Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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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 affilated 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
Khouzestan
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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Khouzestan
Postal code
1985711151
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+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
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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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Latest degree
Master
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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