

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessing the Effect of Foot Reflexology Massage on Anxiety Level and Physiological Indexes in Bronchoscopies candidates

#### Protocol summary

##### Summary

The aim of this study is to determine the effects of foot reflexology massage on anxiety level and physiological indexes among pulmonary patients admitted and candidate for bronchoscopy. Inclusion criteria are: age of 18 to 60, being conscious, having no previous bronchoscopy, having no problem on feet, having no bleeding and vision disorder. Exclusion criteria are: cancellation of bronchoscopy and patient's withdrawal. In this single-blind clinical trial, 70 bronchoscopy candidate patients are divided into two groups, experimental (35 individuals) and control (35 individuals) by assigning a random coin toss between two patients. Researcher one day before the procedure is presented at patient's bedside, and after obtaining informed consent, demographic data questionnaire will have completed by questioner and then patients are given one of experimental or control groups. Physiological indexes (blood pressure, heart rate, respiration rate and arterial oxygen saturation) and anxiety of the subjects, are measured by the second researcher that is unaware of samples in each group in three stages: The first time morning bronchoscopy before the intervention, immediately after the intervention and immediately before bronchoscopy. Foot reflexology intervention is done for each leg about 15 minutes (5 minute warm up, 10 minute massage pressure points), In the experimental group on foot reflexology points on the solar plexus, pituitary, heart and lung. Control group dose not receive any intervention. The main outcome variables are anxiety and physiological indexes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014091319141N1**

Registration date: **2015-01-12, 1393/10/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-12, 1393/10/22

##### Registrant information

###### Name

Hooman Shahsavari

###### Name of organization / entity

The faculty of Nursing and Midwifery of Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6105 4319

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-10-07, 1393/07/15

##### Expected recruitment end date

2015-02-04, 1393/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the Effect of Foot Reflexology Massage on Anxiety Level and Physiological Indexes in Bronchoscopies candidates

##### Public title

Assessing the Effect of Foot Reflexology Massage on Anxiety Level and Physiological Indexes(Blood pressure,

Heart rate, Respiration rate, Arterial oxygen saturation) in Bronchoscopies candidates

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: written consent for participation in the study; age of 18 to 60; ability to speak and comprehend Persian; being conscious; having no problem on feet; no previous record for bronchoscopy or participation in similar research; no prescription for mandatory urgent bronchoscopy; no previous record on psychological or anxiety disorders (according to the patient's self-report or medical history); no pain; no addiction to drug, alcohol, or strong sedatives; no vision impairment that prevents selecting proper choices on visual analog scale for assessing anxiety level; no bleeding disorder.

Exclusion criteria: cancellation of bronchoscopy procedure on the scheduled day; and patient's withdrawal.

### **Age**

From **18 years** old to **60 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical Sciences

##### **Street address**

The Central Building of Tehran University of Medical Scienc, keshavarz Street, Qods Street, Tehran, Iran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-09-28, 1393/07/06

#### **Ethics committee reference number**

130/1629

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Bronchoscopy(diagnostic prosedure)

#### **ICD-10 code**

Z03

#### **ICD-10 code description**

Medical observation and evaluation for suspected diseases and conditions

## **Primary outcomes**

### 1

#### **Description**

Anxiety

#### **Timepoint**

in the morning of the day of bronchoscopy prior to the intervention, immediately after the intervention, and immediately before bronchoscopy (after the intervention)

#### **Method of measurement**

Visual Analog Scale questionnaire

### 2

#### **Description**

Heart rate

#### **Timepoint**

in the morning of the day of bronchoscopy prior to the intervention, immediately after the intervention, and immediately before bronchoscopy (after the intervention)

#### **Method of measurement**

Radial puls count through touch

### 3

#### **Description**

Respiration rate

#### **Timepoint**

in the morning of the day of bronchoscopy prior to the intervention, immediately after the intervention, and immediately before bronchoscopy (after the intervention)

#### **Method of measurement**

Enumeration

### 4

#### **Description**

Arterial Oxygen Saturation

#### **Timepoint**

in the morning of the day of bronchoscopy prior to the intervention, immediately after the intervention, and immediately before bronchoscopy (after the intervention)

#### **Method of measurement**

Vital signs monitoring device

### 5

#### **Description**

Blood pressure

#### **Timepoint**

in the morning of the day of bronchoscopy prior to the intervention, immediately after the intervention, and immediately before bronchoscopy (after the intervention)

**Method of measurement**

Vital signs monitoring device

**Secondary outcomes**

empty

**Intervention groups****1****Description**

foot reflexology massage for 30 minutes on pituitary reflex points, solar plexus, heart, and lungs on the day of bronchoscopy and prior to the bronchoscopy procedure

**Category**

Other

**2****Description**

routine care for the control group

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dr Shariati Hospital

**Full name of responsible person**

Marzieh Ebrahimi Eshrat Abad

**Street address**

Dr Shariati Hospital, North Kargar street, Tehran,

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Masood Younesian

**Street address**

The central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Street, Tehran, Iran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

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

The faculty of Nursing and Midwifery of Tehran University of Medical Sciences

**Full name of responsible person**

Marzieh Ebrahimi Eshrat Abad

**Position**

Master Sciences Student of Nursing

**Other areas of specialty/work****Street address**

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PHD

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## Person responsible for updating data

### Contact

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*