

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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 19 patients 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)

###### Phone

+98 31 3625 7170

###### Email address

shaghayeghnavaei@khuif.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

Klshad

##### Province

Isfahan

**Postal code**  
8456166931  
**Phone**  
+98 31 3491 3913  
**Email**  
shaghayegh.navaei96@gmail.com

## 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  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
3999881551  
**Phone**  
+98 31 3535 4001  
**Email**  
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**  
Ph.D.  
**Other areas of specialty/work**  
Health Promotion

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## Person responsible for scientific inquiries

#### Contact

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Dr. Roya Torkashvand  
**Position**  
Faculty member of Islamic Azad University of Medical Sciences  
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## Person responsible for updating data

#### Contact

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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