Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 admited 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
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 updating data

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

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