Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 (35individuals) 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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Siences

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,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masood Younesian

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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

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Master Sciences Student of Nursing

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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