

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Combined effects of pelvic floor Hold relax and Buteyko technique on urinary incontinence, pulmonary functions and exercise tolerance in COPD patients

#### Protocol summary

##### Study aim

To find the combined effects of pelvic floor Hold relax and Buteyko technique on urinary incontinence, pulmonary functions and exercise tolerance in COPD patients

##### Design

Randomized Controlled Trial

##### Settings and conduct

This Study will be conducted at Gulab Devi Chest Hospital, Lahore.

##### Participants/Inclusion and exclusion criteria

- Patients complaining incontinence link with cough and exercise.
- Age criteria 25-45 years
- Patients having ability to perform voluntary pelvic floor muscle contraction and cooperative.
- Self-reported urinary incontinence.
- Stable COPD Exclusion Criteria:
- Subjects having unstable COPD.
- Also, the subjects with >4 hospital admissions due to COPD during last 1 year.
- Patient 's having Neurological conditions and non-cooperative.
- Subjects having spinal cord injuries.
- Patients having history of Hysterectomy and other gynecological surgeries
- Patients having Malignancy.

##### Intervention groups

Group A: will be treated by Behavioral Therapy along with Pelvic floor hold relax and Buteyko technique. Group B: will be treated by Behavioral Therapy

##### Main outcome variables

Urinary Incontinence, Pulmonary functions, Exercise tolerance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191117045462N14**  
Registration date: **2024-07-18, 1403/04/28**

Registration timing: **retrospective**

Last update: **2024-07-18, 1403/04/28**

Update count: **0**

##### Registration date

2024-07-18, 1403/04/28

##### Registrant information

###### Name

Wajeeha Zia

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 42 35126110

###### Email address

wajeeha\_z@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-29, 1402/07/07

##### Expected recruitment end date

2023-10-28, 1402/08/06

##### Actual recruitment start date

2023-09-29, 1402/07/07

##### Actual recruitment end date

2023-10-28, 1402/08/06

##### Trial completion date

2023-11-28, 1402/09/07

##### Scientific title

Combined effects of pelvic floor Hold relax and Buteyko technique on urinary incontinence, pulmonary functions and exercise tolerance in COPD patients

##### Public title

Combined effects of pelvic floor Hold relax and Buteyko technique on urinary incontinence, pulmonary functions and exercise tolerance in COPD patients

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Patients complaining incontinence link with cough and exercise Age criteria 25-45 years Patients having ability to perform voluntary pelvic floor muscle contraction and cooperative Self-reported urinary incontinence Stable COPD

##### **Exclusion criteria:**

Subjects having unstable COPD Subjects with >4 hospital admissions due to COPD during last 1 year Patient 's having Neurological conditions and non-cooperative Subjects having spinal cord injuries Patients having history of Hysterectomy and other gynecological surgeries Patients having Malignancy

#### **Age**

From **25 years** old to **45 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Investigator

#### **Sample size**

Target sample size: **40**

Actual sample size reached: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Taking into account the aforementioned inclusion and exclusion criteria patients will be divided into two groups by convenient sampling and allocated to 2 groups by simple randomization process by sealed opaque envelope method and labeled as 0 for group A and 1 for group B.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

Investigator will be blind. Assessment will done by 2nd therapist who will not be involved in treatment and data analysis.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

#### **Name of ethics committee**

Riphah college of rehabilitation and Allied Health Sciences

#### **Street address**

13-14-C-civic center, township near Hamdard Chowk Lahore.

#### **City**

Lahore

#### **Postal code**

54000

#### **Approval date**

2023-11-23, 1402/09/02

#### **Ethics committee reference number**

RCR&AHS/REC/MS-CPPT

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

COPD Patients

##### **ICD-10 code**

J44.9

##### **ICD-10 code description**

Chronic obstructive pulmonary disease, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Urinary incontinence and Pulmonary functions

##### **Timepoint**

Pre-Post Treatment

##### **Method of measurement**

International consultation on Incontinence Questionnaire (ICIQ-UI-SF) and for pulmonary functions Master Screen PFT system

### **Secondary outcomes**

#### **1**

##### **Description**

Exercise tolerance

##### **Timepoint**

Pre-Post Treatment

##### **Method of measurement**

6 Minute walk test

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Behavioral Therapy along with Pelvic floor hold relax and Buteyko technique. Patients asked to do Pelvic floor hold relax like 3 sets of 8-12 maximum VPFMC and to hold the contraction for more than three seconds followed by relaxation. Begin by bladder emptying, patients squeeze the muscles around the

urethra as if trying to stop the flow of urine. Buteyko technique given to patients like 8-10 repetitions of 3 sets Patient will be asked to maintain upright posture. In the 1st phase they will do normal breathing for few minutes. Use index finger and thumb to plug nose. After exhalation hold breath as they can, then again inhale and start breathing normally for 10 seconds. In 2nd phase patients will hold breath twice the timing of 1st phase. Patients were also instructed to do exercises for twice a week for 16 weeks. Educational session given to patients about Behavioral Therapy. It includes proper fluid intake schedule that is drink more fluids in the morning and afternoon, not at night. Stop drinking a few hours before bedtime, reducing alcohol, caffeine, spicy foods, voiding interval of 2-3 hours starting from 5 minutes, stop smoking, avoid lifting.

### Category

Rehabilitation

## 2

### Description

Control group: Behavioral Therapy. Educational session given to patients about Behavioral Therapy. It includes proper fluid intake schedule that is drink more fluids in the morning and afternoon, not at night. Stop drinking a few hours before bedtime, reducing alcohol, caffeine, spicy foods, voiding interval of 2-3 hours starting from 5 minutes, stop smoking, avoid lifting.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Riphah college of rehabilitation & Allied Health Sciences.

#### Full name of responsible person

Fazelat Nasir

#### Street address

13-14-C-civic center, township near Hamdard Chowk, Lahore

#### City

Lahore

#### Postal code

54000

#### Phone

+92 42 35126110

#### Email

fazelatmirza@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Riphah International University

#### Full name of responsible person

Wajeeha

#### Street address

13-14-C-civic center, township near Hamdard Chowk, Lahore

#### City

Lahore

#### Postal code

54000

#### Phone

+92 42 35126110

#### Email

wajeeha\_z@yahoo.com

#### Grant name

Educational

#### Grant code / Reference number

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

Yes

#### Title of funding source

Riphah International University

#### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Riphah International University

#### Full name of responsible person

Fazelat Nasir

#### Position

Student

#### Latest degree

Master

#### Other areas of specialty/work

Physiotherapy

#### Street address

13-14-C-civic center, township near hamdard chowk, lahore.

#### City

Lahore

#### Province

Punjab

#### Postal code

54000

#### Phone

+92 42 35126110

#### Email

wajeeha\_z@yahoo.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Wajeeha

**Position**

Senior Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Fazelat Nasir

**Position**

Students

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**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**

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

**Data Dictionary**

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