Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Acupressure on Spirometry Indicators and Functional Exercise Capacity in people with Chronic Obstructive Pulmonary Disease (COPD)

Protocol summary

Study aim

To determine the effect of acupressure on spirometry indicators and functional exercise capacity in people with chronic obstructive pulmonary disease.

Design

This research study is a randomized triple-blinded clinical trial with parallel groups. The three groups will be similar in age and gender. For placement of the samples in the three intervention groups, placebo and the routine care group (control), a simple random method will be used. The sample size was estimated by the results of the studies and the sample size formula was estimated to be 40 in each group.

Settings and conduct

The patients of the intervention and Placebo group will be selected from the Pulmonary clinic of Imam Sajjad Hospital, Ramsar. The control group will be selected from the Pulmonary clinic of Shahid Rajaei Tankabon Hospital. The data will be collected by the interview method. In this study, the participants are blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: full consciousness, ability to walk independently, Absence of allergies, Non-smoking, ability to sleep in the prone position. Exclusion criteria: exacerbated chronic obstructive pulmonary disease (COPD), Acute respiratory disease

Intervention groups

In the intervention group, four points were selected including Dingchuan point EX.17, UB.13 Feishu point, UB.23 Shenshu point and St.36 Zusanli point,Then acupressure will be done for 3 minutes, 3 times a week and for 4 weeks. In the placebo group, acupressure will be performed at a distance of 1.5 centimeters from the main points. In the control group, routine care will be taken and there will be no intervention.

Main outcome variables

Spirometric indicators, Functional exercise capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160802029159N2**
Registration date: **2022-09-26, 1401/07/04**
Registration timing: **prospective**

Last update: **2022-09-26, 1401/07/04**
Update count: **0**

Registration date

2022-09-26, 1401/07/04

Registrant information

Name

Moloud Sharifi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acupressure on Spirometry Indicators and Functional Exercise Capacity in people with Chronic Obstructive Pulmonary Disease (COPD)

Public title

The Effect of Acupressure on Spirometery Indicators and Functional Exercise Capacity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Full consciousness Ability to walk independently Diagnosis of COPD by an internal medicine Having an FEV1 to FVC ratio of less than 0.7 after bronchodilators No smoking (cigarettes and hookahs) Lack of allergies, Absence of an obstacle to the practice of acupressure Lack of visual impairment The ability to get on the prone position Not having previous experience of acupressure or acupuncture

Exclusion criteria:

Exacerbated Chronic Obstructive Pulmonary Disease Acute Respiratory Disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized controlled trial with patients and evaluators blinded to the group allocation. A total of 120 participants with Chronic Obstructive Pulmonary Disease will be randomly assigned into one of three groups: one intervention group (acupressure), one control group; and one placebo group. The eligible people will be in the study groups by a randomization process. The random allocation of this study will be achieved using an online random number generator (randomization.com) following a balanced 1:1 pattern. The information on the allocation list will remain strictly confidential and sequentially numbered; opaque, sealed envelopes will be used to contain the randomization assignments. The Acupressure Specialist will open the envelopes according to the numerical sequence, immediately before the first session of treatment

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will remain blinded regarding the category of their allocation throughout the study data collection period. Additionally, the evaluators responsible for the data collection and the outcomes assessor will also be blinded to the patient allocation. The Acupressure Specialist will be the only person not blind to the type of treatment to be performed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Gangafrooz Street, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.001

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

Z82.5

ICD-10 code description

Family history of asthma and other chronic lower respiratory diseases

Primary outcomes

1

Description

Spirometric indices

Timepoint

The spirometric indices are evaluated in three sessions of the first, sixth and twelfth sessions (immediately before the first session, the sixth session and immediately after the 12th session).

Method of measurement
Spirometry machine model HI-801

2

Description
Functional exercise capacity
Timepoint
Functional exercise capacity will be evaluated in three sessions of the first, sixth and twelfth sessions (immediately before the first session, sixth session and immediately after the twelfth meeting).
Method of measurement
Six-Minute Walking Practice Test (6MWT): This is a simple test to assess the ability of a person's performance and can reflect the ability of an individual to operate on a daily basis.

Secondary outcomes

1

Description
Dyspnea
Timepoint
Dyspnea will be evaluated in three sessions of the first, sixth and twelfth sessions (immediately before the first meeting, sixth session and immediately after the twelfth meeting).
Method of measurement
Dyspnea Visual Analogue Scale

Intervention groups

1

Description
Intervention group: In the intervention group, 4 points including the point (EX.17)Dingchuan (at 5 cun intervals with the C7 neck neck) (due to the fact that each cun is approximately the same as the width of the thumb), the point (UB.13) Feishu (1 / 5th cun is located next to the T-3 thoracic vertebra), point (UB.23) Shenshu is located 1 / 5th cun along the lumbar vertebra L2) and the point (St.36) Zusanli (lower than the lower knee joint of the tibia tetanus) and then acupressure (12 sessions) for 3 minutes (a total of 12 minutes), 3 times per week and for 4 weeks.
Category
Rehabilitation

2

Description
Control group: In the placebo group, 1.5 centimeters distance from the main acupressure program will be implemented.
Category
Rehabilitation

3

Description
Control group: In the control group, routine care will be taken and there will be no intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
Full name of responsible person
Moloud Sharifi
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences

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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Moloud Sharifi
Position
Non-faculty educator
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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
The data will be shared with the Ethics Committee of the Babil University of Medical Sciences after the analysis in the text of the article and the report of the end of the work.

When the data will become available and for how long
7 months

To whom data/document is available
Only the research team and the Ethics Committee of the Babil University of Medical Sciences have access to raw data.

Under which criteria data/document could be used
Increased clinical application of the study results

From where data/document is obtainable
Refer to the administrator and address of Fatemeh Zahra Faculty of Nursing, Ramsar

What processes are involved for a request to access data/document
The request must be submitted to the administrator's email address and the submitter, after consulting and consulting with the research team, will refer the request to the university's ethics committee and, upon receipt of the approval of the ethics committee, will provide the applicant with the data.

Comments