Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the impact of breathing exercise (through virtual education)on the general health of patients infected with Covid-19 in shiraz . Randomized clinical trial

Protocol summary

Study aim

Improving general health in patients infected with Covid-19, by using virtual education of breathing exercises.

Design

Clinical trial with control group, with parallel group, double-blind, randomized, phase 3 on 70 patients. Blocked random method is used for randomization.

Settings and conduct

Patients in the treatment group learn respiratory exercises through virtual training and are regularly monitored during the 4 weeks of study; While the control group only receives sports training in the form of pamphlets and basic explanations. Patients in both groups complete the general health questionnaire before and after the study and the results are compared. Questionnaire questioner and statistical analyzer are blind in this study

Participants/Inclusion and exclusion criteria

The inclusion criteria: 1) being diagnosed with COVID through PCR test or typical pattern through X-ray or CT Scan 2) a mild form of this virus which enables patients to look after themselves at home and they do not need to be hospitalized 3)having clinical stability 4)being able to understand and do breathing exercises online 5)being in the 18 to 65 age groups. The exclusion criteria : 1) having other lung diseases such as COPD and asthma 2) having advanced background heart diseases 3) having background uncontrolled diseases 4) being infected and hospitalized due to COVID 5) having background lower and upper motor neuron diseases 6) lack of awareness of and access to virtual world 7) refusing consent for participating in this study

Intervention groups

Patients in the treatment group learn breathing exercises through virtual training and are monitored regularly throughout the 4 weeks of study; While the control group only receives sports training in the form of pamphlets and basic explanations.

Main outcome variables

Improving public health and reduction of anxiety and depression in patients with Corona Virus

General information

Reason for update

Due to the late acceptance of the proposal, the start date of the work and the patient were postponed, and since this study is a clinical coincidence, the start and end date of the work is edited.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201204049600N1**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **prospective**

Last update: **2021-04-27, 1400/02/07**
Update count: **1**

Registration date

2021-04-06, 1400/01/17

Registrant information

Name
Sheida Shojaei
Name of organization / entity
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Iran (Islamic Republic of)
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+98 71 4224 1345
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-05-31, 1400/03/10
Expected recruitment end date
2021-09-11, 1400/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the impact of breathing exercise (through virtual education)on the general health of patients infected with Covid-19 in shiraz . Randomized clinical trial

Public title
Investigating the impact of breathing exercises on general health of patient infected with Covid-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being diagnosed with COVID-19 through PCR test. Pulmonary involvement with typical pattern through Chest X-ray or Chest CT Scan. A mild form of disease which enables patients to look after themselves at home and they do not need to be hospitalized. Having clinical stability. Being able to understand and do breathing exercises online. Being in the 18 to 65 age groups.
Exclusion criteria:
Presence and history of other lung diseases such as COPD and asthma... History of advanced heart disease such as IHD and CHF... History of uncontrolled diseases including liver, kidney and thyroid and... History of hospitalization in ICU due to Corona VIRUS. History of lower motor neuron diseases including motor neuron diseases, peripheral neuropathy, neuromuscular junction disease and myopathy History of upper motor neuron diseases such as stroke and M.S and... . Lack of access and awareness of cyberspace. Dissatisfaction with participating in the study.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical intervention study, patients in both groups are the same and are randomly assigned; Thus, random allocation of patients is done using block randomization with two permutations AB and BA. In this way, 35 numbers are randomly selected from the table of random numbers, and if the numbers are between zero and 4, block AB is assigned to them, and if they are 5-9, block BA is assigned to them, and thus two lists of 35 people include two We will have an intervention and control group at random. For concealment, this method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by this person who is unaware of the division of groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participant: In this study, we are not able to blind the patient, because patients of both interventions are aware of the type of intervention. Clinical caregiver: We teach the person in charge of patient care and follow-up how to complete the questionnaire. This person has no knowledge of the type of patient intervention. Researcher: In this study, we do not have the ability to blind the researcher, because the research does both studies himself and is aware of the type of intervention in each group. Outcome Assessor: Completed questionnaires are given to a person who is not aware of the interventions performed and he / she is asked to determine the amount of stress, anxiety and depression reduction and increase general health in each person according to the questionnaire. Data Analyzer: The questionnaires are finally given to a person to review the information after completing and collecting all the information. This person does not know any of the steps of the work and how to divide the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Doostan apartment, Alley 24th, Narvan street, Eram blvd., shiraz
City
Shiraz
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Postal code
71447-54388
Approval date

2020-11-14, 1399/08/24

Ethics committee reference number

IR.SUMS.MED.REC.1399.433

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce general health of patient infected with Covid-19

Timepoint

The beginning and the end of the study.

Method of measurement

General health qustionnair (GHQ)

Secondary outcomes

1

Description

Function of patient

Timepoint

The beginning and the end of the study.

Method of measurement

Medical Research Council Breathlessness Scale (MRC dyspnea scale)

Intervention groups

1

Description

Intervention group: This group learns breathing exercises completely for a month through cyberspace (WhatsApp and Instagram). Then we will contact them regularly (two to three times a week) and answer their questions. Patients fill in the questionnaires at the beginning and end of the study. Patients exercise for one month and six days a week, three times a day and five times a day.

Category

Rehabilitation

2

Description

Intervention group: This group only receives educational pamphlets and basic trainings at the beginning of the month. But they are asked to do exercises 6 times a week, 3 times a day, 5 times a day. The difference is that we do not have much contact with patients during a month and only at the beginning and end of the study, the questionnaires are filled out by patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Mohammad Sadegh Masoudi

Street address

Namazi Hospital, Namazi Square, Zand street, Shiraz City.

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2

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Seyyed Ali Hashemi

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Shahid Chamran Hospital, Shahid Chamran Boulevard, Shiraz City.

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3

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Educational and Medical Center.

Full name of responsible person

Ramin Afshari

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Hazrat Ali Asghar Educational and Medical Center, in front of Homa Hotel, Meshkinfam street, Shiraz.

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4

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Younes Ghasemi
Street address
Khalili Aveno, front of Maaref school
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Province
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Postal code
7134814336
Phone
+98 71 3628 1506
Email
Info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sheida Shojaei
Position
Intern
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Intern

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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
All available data can be shared after making people unidentifiable

When the data will become available and for how long
Access period starts 1year after the results are published.

To whom data/document is available
everyone can access to this information

Under which criteria data/document could be used
If the information in this study helps to improve the science process

From where data/document is obtainable
Drsheidashojaei@gmail.com 00989214783046

What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of the three weeks if permited.

Comments