

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

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+98 61 5326 5361

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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

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Opposite Azad University, Station 12, Ayatollah Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

Dr Esmat Radmanesh

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

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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

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

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Person responsible for scientific inquiries

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Latest degree
Master
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