

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Spirometric indicators, Functional exercise capacity

##### 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

#### 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

+98 11 5525 8118

##### Email address

m.sharifi@mubabol.ac.ir

##### 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 Spirometry 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

#### Street address

Motahhari Ave; Revolution Square; Ramsar; Mazandaran

#### City

رامسر

#### Province

Mazandaran

#### Postal code

4691714141

#### Phone

+98 11 5522 5151

#### Fax

+98 11 5522 6413

#### Email

sharifi.molod@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

Shahid Rajaei Hospital

#### Full name of responsible person

Moloud Sharifi

#### Street address

Imam Street, In front of the Bank Melli Iran

#### City

Tonekabon

#### Province

Mazandaran

#### Postal code

4281989888

#### Phone

+98 11 5423 7001

#### Email

rajaehospital995@gmail.com

#### Web page address

<http://en-ipd-h-rajaei.mazums.ac.ir/Home>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Babol University of Medical Sciences; Gangafrooz Ave; Babol; Mazandaran

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**Email**

rezaghadimi@yahoo.com

**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**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Motahhari Ave; Enghelab Square; Ramsar; Mazandaran; Iran

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Ramsar

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4691857995

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

Master

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Moloud Sharifi

**Position**

Non-faculty educator

**Latest degree**

Master

**Other areas of specialty/work**

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+98 11 5522 6413

**Email**

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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**