Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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 reflexlogy 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
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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