Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of guided imagery and progressive muscle relaxation on sedation of non invasive mechanically ventilated patients

Protocol summary

Study aim

The aim of this study will be to determine the effect of guided imagery and progressive muscle relaxation on sedation of noninvasive mechanically ventilated patients admitted to covid 19 intensive care unit.

Design

A clinical trial with a parallel-group, without blinding, will be performed on 80 patients with Covid 19 under non-invasive mechanical ventilation admitted to the intensive care unit. The samples will be divided into two interventional (n = 40) and control groups (n = 40) by simple randomization.

Settings and conduct

study will be performed on patients under non-invasive mechanical ventilation admitted in intensive care unit of Modares Hospital.

Participants/Inclusion and exclusion criteria

Patients with consciousness 15 according to Glasgow coma scale; Patients aged 18 to 70 years old; Patients admitted to the covid 19 intensive care unit for at least three days; Patients undergoing oxygen therapy through non-invasive mechanical ventilation for at least three days; Patients with no previous history of non-invasive mechanical ventilation; Patients with no visual or hearing problems; Patients with no movement disorders and paralysis; Patients with no psychological disorders and taking sedatives before hospitalization.

Intervention groups

In the control group, patients will receive routine sedative care in the form of sedative drugs prescribed by a physician. In the intervention group, guided imagery and progressive muscle relaxation sessions will be held as a non-pharmacological treatment for each patient individually.

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170617034592N2**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date

2022-03-02, 1400/12/11

Registrant information

Name

Atefe Salimi Akin Abadi

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 4474 1308

Email address

atefe-salimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of guided imagery and progressive muscle relaxation on sedation of non invasive mechanically ventilated patients

Public title
Guided imagery and progressive muscle relaxation on sedation of non invasive mechanically ventilated patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with consciousness 15 according to Glasgow coma scale Patients aged 18 to 70 years old Patients admitted to the corona intensive care unit for at least 3 days Patients undergoing oxygen therapy through non-invasive mechanical ventilation for at least 3 days

Exclusion criteria:
Patients with a history of non-invasive mechanical ventilation prior to hospitalization Patients with visual and auditory problems Patients with movement disorders and paralysis Psychiatric patient and taking sedatives before hospitalization

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Available sampling method will be used for sampling. Then, patients with Covid 19 will be placed under non-invasive mechanical ventilation in the intensive care unit with inclusion criteria, alternately using a simple random method in the interventional and control groups.

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
Shahid Beheshti University of Medical Sciences, School of Nursing and Midwifery

Street address
Arabi Ave, Bldg No.2 SBUMS, 7th Floor, Velenjak, Tehran, Tehran Province

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-02-21, 1400/12/02

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.1026

Health conditions studied

1

Description of health condition studied
Covid-19 patients

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
sedation

Timepoint
In the intervention group before of the intervention and after the intervention / in the control group at the beginning of the study and one week after the initial completion of the questionnaire

Method of measurement
Adaptation to the intensive care environment (ATICE), new sedation assessment instrument

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before performing the intervention, after explaining the objectives of the study, informed consent will be obtained from the patients of the intervention group and in order to observe research ethics, they will be assured about the confidentiality of information and the possibility of leaving the study at any stage. The intervention will be performed on patients in this group. Prior to the intervention, demographic questionnaires, physiological criteria and Adaptation to the intensive care environment (ATICE), new sedation assessment instrument will be completed. In this group, in addition to routine care, the intervention will be an explanation of the goals of guided imagery and

