Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≥ 140mmHg and Diastolic Blood Pressure ≥ 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 ≥ 140mmHg and Diastolic Blood Pressure ≥ 90 mmHg will be recruited. 40 to 60 years of age people will be inculded. Both males and females will be recruited. Patients who would have taken any anti hypertensive medicines (ACE inhibitors, calcium channel blockers, thiazide dieuretics, 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
Goverment Girls High School Arriyan
Full name of responsible person
Noreen Arshad
Street address
Govt. Girls High School Arriyan, Raiwind Road, Lahore.
City
Lahore
Postal code
55150
Phone
+92 42 35330050
Email
noreenarshad437@gmail.com

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
Postal code
54570
Phone
+92 42 99260246
Email
muhammadsajjadaslam63@gmail.com

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
54760
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
Street address
137 A block A Kahloon House, Nawab Town, Raiwind Road, Lahore
City
Lahore
Province
Punjab
Postal code
53700
Phone
+92 42 36684109
Email
yashasajjad68@gmail.com

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
137 A, Block A Kahloon House, Nawab Town, Raiwind Road, Lahore
City
Lahore
Province
Punjab
Postal code
53700
Phone
+92 42 36684109
Email
yashasajjad68@gmail.com

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
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
137 A, Block A Kahloon House, Nawab Town, Raiwind Road, Lahore
City
Lahore
Province
Punjab
Postal code
53700
Phone
+92 42 36684109
Email
yashasajjad68@gmail.com

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