible participants enter the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

13th floor, block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Ghods Town (West), Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

IR.TUMS.FNM.REC.1400.175

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

anxiety, stress, depression

ICD-10 code

41.2

ICD-10 code description

Mixed anxiety and depressive disorder

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

Anxiety score in DASS-21 questionnaire

Timepoint

assessing anxiety at the beginning and end of the research after 3 month of intervention

Method of measurement

anxiety measured by DASS-21 questionnaire

2

Description

Stress score in DASS-21 questionnaire

Timepoint

assessing Stress at the beginning and end of the research after 3 month of intervention

Method of measurement

Stress measured by DASS-21 questionnaire

3

Description

Depression score in DASS-21 questionnaire

Timepoint

assessing Depression at the beginning and end of the research after 3 month of intervention

Method of measurement

Depression measured by DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Forming a WhatsApp group - Sending a link to provide online sessions and explanations about it and a link to the online demographic and DASS-21 questionnaires before the intervention - Completing the questionnaires online through the Pors-Line site by individuals - Providing sitting exercises online Through the Skype application by the sports expert trainer, during 12 weeks, three days a week, each session lasts for 30-45 minutes and the exercises are performed by people at the same time. Exercise with soft music including topics such as flexibility, deep breathing with up and down arm pulling, wrist grip, wrist pressure, knee support, quadriceps muscle training and mind focus - Completion of DASS-21 questionnaire after the last session by Persons

Category

Rehabilitation

2

Description

Control group: Formation of WhatsApp group - Send the link of online demographic and DASS-21 questionnaires before the intervention - Complete the questionnaires online through the Press Line site - Send only 30-45 minute short sports training videos (if you do not send this period) Video time is cut by WhatsApp, videos are sent in several videos of 10-15 minutes in a group.)

Three times a week for 12 weeks in a group - Doing exercises in person if they want to (the exercises are not online and they are not supervised by the constructor and they are not mostly seated exercises so some of the participants may have trouble doing them due to their frailty)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Base No. 2

Full name of responsible person

Shadi Ghadiri

Street address

Ground floor, Arian Building, After the Clergy School, Barghan St., Azadegan Square

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salamat2krj@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

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afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran School of Nursing and Midwifery

Proportion provided by this source

1

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

Shadi Ghadiri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions, or people who are also involved in industry can apply for it.

Under which criteria data/document could be used

Data analysis is allowed for scientific and statistical review, and the necessary conditions for submitting a

request for access to data or documents include the provision of legal permission.

From where data/document is obtainable

Name: Shadi Ghadiri- Adress: N0.80, Ardalan 2 Ave,
Emam Reza Blv- Postal Code: 3149658857- Tell:
09120427148- 02632533478- Email:
shadikio95@gmail.com

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

After sending my details and documents including personal, professional and scientific details and also the reason for the need to access project information via email to me, I will contact you at the earliest opportunity and after consulting with the project supervisor and his approval and University information will be sent to you via email. It takes a week to confirm and send the data.

Comments