

# 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

##### **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

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Bachelor

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**Email**

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

Nausha Polyclinic, Raiwind

**Full name of responsible person**

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53700

**Phone**

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**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