

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Immediate effects of diaphragmatic breathing versus pursed lip breathing on blood pressure, pulse rate and oxygen saturation of patients with hypertension

Protocol summary

Study aim

To compare the immediate effects of diaphragmatic breathing (DB) and pursed lip breathing exercise (PLBE) on blood pressure, pulse rate and oxygen saturation in hypertensive people

Design

Community based, parallel group design, single blinded, randomized clinical trial

Settings and conduct

Settings: Government girls high school Arriyan and Punjab workers welfare fund office, Lahore. Conduct: Trial will be completed in a period of 5 months by three physiotherapists. Single blinded study with blinding of outcome measure assessor who will be called from other place to record outcome measures without knowing about patient's group.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with hypertension (stage 1 and stage 2) with Systolic Blood Pressure \geq 140mmHg and Diastolic Blood Pressure \geq 90 mmHg will be recruited. ✓ 40 to 60 years of age people will be included. ✓ Both males and females. ✓ Patients either who would have taken any anti hypertensive medicines (ACE inhibitors, calcium channel blockers, thiazide diuretics, ACE receptor inhibitors, beta blockers) at least 6 hours ago or no medicine at all to be certain that results are purely because of mentioned techniques. Exclusion: Participants who are unwilling to participate. Patients who are critically terminally ill e.g. patients with mental illness, psychosocial factors, cancer, infectious diseases, and comatose patients.

Intervention groups

There will be 2 groups 1 will receive PLBE and other will receive DBE. For PLBE, patients will be asked to inhale through nose with mouth closed for 2 seconds and then exhale with pursed lips for four seconds. DBE group will be asked to assume a relaxed position with back and

head supported. Start with breathing in slowly through the nose such as abdomen is filling first and then exhale slowly through the mouth.

Main outcome variables

Blood Pressure, Oxygen saturation, Pulse Rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050209N1**

Registration date: **2021-03-27, 1400/01/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

Registration date

2021-03-27, 1400/01/07

Registrant information

Name

Yasha Sajjad

Name of organization / entity

Riphah International University, Pakistan

Country

Pakistan

Phone

+92 42 36684109

Email address

yashasajjad68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-22, 1399/12/04

Expected recruitment end date

2021-05-01, 1400/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Immediate effects of diaphragmatic breathing versus pursed lip breathing on blood pressure, pulse rate and oxygen saturation of patients with hypertension

Public title
Immediate effects of diaphragmatic breathing exercise versus pursed lip breathing exercise on blood pressure, pulse rate and oxygen saturation of patients with hypertension

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hypertension (stage 1 and stage 2) with Systolic Blood Pressure \geq 140mmHg and Diastolic Blood Pressure \geq 90 mmHg will be recruited. 40 to 60 years of age people will be included. Both males and females will be recruited. Patients who would have taken any anti hypertensive medicines (ACE inhibitors, calcium channel blockers, thiazide diuretics, ACE receptor inhibitors, beta blockers) more than 6 hours ago or none will be included.
Exclusion criteria:
Participants who are unwilling to participate will not be recruited. Patients who are critically terminally ill e.g. patients with mental illness, psychosocial factors, cancer, infectious diseases, and comatose patients will not be considered

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Non probability consecutive sampling will be used for recruiting people in study and simple random method (coin toss method) will be used for allocating sample in each group. Flipping of coin will be done at the time of group allocation to odd numbers of subjects such as if 1st person receives head of coin then 2nd person will receive tail of coin. At the time of 3rd person recruitment, coin will be flipped, then on the 5th person and so on.

Blinding (investigator's opinion)
Single blinded

Blinding description
Only outcome assessor will be blinded. An outcome assessor will be called from other place and will collect pulse rate, blood pressure and oxygen saturation of patients before and after treatment without knowing about patient's groups so this study is single blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Riphah Research Ethical committee
Street address
Madar e millat road, Quaid e azam industrial estate ,
Lahore
City
Lahore
Postal code
54000

Approval date
2020-10-23, 1399/08/02

Ethics committee reference number
RCRS-RE-MS-PT/Fall20/097

Health conditions studied

1

Description of health condition studied
people with raised blood pressure. Hypertension stage 1 and stage 2 are focused in this study

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood Pressure

Timepoint
Blood pressure will be recorded before and after 5 minutes of giving each intervention.

