

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

AgeFrom **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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymoor Aghamolaei

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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

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Fax**Email**

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Email

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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

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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