# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**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.

**City**
Tehran

**Province**
Tehran

**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

**Street address**
corner of Ghods Street, Boulevard

**City**
Tehran

**Province**
Tehran

**Postal code**
۱۴۱۷۶۵۳۷۶۱

**Phone**
+98 21 7752 8468

**Email**
s-fereydounnia@sina.tums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Mohammad Ali Sahraian

**Street address**
Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

**City**
Tehran

**Province**
Tehran

**Postal code**
۱۴۱۷۶۵۳۷۶۱

**Phone**
+98 21 8163 3639

**Email**
research@tums.ac.ir

**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.

**Other areas of specialty/work**
Physiotherapy

**Street address**
School of Rehabilitation, Piche shemiran, Enghelab Avenue

**City**
Tehran

**Province**
Tehran

**Postal code**
1148965111

**Phone**
+98 21 7752 8468

**Email**
s-fereydounnia@sina.tums.ac.ir

## Person responsible for scientific 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.

**Other areas of specialty/work**
Physiotherapy

**Street address**
School of Rehabilitation, Piche- Shemiran, Enghelab Street

**City**
Tehran

**Province**
Tehran

**Postal code**
1148965111

**Phone**
+98 21 7752 8468

**Fax**

**Email**
S-fereydounnia@sina.tums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**

Sara Fereydounnia
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Physiotherapy
**Street address**
School of Rehabilitation, Piche- Shemiran, Enghelab Street
**City**
Tehran
**Province**
Tehran
**Postal code**
1148965111
**Phone**
+98 21 7752 8468
**Fax**
**Email**
S-fereydounnia@sina.tums.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**
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**