Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Myofascial Release Therapy on the Respiratory Functions in Patients with COVID- 19

Protocol summary

Study aim
To investigate the effect of myofascial release of the muscles and fascia of the neck, thorax and diaphragm on respiratory function and tolerance in patients with Covid-19.

Design
Fifty patients with Covid-19 are divided into two intervention groups and the control group (simple randomization using a sealed envelope) .The study is double blinded and the third phase.

Settings and conduct
In patients with respiratory diseases, respiratory mechanics and ineffective breathing, involvement and adaptive changes are seen in the respiratory accessory muscles and fascia of this area, so the present study intends to investigate the effect of myofascial release of muscles and fascia of this area on respiratory function and tolerance of patients with Covid-19 hospitalized in the wards. The study will be double blinded and coding to the evaluation forms will be used for blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: With definitive diagnosis of Covid-19, more than 6 months have passed since the onset of other acute diseases, the patient does not have COPD or other respiratory diseases. Exclusion criteria: Fever and unstable Cardiopulmonary Condition

Intervention groups
In the control group, routine respiratory physiotherapy will be performed, which includes: Respiratory, Cough, Diaphragmatic trainings, and use external vibration. In the intervention group, in addition to the routine respiratory physiotherapy, 4 techniques including: sub-occipital, anterior thoracic and sternal release, anterior cervical, and diaphragm release will be performed.

Main outcome variables
Heart rate, Blood pressure, Respiration rate, Blood oxygen saturation, The amount of chest expansion, Ease of breathing, Dyspnea perception, Fatigue Perception, Exercise tolerance, The level of satisfaction of the person with the treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210214050356N1**
Registration date: **2021-02-22, 1399/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-22, 1399/12/04**
Update count: **0**

Registration date
2021-02-22, 1399/12/04

Registrant information
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Sara Fereydounnia
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-07-21, 1400/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Efficacy of Myofascial Release Therapy on the Respiratory Functions in Patients with COVID- 19

Public title
Effect of Muscle Release Treatment in Patients Infected by Corona- Virus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
With definitive diagnosis of Covid-19 (PCR test positive) More than 6 months have passed since the onset of other acute diseases. The patient does not have COPD or other respiratory diseases.

Exclusion criteria:
Body temperature over 38 degrees The time of initial diagnosis or onset of symptoms is 3 days or less The initial onset of dyspnea is 3 days or less The chest image has improved by more than 50% in the last 24 to 48 hours SpO2 90% or less Blood pressure less than 90/60 mm Hg and more than 180/90 mm Hg The number of breaths is more than 40 per minute Heart rate less than 40 and more than 120 beats per minute New onset of arrhythmia and myocardial ischemia Moderate to severe heart disease (grade 3 or 4, according to the New York Heart Association) with ischemic or hemorrhagic stroke or neurodegenerative diseases Decreased level of consciousness Reluctance to continue treatment and discharge with personal consent

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be based on a single sequence (simple randomization) and the random number table method will be used, so that the table is read from above and even numbers will be considered for the control group and odd numbers for the intervention group (myofascial release).Allocation concealment will be done using sealed opaque envelopes. In this way, 50 envelopes are prepared with aluminum wrappers and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. Finally, the lid of the envelope is glued and placed inside a box, respectively. At the beginning of the study, one of the envelopes is opened in order and the assigned group of the patient is revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
The present study will be single blinded. In this way, the participants and the therapist, who is the evaluator too, are aware of the study groups. But the date analyzer will be unaware of the study's groups (control or release of fascia).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd.

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Approval date
2021-02-04, 1399/11/16

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1059

Health conditions studied

1

Description of health condition studied
COVID- 19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Heart Rate

Timepoint
Before Intervention- After the first session and third sessions

Method of measurement
Cardiopulmonary Monitoring

2

Description
Blood Pressure
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Cardiopulmonary Monitoring

3

Description
Respiratory Rate
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Cardiopulmonary Monitoring

4

Description
Blood O2 Saturation
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Pulse Oximetry

5

Description
Chest Expansion
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Tape meter

6

Description
Ease of Breathing
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
VAS ruler

7

Description
Dyspnea perception
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Modified Borg Scale

8

Description
Fatigue Perception
Timepoint
Before Intervention- After the first session and third sessions
Method of measurement
Modified Borg Scale

9

Description
Exercise Tolerance
Timepoint
Before Intervention- After the third session
Method of measurement
Six Minutes Walking Test

10

Description
Patient’s thoughts about the treatment
Timepoint
Before Intervention- After the third session
Method of measurement
Six Minutes Walking Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine respiratory physiotherapy, 4 myofascial release techniques including : sub occipital release technique, anterior thoracic and sternal myofascial, anterior cervical myofascial, and diaphragm will be performed for approximately 5 minutes for each technique.
Category
Rehabilitation

2

Description
Control group: Routine respiratory physiotherapy will be performed, which includes: 1) Breathing exercises training (deep inhalation and exhalation) 2) Cough training 3) Diaphragmatic training (For diaphragmatic training, each person performs 30 diaphragmatic breaths in the supine position and a medium weight (1 kg) will be placed on the anterior abdominal wall to resist the descent of the diaphragm.) 4) Using external vibration to drain mucus. Because posture plays a vital role in respiratory function, patients should be encouraged to be as erect as possible in the head and neck during these procedures and to avoid slumped position.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Sara Fereydounnia

Position
Assistant Professor

Latest degree
Ph.D.

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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
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
Access period starts 3 months after the articles are published.
To whom data/document is available
For researchers working in academic, scientific and hospital institutions
Under which criteria data/document could be used
Researchers working in the field of lung diseases and respiratory care and manual therapies.
From where data/document is obtainable
Applicants for documentation can contact Dr. Sara Fereydoonnia via email. S-fereydounnia@sina.tums.ac.ir
What processes are involved for a request to access data/document
Once they have the necessary criteria, the information will be provided to them within a month.
Comments