

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Sara Fereydounnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 8468

Email address

s-fereydounnia@sina.tums.ac.ir

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		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 data analyzer will be unaware of the study's groups (control or release of fascia).
Scientific title	Efficacy of Myofascial Release Therapy on the Respiratory Functions in Patients with COVID- 19	Placebo	Not used
Public title	Effect of Muscle Release Treatment in Patients Infected by Corona- Virus	Assignment	Parallel
Purpose	Treatment	Other design features	
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	Secondary Ids	empty
Age	No age limit	Ethics committees	
Gender	Both	1	
Phase	N/A	Ethics committee	
Groups that have been masked	Data analyser	Name of ethics committee	Ethics Committee of Tehran University of Medical Sciences
Sample size	Target sample size: 50	Street address	Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd.
Randomization (investigator's opinion)	Randomized	City	Tehran
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.	Province	Tehran
Blinding (investigator's opinion)	Single blinded	Postal code	۱۴۱۷۶۵۳۷۶۱
		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
Sara Fereydounnia
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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
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Person responsible for scientific inquiries

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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