

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation the effect of progressive muscle relaxation training with demonstration method on the level of stress, anxiety and depression of nurses encountering of COVID-19

Protocol summary

Registration timing: **prospective**

Study aim

Determining the effect of progressive muscle relaxation training with demonstration methods on the level of stress, anxiety, and depression of nurses encountering COVID-19

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Design

A clinical trial with the control group, with a parallel-group design, non-blind, randomized, 2-phase groups on 46 nurses. Randomization software and block randomization method will be used for randomization.

Registrant information

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Samaneh گنجعلی

Name of organization / entity

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Settings and conduct

The study site will be COVID-19 wards of Khanevadeh and Besat hospitals in Tehran, where nurses working in COVID-19 wards will be selected by available methods. No blinding is performed in this study.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nurses with at least a bachelor's degree in nursing, with at least six months of clinical experience. Non-inclusion criteria: taking anti-anxiety and psychoactive drugs; the history of receiving previous training on the Jacobson technique; the experience of crisis during the last 6 months.

Expected recruitment start date

2021-09-11, 1400/06/20

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: The intervention group will perform Jacobson's progressive muscle relaxation technique at home, 20 minutes once a day for 2 weeks. Control group: No special intervention will be performed in this group.

Main outcome variables

Stress, anxiety, depression

Scientific title

Evaluation the effect of progressive muscle relaxation training with demonstration method on the level of stress, anxiety and depression of nurses encountering of COVID-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210808052111N1**

Registration date: **2021-09-04, 1400/06/13**

Public title

The effect of progressive muscle relaxation training with demonstration methods on the level of stress, anxiety and depression

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have at least a bachelor's degree in nursing Has at least six months of clinical experience
Exclusion criteria:
 Taking anti-anxiety and psychoactive drugs History of previous training in Jacobson relaxation technique Crisis experience by participants in the study during the last 6 months

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
 The sampling method will initially be available; the samples will then be placed in quadruple blocks by block random sampling. The size of all blocks is equal and in this two-group Clinical Trial, we will have blocks of size 4 (including 2 people participating in the intervention group and 2 people participating in the control group). Random allocation software is also used for randomization tools. For hiding, allocation concealment is used, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the person is assigned. Using opaque envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes) in which in this method each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to keep up a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the envelopes will be closed and placed inside a box. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

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 Aja University of Medical Sciences

Street address

Etemadzadeh Street, West Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-06-01, 1400/03/11

Ethics committee reference number

IR.AJAUMS.REC.1400.041

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

Z56.3

ICD-10 code description

Stressful work schedule

2

Description of health condition studied

Anxiety

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

3

Description of health condition studied

depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description

Stress

Timepoint

Before and one month after the intervention

Method of measurement

DASS-21 questionnaire

2

Description

Anxiety

Timepoint

Before and one month after the intervention

Method of measurement

DASS-21 questionnaire

3

Description

Depression

Timepoint

Before and one month after the intervention

Method of measurement

DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will perform Jacobson's progressive muscle relaxation technique for 2 weeks, once a day for 20 minutes each time at home. The practical demonstration of a progressive muscle relaxation technique is performed and taught by the researcher himself in the hospital amphitheater during two 60-minute sessions (Every other day). The first session will be a practical demonstration of how to relax and the second session will be a repetition of the first session in order to consolidate the training. At the end of the training sessions, the video of that session will be given to the test group to act only according to the training they have received in practice. The progressive muscle relaxation technique taught will be such that the nurse is sitting or lying in a comfortable chair. Preferably, the subjects' clothes are loose and the watch takes off its bracelet. Then, with the guidance of the instructor and by listening to the audiotope, he contracts and relaxes different muscle groups along with effective and deep breathing. In this technique, large muscle groups are first contracted and relaxed; Because the contraction and relaxation of these muscles and understanding the difference between these two feelings at the beginning of the work is more tangible for people. When the participant contracts and relaxes each of his muscles, he is able to easily and spontaneously relax his whole body in the way he has learned, and from anxiety, stress, and any unpleasant mental, psychological and physical feelings. Clear

Category

Treatment - Other

2

Description

Control group: No special intervention will be performed

in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khanevadeh Artesh Hospital

Full name of responsible person

Samaneh Ganjeali

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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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
 Artesh 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
 Undecided - It is not yet known if there will be 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
 Undecided - It is not yet known if there will be 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