

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of plantar reflexology on dyspnea, fatigue and anxiety of patients with coronavirus

#### Protocol summary

##### Study aim

The aim of this study was to investigate the effect of foot reflexology on the level of anxiety, shortness of breath and fatigue in patients with coronavirus.

##### Design

The clinical trial has a control group, two-way blind, randomly, simple random method on 40 patients with COVID 19.

##### Settings and conduct

The present study is a quasi-experimental study of clinical trial type will be performed on hospitalized patients with coronavirus with moderate to severe lung involvement in hospitals affiliated to Abadan University of Medical Sciences. Reflexology sessions for the intervention group will be held for 6 consecutive weeks for 30 minutes each time using sweet almond oil for the intervention group. The foot massage will be performed in a supine position for both feet (15 minutes for each foot). Both patients and researchers will be unaware of the patient's exposure. Since this study is multi center an encrypted computer file indicate that what every code means.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Having relative independence in performing daily life activities- having appropriate level of consciousness- Corona virus with moderate to severe lung involvement exclusion criteria: decreasing level of consciousness- having problems in feet include circulation disorders, paraesthesia, tissue ulcers, amputation- pregnant - psychiatric - sever hepatic, cardiac and renal patients- applying complementary and alternative therapies

##### Intervention groups

intervention group will received reflexology sessions for the sole of the foot for 6 sessions of 30 minutes as 10 minutes of general foot massage and 5 minutes for massage of lung area in the sole of the foot. General massage of the foot without using oil will be performed for the control group.

#### Main outcome variables

Determining the effectiveness of plantar reflexology in fatigue, anxiety and dyspnea in patients with coronavirus

#### General information

##### Reason for update

##### Acronym

COVID- SARS

##### IRCT registration information

IRCT registration number: **IRCT20220405054421N1**

Registration date: **2022-04-12, 1401/01/23**

Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**

Update count: **0**

##### Registration date

2022-04-12, 1401/01/23

##### Registrant information

##### Name

Motahareh Mousavi Ghahfarokhi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5326 5361

##### Email address

m.musavighahfarokhi@abadanums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-05, 1401/02/15

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of plantar reflexology on dyspnea, fatigue and anxiety of patients with coronavirus

**Public title**

The effect of plantar reflexology on dyspnea, fatigue and anxiety of patients with coronavirus in educational hospitals affiliated to Abadan of medical sciences university in 1400-1401

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having relative independence in performing daily life activities having appropriate level of consciousness  
Corona virus with moderate to severe lung involvement  
willingness to participate in the study

**Exclusion criteria:**

decreasing level of consciousness having problems in feet include circulation disorders paraesthesia tissue ulcers amputation pregnant women psychiatric patients sever hepatic, cardiac and renal patients applying complementary and alternative therapies

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **32**

intervention group will received reflexology sessions for the sole of the foot for 6 sessions of 30 minutes as 10 minutes of general foot massage and 5 minutes for massage of lung area in the sole of the foot. General massage of the foot without using oil will be performed for the control group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible samples, after being selected from medical centers, based on the file number in a simple random method, will be assigned to the control and intervention groups. For concealment, we use allocation concealment that is related to used method for implementing execution of random sequence on study participants so that the assigned group not be known before the individual is assigned. using opaque envelopes, Sequentially numbered, sealed with random sequence in which record on a card and replace into envelopes orderly. In order to maintain a random sequence,

numbering on external surface of envelopes be done orderly. finally, the envelopes are glued and placed inside a box, respectively. Based on the order of entry of eligible participants, at the time of registration of participants, one of the envelopes of the letter is opened in order and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both patients and researchers will be unaware of the patient's exposure. Since this study is multi center an encrypted computer file indicate that what every code means. Only if the person's health is endangered will that code be broken.

**Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Abadan university of medical sciences

**Street address**

airport square, next to international airport, Deputy of educational, Abadan university of medical sciences, Abadan, Iran

**City**

Abadan

**Province**

Khuzestan

**Postal code**

6313833177

**Approval date**

2022-02-23, 1400/12/04

**Ethics committee reference number**

IR.ABADANUMS.REC.1400.156

**Health conditions studied****1****Description of health condition studied**

Dyspnea, anxiety, fatigue, reflexology in related to corona virus disease

**ICD-10 code**

reflexolog

**ICD-10 code description**

Dyspnea, anxiety, fatigue, reflexology, COVID 19

## Primary outcomes

### 1

#### Description

level of fatigue, dyspnea and anxiety in patients with Corona virus

#### Timepoint

Evaluation of fatigue, dyspnea and anxiety in COVID patients after 6 weeks

#### Method of measurement

Fatigue Sever Scale, Burge dyspnea scale, Spielberger overt and covert anxiety questionnaire

## Secondary outcomes

### 1

#### Description

The rate of dyspnea, fatigue and anxiety in patients with coronavirus

#### Timepoint

dyspnea, fatigue and anxiety in patients with coronavirus after 6 weeks

#### Method of measurement

Spielberger Manifest and Visible Anxiety Inventory, Fatigue Intensity Scale and Burge dyspnea

## Intervention groups

### 1

#### Description

Intervention group: Reflexology of the sole of the foot with sweet almond oil for 6 weeks, once a week, 30 minutes each time, 10 minutes of general massage of the sole of the foot and 5 minutes of massage of the lung areas in the sole of the foot

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Motahareh Mousavi Ghahfarokhi

##### Street address

Opposite Azad University, Station 12, Ayatollah Taleghani Hospital

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Abadan

##### Province

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1985711151

##### Phone

+98 61 5336 1003

#### Email

taleghani@abadanums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Abadan University of Medical Sciences

##### Full name of responsible person

Dr Esmat Radmanesh

##### Street address

airport square, next to the international airport, deputy of educational, Abadan university of medical sciences, Abadan, Iran

##### City

Abadan

##### Province

Khuzestan

##### Postal code

6313833177

##### Phone

+98 61 5326 5357

##### Email

info@abadanums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Abadan 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

Abadan University of Medical Sciences

##### Full name of responsible person

Motahareh Musavi Ghahfarokhi

##### Position

instructor, member of faculty

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

airport square, next to international airport, deputy of educational, Abadan university of medical sciences

##### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Abadan University of Medical Sciences  
**Full name of responsible person**  
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instructor, member of faculty  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

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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

Not applicable

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All parts of the article (including introduction, purpose, method, results and discussion and sources) will be available after completion and publication in a reputable journal. All data is potentially shareable after unidentified individuals

### When the data will become available and for how long

The access period will start 6 months after the results are published.

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Applicants can access some of the required documents if they do research and introduce their work

### From where data/document is obtainable

Applicants will receive the documentation of the article after the publication of the article through google scholar website or pub med

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

If the applicant receives the article file after publication from a particular journal, according to the rules of the journal, she must go through the necessary processes to access the article, such as payment, membership in the website, obtaining a username and password.

### Comments