Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

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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

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inquiries

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Position
Senior Lecturer

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Ph.D.

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Physiotherapy

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Person responsible for updating data

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Position
Students

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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