

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the Effect of Foot Reflexology and Foot Rub Olive Oil on Asthma Control

#### Protocol summary

##### Summary

This study is a randomized controlled clinical trial. It will be done with purpose of comparing the effects of foot reflexology and foot rub olive oil on asthma control. The project will be implemented after receiving referral letter from the vice chancellor for research of Tabriz university of medical sciences and obtain permission from the ethics committee of Tabriz university of medical sciences and coordination with the officials of specialized and professional pulmonary clinic of Imam Khomeini hospital in Ardabil for patients admitted to this place. The study comprised two intervention groups (a group of foot reflexology and other foot rub olive oil) and a control group. The number of participants in the study determined at least 40 patients by means of this formula:  $n > \frac{sd^2}{d^2} (z\alpha + z\beta)^2$ , (51 patients were selected). It is noteworthy that the standard deviation of the difference between the two groups of studies with variable FEV1, 4.5 is obtained. Participants will be selected through available. The samples will elected from patients who referred to a physician in specialized and professional pulmonary clinic of Imam Khomeini hospital and his medical office in Ardabil. All the adult women should be over 12 years with a diagnosis of asthma. In the first session for each groups of this study the purpose of the study and how to carry out it will be explained and after completion the consent form, the Asthma Control Questionnaire (containing 6 questions, seven points in each question that evaluate asthma control) will be completed By the participants and supervised by a trained researcher assist to avoid bias while completing the questionnaire. All three groups will continue previous asthma medications as directed by their doctors as the routine. Interventions will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher. Interventions will be done in a private room of the clinic. At the end of 10 session intervention and one day after that the questionnaires will be completed again. The implement of Interventions

and completion of questionnaires in all three groups will be conducted in parallel and simultaneously. To avoid interference with other group participants, participants in each group will receive the intervention in separate days. The data collected will be compared with each other and asthma control variable will be compared at the beginning and end of the study and between three groups and with the aid of the SPSS 13 will analyze. 1 - Objectives: Comparison of the effects of foot reflexology and foot rub olive oil on asthma control. Dedicated objectives: Determine and comparison the adequacy of asthma control in foot reflexology group before and after intervention; Determine and comparison the adequacy of asthma control in foot rub olive oil group before and after intervention; Determine and comparison the adequacy of asthma control in control group at the beginning and end of the study; comparison of the adequacy variations of asthma control in the three groups at the beginning and end of the study. 2 - Design: randomized controlled clinical trial. 3 - Setting and conduct: After completion of consent form the Asthma Control Questionnaire will be completed By the participants. All three groups will continue previous asthma medications as directed by their doctors by routine. Interventions will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher. At the end of 10 session intervention and one day after that the questionnaires will be completed again. Intervention implementation and completion of questionnaires in all three groups will be conducted in parallel and simultaneously. 4 - Participants including major eligibility criteria: All the adult women should be over 12 years with a diagnosis of asthma. Inclusion criteria: Women should be over 12 years old; Suffering from asthma. Exclusion criteria: Be pregnant; Having injury or infection in foot; Suffering from cancer or any other blood infections; Taking psychiatric drugs; Have any fracture in the foot; Have leg edema; Have DVT; Will be hospitalized during the study; Suffering from diabetic neuropathy; Using of other asthma treatments other than drugs prescribed by doctors. 5 - Intervention: Foot reflexology; Foot rub olive

oil: Control( without intervention). 6 -Main outcome measures variables: Asthma control.

## General information

### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2012122011825N1**

Registration date: **2013-05-27, 1392/03/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2013-05-27, 1392/03/06

#### Registrant information

##### Name

Seemin Dashti

##### Name of organization / entity

Medical Sciences University Of Tabriz, Faculty Of Nursing And Midwifery of Tabriz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

s\_moghaddasian@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

#### Expected recruitment start date

2013-04-29, 1392/02/09

#### Expected recruitment end date

2013-05-14, 1392/02/24

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the Effect of Foot Reflexology and Foot Rub Olive Oil on Asthma Control

#### Public title

Comparison of the Effect of Foot Massage and Foot Rub Olive Oil on Asthma Control

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Women should have over 12 years old: Suffering from asthma. Exclusion criteria: Be pregnant: Having injury or infection in foot : Suffering from cancer or any other blood infections: Taking psychiatric drugs: Have any fracture in the foot: Have leg edema (Increase in diameter of the ankle or forearm with or without

pitting): Have DVT (warmth, swelling, edema and pain in leg): Be hospitalized during the study: Suffering from diabetic neuropathy (Eliminating the achilles reflex, Decreased pain and temperature sensation in patients with diabetes): Using of other asthma treatments except drugs that prescribed by doctors.

#### Age

From **12 years** old to **100 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **51**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University Of Medical Sciences

##### Street address

Faculty of Nursing & Midwifery, Shariety South Street,Tabriz, Iran

##### City

Tabriz

##### Postal code

#### Approval date

2013-04-29, 1392/02/09

#### Ethics committee reference number

1922

## Health conditions studied

### 1

#### Description of health condition studied

Asthma

#### ICD-10 code

J45.8

#### ICD-10 code description

Mixed asthma

## Primary outcomes

1

### Description

Asthma Control

### Timepoint

Before the intervention, A day after intervention

### Method of measurement

Asthma Control Questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Foot reflexology: A special massage for the bottom, metatarsus and sides of the foot. It will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher.

### Category

Other

2

### Description

Olive oil rubbing: Rub olive oil on the metatarsus, sides and bottom of foot. It will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher.

### Category

Other

3

### Description

Control: Without intervention

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Specialty Pulmonary Clinic of Imam Khomeini Hospital in Ardabil; Dr Muhammad Mirzaaqhazadeh Medical

#### Full name of responsible person

Seemin Dashti

#### Street address

Imam Khomeini Hospital, Bagheri Jeddi street, Ardabil; Navid Practitioners Building, Tavar alley, Sarcheshmeh street, Ardabil

#### City

Ardabil

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

#### Full name of responsible person

Dr. Seyed Kazem Shakouri (Vice chancellor for research, Tabriz University of Medical Sciences)

#### Street address

Deputy of Tabriz University of Medical Sciences, Goltasht Street, Azadi Street, Tabriz

#### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Tabriz 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

Tabriz University of Medical Sciences, Faculty of Nursing & Midwifery

#### Full name of responsible person

Seemin Dashti

#### Position

MSN Student

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

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Sima Moghaddasian

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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*