Method of measurement
Blood Pressure will be recorded by using aneroid sphygmomanometer rate.

2

Description

Oxygen Saturation

Timepoint

Oxygen Saturation will be recorded before and after 5 minutes of giving each intervention.

Method of measurement

oxygen saturation will be measured using pulse oximeter

3

Description

Pulse Rate

Timepoint

Pulse rate will be recorded before and after 5 minutes of giving each intervention.

Method of measurement

Pulse Rate will be recorded using pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Pursed Lip Breathing Exercise (PLBE). This is a breathing exercise. In this study, we will record the impact of pursed lip breathing exercise on blood pressure, oxygen saturation and pulse rate of patients with hypertension. There will be one group of 23 subjects with systolic bp of more than or equal to 140 mm Hg and diastolic bp of more than or equal to 90 mm Hg. Using Aneroid Sphygmomanometer bp will be taken before exercise and 5 minutes after exercise. Likewise, using pulse oximeter pulse rate and oxygen saturation will be taken before exercise and after 5 minutes of exercise. Procedure: One physiotherapist will guide the one group of patients to do PLBE by inhaling through the nose for two counts, keeping mouth closed in relaxed sitting position. Then the subjects will be asked to purse their lips, and breathe out (exhale) slowly and gently through pursed- lips while counting to four. The intervention will be applied for 3 to 4 times and then rest (for one minute), five sets will be applied in a treatment session. Assessor will be blinded only.

Category

Rehabilitation

2

Description

Intervention group2: Diaphragmatic Breathing Exercise (DBE). 2nd group with 23 subjects (male and females with 1:1 representation) with systolic bp of more than or equal to 140 mm Hg and diastolic bp of more than or equal to 90 mm Hg will be asked to perform diaphragmatic breathing exercise. Using Aneroid Sphygmomanometer bp will be taken before exercise and 5 minutes after exercise. Likewise, using pulse

oximeter pulse rate and oxygen saturation will be taken before exercise and after 5 minutes of exercise.

Procedure: One physiotherapist will guide the one group of patients to do DBE. Procedure: Patients will be asked to assume a relaxed position with back and head supported with full abdominal relaxation. Then they will be asked to breathe in slowly and deeply through the nose such as abdomen fills out, relax the shoulder and keep the upper chest quiet. Then the patient will be instructed to slowly let all the air out through the mouth and causing the abdomen to fall first. The intervention will be applied for 3 to 4 times and then rest (for one minute), five sets will be applied in a treatment session. Assessor will be blinded only.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Government Girls High School Arriyan

Full name of responsible person

Noreen Arshad

Street address

Govt. Girls High School Arriyan, Raiwind Road, Lahore.

City

Lahore

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55150

Phone

+92 42 35330050

Email

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2

Recruitment center

Name of recruitment center

Directorate Education Punjab Workers Welfare Board, Pakistan

Full name of responsible person

Muhammad Sajjad Aslam

Street address

F-A/1, Khyber Block, Allama Iqbal Town, Lahore

City

Lahore

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54570

Phone

+92 42 99260246

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Dr. Quratulain

Street address

madar-e-millat road, quaid-e-azam industrial estate
quaid e azam industrial estate, lahore, punjab

City

Lahore

Postal code

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Phone**Email**

qurat.ain@riphah.edu.pk

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

No

Title of funding source

investigator initiated

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Other

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

Nausha Polyclinic, Raiwind, Lahore District, Pakistan

Full name of responsible person

Yasha Sajjad

Position

Clinical Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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

Nausha Polyclinic, Raiwind

Full name of responsible person

Yasha Sajjad

Position

clinical physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for updating data**Contact****Name of organization / entity**

Nausha Polyclinic, Raiwind

Full name of responsible person

Yasha Sajjad

Position

clinical physiotherapist

Latest degree

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Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable