

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of progressive muscle relaxation technique on anxiety and sleep quality in patients with COVID-19

#### Protocol summary

##### Study aim

Determining the effect of progressive muscle relaxation technique on anxiety and sleep quality in patients with Covid-19

##### Design

Use blocking method for randomization Create 6 blocks of 4 such as (AABB, BBAA) (ABAB), (BABA), (ABBA), (BAAB) combinations, then consider the digits 1 to 6 for each of these combinations. Depending on the sample size, 16 quadruple blocks are randomly selected by placement of 6 designed blocks. A (intervention group) means: recipient of progressive muscle relaxation technique and B (control group): recipient of the inpatient care method.

##### Settings and conduct

Location: Kovid ward of Valiasr Fasa hospital. The intervention group will be taught to perform Jacobsen's progressive muscle relaxation technique. Then perform this technique once in the morning and once at night for 20 minutes for 5 consecutive days. During this period, the control group receives only normal care. Completion of questionnaires before and after the intervention in two groups

##### Participants/Inclusion and exclusion criteria

Entry requirements: 1. Confirmation of Covid-19 infection through laboratory findings and physician diagnosis 2. Having an age range between 65-15 3. Ability to read and write 4. Absence in the acute stage of the disease according to the doctor's diagnosis 5. Do not suffer from mental illness 6. No musculoskeletal disorders 7. Ability to do exercises during the day Exit conditions: 1. Reluctance to continue cooperation at any stage of the study 2. Worsening disease conditions and the need for mechanical ventilation 3. Do not perform exercises according to the specified schedule 4. Pregnancy

##### Intervention groups

Intervention group: Jacobsen's progressive muscle relaxation technique. Control group: receive only normal care

#### Main outcome variables

Anxiety status, sleep quality, quality of life,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210411050929N1**

Registration date: **2022-02-25, 1400/12/06**

Registration timing: **retrospective**

Last update: **2022-02-25, 1400/12/06**

Update count: **0**

##### Registration date

2022-02-25, 1400/12/06

##### Registrant information

##### Name

samaneh dinari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5336 2724

##### Email address

dinari821@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-20, 1400/02/30

##### Expected recruitment end date

2021-09-21, 1400/06/30

##### Actual recruitment start date

2021-07-05, 1400/04/14

##### Actual recruitment end date

2021-12-18, 1400/09/27

**Trial completion date**

2021-12-18, 1400/09/27

**Scientific title**

The effect of progressive muscle relaxation technique on anxiety and sleep quality in patients with COVID-19

**Public title**

The effect of relaxation technique on anxiety and sleep quality in patients with COVID-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with COVID-19 admitted to Hospital Absence in the acute stage of the disease according to the doctor's diagnosis No musculoskeletal disorders

**Exclusion criteria:**

Worsening disease conditions and the need for mechanical ventilation Pregnancy عدم تمایل به ادامه همکاری  
Do not do the technique according to the plan

**Age**

From **15 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **62**

Actual sample size reached: **59**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blocking method In the blocking method, first six blocks of four sizes are created, such as combinations such as (AABB, (BBAA) (ABAB), (BABA), (ABBA), (BAAB), then for each of these combinations four One of the digits will be considered from 1 to 6. In the next step, according to the sample size, 16 blocks of four will be selected randomly by placing 6 of the designed blocks. In randomized allocation by blocking method, the meaning of A (intervention group): the recipient of progressive muscle relaxation technique and B (control group): the recipient of the common care method of the hospital ward.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

**Street address**

Imam Hossein Boulevard - Hormozgan University of Medical Sciences Campus Complex

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Approval date**

2021-04-26, 1400/02/06

**Ethics committee reference number**

IR.HUMS.REC.1400.031

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

covid-19

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Spielberger State-Trait Anxiety Inventory

**Timepoint**

Before the intervention \_ Day 5, end of the intervention

**Method of measurement**

Spielberger State-Trait Anxiety Inventory (STAI)

**2****Description**

sleep quality

**Timepoint**

Before the intervention \_ Day 5, end of the intervention

**Method of measurement**

Verran and Snyder-Halpern Sleep ( ScaleVSH Sleep Scale)

**Secondary outcomes****1****Description**

no

**Timepoint**

no

**Method of measurement**

no

## Intervention groups

### 1

#### Description

Intervention group: progressive muscle relaxation technique .Patients perform the Jacobsen Progressive Muscle Relaxation Technique, which they are trained in in one session, for 5 consecutive days in the morning and evening for 20-30 minutes.

#### Category

Rehabilitation

### 2

#### Description

Control group: dont the progressive muscle relaxation technique .This group receives only the usual care of the ward.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vali→Asr Hospital in Fasa

##### Full name of responsible person

Samaneh Dinari

##### Street address

Ibn Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

۷۴۶۱۶-۸۶۶۸۸

##### Phone

+98 71 5331 5024

##### Email

info@fums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Teymoor Aghamolaei

##### Street address

Imam Hossein Square - Hormozgan University of Medical Sciences

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7916613885

##### Phone

+98 76 3333 3280

##### Email

info@hums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Samaneh Dinari

##### Position

Master of science student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

No87.20alley.khezri ave.faz 5.FASA.FARS

##### City

Fasa

##### Province

Fars

##### Postal code

7461466584

##### Phone

+98 71 5336 2724

##### Fax

##### Email

dinari821@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Samaneh Dinari

##### Position

Master of science student

##### Latest degree

Bachelor

**Other areas of specialty/work**

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**Fax****Email**

dinari821@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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Only part of the data can be shared.

**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**

Researchers of medical universities

**Under which criteria data/document could be used**

Protect the moral and legal rights of the author and publisher

**From where data/document is obtainable**

dinari821@gmail.com

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

Send email and introduce yourself to the author

**Comments**