progressive muscle relaxation , an explanation of the positive effects and usefulness of this method, based on the article by Ghaffari et al. (2007), guided imagery and progressive muscle relaxation as a non-pharmacological treatment will be held individually for 4 days a week for 30 minutes every other day. The researcher will be present at each patient's bedside and will teach guided imagery and progressive muscle relaxation techniques. In this way, in the evening shift, when the ward is quieter and environmental stimuli such as noise and commuting caused by visits are less, he is present in the intensive care unit and is present at each patient's bedside and tells the patient about guided imagery and progressive muscle relaxation. guided imagery and progressive muscle relaxation are often used together because visualization can enhance the relaxation process and enhance its effect. This method is one of the components of cognitive-behavioral therapy that is designed to reduce stress and anxiety through muscle relaxation. In the first session, regarding the goals and stages of the training program, theoretical foundations related to the guided imagery and progressive muscle relaxation technique, introducing muscles and muscle groups, training on how and steps to perform the relaxation technique along with guided imaging and the time of relaxation technique. Will be trained. During the second to fourth sessions to start the exercises, for physical relaxation, the patient is asked to be in the supine position, after a few deep breaths of the abdomen and diaphragm with the eyes closed and comfortable, in the best position in which he feels relaxed. In the first 20 minutes of the session, relaxation exercises will be performed, during which the mind will focus on the contraction of the muscles of different parts of the body and then their rest. Relaxation exercises for 8 muscle groups including arm muscles, upper arm muscles, shoulder and neck muscles, back and shoulder muscles, facial muscles, chest muscles involved in the process of breathing exercises, abdominal muscles, muscles The first step is to consciously relieve tension on the muscles, and in the final 10 minutes of the session, guided imagery with a focus on depicting a desirable scene and custom (forest, beach, religious places, hospital discharge and presence with family, reducing the need for oxygen therapy and comfortable breathing ...) will be done. During the imaging, the patient will visualize a scene in which he feels safe and free from tension and anxiety, and with the voice of the researcher, the imaging is done for the patient and the patient enters a pleasant atmosphere that is his favorite. In general, people are encouraged to take deep abdominal and diaphragmatic breaths and then combine muscle release with depictions of landscapes such as forests, the beach, or places of pilgrimage. Progressive muscle relaxation and visualization are often used together because visualization can enhance the relaxation process and increase its effectiveness. The patient will perform sedation technique under the supervision of the researcher and feedback will be taken from the patient after each session. Before the start of each session, the researcher will answer patients' possible questions about the relaxation technique and feedback on the positive experiences of the previous session. Patients' physiological criteria will also be recorded before and after each relaxation session. At the end of the session, patients are asked to write down the number of times they do relaxation exercises and guided imagery. Finally, after the end of the fourth session, the information of this group will be collected using questionnaires and will be analyzed according to the goals of the study.

Category

Other

2

Description

Control group: informed consent will be obtained from the patients of the control group and in order to observe research ethics, they will be assured about the confidentiality of information and the possibility of leaving the study at any stage. Questionnaires of demographic characteristics, physiological criteria and Adaptation to the intensive care environment (ATICE), new sedation assessment instrument will be completed in patients in the control group. In this group, patients will receive only routine sedation care in the form of sedatives prescribed by a physician. After a week, the information of the control group will be collected using questionnaires and will be analyzed according to the goals of the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Dr Saeed Alipour Parsa

Street address

Shahid Modarres hospital, Saadatabad intersection , Yadegar Imam Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2207 4087

Email

modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahid Beheshti University of Medical Sciences Vice-Chancellor of Research Affair

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 23871

Email
info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Atefe Salimi Akin Abadi

Position
nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Shahid Modarres hospital,Saadatabad intersection, Yadegar Imam Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2207 4087

Email
atefe-salimi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Atefe Salimi Akin Abadi

Position
nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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Postal code
1998734383

Phone
+98 21 2207 4087

Email
atefe-salimi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Atefe Salimi Akin Abadi

Position
nurse

Latest degree
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Other areas of specialty/work
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Province
Tehran

Postal code
1998734383

Phone
+98 21 2207 4087

Email
atefe-salimi@sbmu.ac.ir

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the study will be published in the form of research project report and article without mentioning the names of the participants.

When the data will become available and for how long

The access period will start 6 months after the publication of the results.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There will be access to data to compare the results of the study in similar trials.

From where data/document is obtainable

phone:09199135395 email:atefe.salimi@yahoo.com

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

In the articles resulting from the study, the e-mail of the responsible author and other authors will be included, and through this, researchers can communicate with the authors and submit their request, which will be answered in the shortest possible time.

Comments