

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effects of reflexology massage and stroke on symptoms and ventilatory parameters in patients with bronchial asthma

Protocol summary

Study aim

Determination and Comparison of the Effect of Reflexology and Stroke Massages on Symptoms and Ventilation Index of Patients with Bronchial Asthma

Design

Randomized Clinical trial with a parallel control, supportive group with blinding

Settings and conduct

Study location: Shahid Mofateh Clinic and Health Center, Yasuj The samples are divided into three groups of control, reflexology, and stroke massage. All patients receive routine asthma treatment during the study, and massage therapy is performed along the routine treatment. Patients suffer from mild to moderate asthma. The study last one month including one session a week for four weeks. In both intervention groups, variables are measured before and after the intervention. The effect of massage on the symptoms of asthma during the one-month period is evaluated before the beginning of the intervention in the first session and after the end of the study in all three groups. This is a single-blind study and the participants are not aware of their group.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Mild to moderate asthma, forced expiratory volume in 1 second (FEV1) >60% or <95%, no hematologic disease such as hemophilia, no other treatments such as relaxation and psychotherapy. Exclusion criteria Exacerbation and persistence of the disease and acute asthma attack.

Intervention groups

In this group FEV1 and respiratory rate are measured in four sessions (once a week) before and after foot massage and stroke massage. The signs are checked at the beginning and the end of the intervention. The foot massage is performed for 15 minutes and stroke massage for 10 minutes. In the control group, only the parameters are measured.

Main outcome variables

Daily Cough; Forced expiratory volume in 1 second;

Level of oxygen saturation in blood; Respiratory rate; Night cough.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040924N1**

Registration date: **2019-01-29, 1397/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-29, 1397/11/09**

Update count: **0**

Registration date

2019-01-29, 1397/11/09

Registrant information

Name

Elham Sarikhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4446 7175

Email address

elham.sarikhani@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of reflexology massage and stroke on symptoms and ventilatory parameters in patients with bronchial asthma

Public title

Comparison of the effects of reflexology massage and stroke on patients with bronchial asthma

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 65 years; No cognitive, hearing, and visual impairment; Ability and willingness to participate in the study; no use of drugs or psychotropic substances; Definite diagnosis of mild to moderate sustained asthma according to the physician's opinion for more than 1 year; Forced expiratory volume in 1 second (FEV1) >60% or <95%; No hematologic disease such as hemophilia, reduced platelet, and deep vein thrombosis (DVT); No other treatments such as relaxation and psychotherapy.

Exclusion criteria:

Unwillingness to continue participating in the study New disease The progression of the disease to a severe and persistent Death If the patient has an acute asthma attack.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly allocated in two groups of intervention and two group control, and a code are assigned for each participant.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

does not have

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj, Shahid Motahari Blvd, Yasuj University of Medical Sciences

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

00

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.YUMS.REC.1397.066

Health conditions studied**1****Description of health condition studied**

Bronchial asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes**1****Description**

The volume of air that is exerted by pressure in the first second from the lungs is measured as a percentage, the breathing rate per minute,

Timepoint

Each session is measured before and after intervention.

Method of measurement

Spirometer

2**Description**

Respiratory rate in one minute

Timepoint

Before and after intervention in each session

Method of measurement

Clinical examination

3**Description**

Oxygen saturation

Timepoint

Before and after intervention in each session

Method of measurement

Pulse oximeter

Secondary outcomes

1

Description

Daily cough (more than twice a week)

Timepoint

Before the intervention and at the end of the intervention (in the final session)

Method of measurement

Questionnaire according to severity classification of asthma

2

Description

Overnight cough 3-4 times a month, 1 time or more per week

Timepoint

Before the intervention and at the end of the intervention (in the final session)

Method of measurement

Questionnaire according to severity classification of asthma

3

Description

Shortness of breath 1 times per year due to shortness of breath / twice and more admitted due to shortness of breath,

Timepoint

Before the intervention and at the end of the intervention (in the final session)

Method of measurement

Questionnaire according to severity classification of asthma

4

Description

Restricted activity

Timepoint

The beginning of the intervention before the intervention and the end of the intervention in the final session of the study

Method of measurement

Questionnaire according to severity classification of asthma

Intervention groups

1

Description

Reflexology massageThe patients in this group are selected according to the inclusion criteria after completing the questionnaire, and their FEV1 and respiratory rate are measured in four sessions (once a week) before and after reflexology massage . The signs are checked at the beginning and the end of the intervention. The reflexology massage is performed for

15 minutes.

Category

Rehabilitation

2

Description

stroke massage;The patients in this group are selected according to the inclusion criteria after completing the questionnaire, and their FEV1 and respiratory rate are measured in four sessions (once a week) before and after stroke massage . The signs are checked at the beginning and the end of the intervention. The reflexology massage is performed for 10 minutes.

Category

Rehabilitation

3

Description

Control group: Do not get an intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh Clinic

Full name of responsible person

Behrozi Shokroallah

Street address

Shahid Montazeri Ave

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

0

Phone

+98 74 3322 8212

Email

sarikhani6491@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Shahid Damideh Health Center

Full name of responsible person

Moradi Mohsen

Street address

Imam Hossein Square, Yasuj University of Medical Sciences, Yasuj,

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

0

Phone
+98 74 3334 6078
Email
sarikhani6491@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Ali Mousavi Zadeh
Street address
Motahari Ave, Yasouj University of Medical
City
Yasuj
Province
Kohgilouyeh-va-Boyer-Ahmad
Postal code
0
Phone
+98 74 3334 6078
Fax
+98 74 3334 6079
Email
mousavizadeh@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Elham Sarikhani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
NO, 18, Kosar Ave

City
Safashahr
Province
Fars
Postal code
73961
Phone
+98 71 4446 7175
Email
elhamsarikhani@yums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Shahla Najafi
Position
science Committee
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Motahari Blvd, Yasouj University of Medical Sciences
City
Yasuj
Province
Kohgilouyeh-va-Boyer-Ahmad
Postal code
0
Phone
+98 987433230327
Email
najafi.shahla@yums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Elham Sarikhani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
NO.18.Kosar street
City
Safashahr
Province
Fars
Postal code
7396176491
Phone
+98 71 4446 7175
Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable