Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study the effect of Benson's relaxation technique on self_care and anxiety of post Covid- 19 patients

Protocol summary

Study aim
Study the effect of Benson's relaxation technique on self_care and anxiety of post-Covid 19patients in Shafa hospital of Kelishad city of Isfahan in 2021

Design
This randomized clinical trial is a parallel study, a non-blinded one with a control group. This randomized study will perform on at least 100 patients with Covid-19. The random number table will use for randomization, and participants will be assigned to two intervention and control groups.

Settings and conduct
This study, which will be conducted at Shafa Hospital of Isfahan, is a none-blinded one. A questionnaire of the Coronavirus Anxiety and Self-Care Scale will be completed and recorded for each person in the intervention and control group. In this study, a completely quiet environment is provided by minimizing environmental stimuli (such as low room light, going to the patient's room) to perform the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 20 to 90 years; No chronic respiratory diseases Exclusion criteria: History of anxiety disorders; Taking anti-anxiety and sedative medicine

Intervention groups
The intervention group will receive an audio file containing Benson's relaxation instructions via headphones (three times a day for 20 minutes)for five days. The control group will not receive any intervention.

Main outcome variables
Corona anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210518051340N1**
Registration date: **2021-07-22, 1400/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-22, 1400/04/31**
Update count: **0**

Registration date
2021-07-22, 1400/04/31

Registrant information

Name
Shaghayegh Navaei Brojeni

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3625 7170

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shaghayeghnavaei@khuisf.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-22, 1400/04/31

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the effect of Benson's relaxation technique on self_care and anxiety of post Covid- 19 patients

Public title
Study the effect of Benson's relaxation technique on self_care and anxiety of post-Covid 19

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 90 years No chronic respiratory diseases
Exclusion criteria:
History of Anxiety Disorders Taking anti-anxiety and sedative medicine
Age
From **20 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the random number table, patients are divided into two groups of 50. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group
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 Islamic Azad University of Tehran Medical Sciences
Street address
Headquarters of Tehran Islamic Azad University of Medical Sciences, corner of Gol-e-Yakh street, Ayneh boulevard, Gholhak crossroads, Dr. Shariati St.
City
Tehran
Province
Tehran
Postal code
1916893813
Approval date
2021-06-13, 1400/03/23
Ethics committee reference number
IR.IAU.PS.REC.1400.064

Health conditions studied

1

Description of health condition studied
anxiety of Corona
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Corona anxiety
Timepoint
Baseline of study and end of study (five days later)
Method of measurement
Corona Disease Anxiety Scale (CDAS)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive an audio file containing Benson's relaxation instructions via headphones (three times a day for 20 minutes)for 5 days.
Category
Treatment - Other

2

Description
The control group will not receive any intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Shaghayegh Navabi
Street address
Shafa Specialized Hospital, Baharestan Belt
City
Klishad
Province
Isfehan

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8456166931
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Mohammad Roholah Yazdani
Street address
Vice Chancellor for Research and Technology, University Blvd, Arghavanieh, Jay Street East
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m.yazdani@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Dr. Roya Torkashvand
Position
Faculty member of Islamic Azad University of Medical Sciences
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available