

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

COMPARATIVE EFFECTS OF DIAPHRAGMATIC BREATHING AND PACED BREATHING ON PULMONARY FUNCTION, HOT FLASHES AND POST-MENOPAUSAL SYNDROME IN WOMEN

Protocol summary

Study aim

To determine the effects of diaphragmatic and paced breathing on pulmonary function, hot flashes and postmenopausal syndrome in women.

Design

44 participants will be recruited. Two parallel groups, double blinded, randomized clinical trial with pre and post assessment.

Settings and conduct

This study will be conducted in gynecology department at Mussarat Razzaque hospital 196 G.T road baghbanpura Lahore. Participants and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA Menopausal women having symptoms Hot Flashes during menopause Not currently taking hormonal replacement therapy, a psychoactive medication, and not using complementary therapy for menopausal symptoms. EXCLUSION CRITERIA Had hormonal replacement therapy Having any cardiac and lung diseases will be excluded If they had history of breast cancer, myocardial infarction and pulmonary embolism.

Intervention groups

Group A: will be treated by Diaphragmatic Breathing
Group B: will be treated by Paced Breathing

Main outcome variables

Menopause rating scale (MRS), Hot flash-related daily interference scale, Pulmonary function changes by using a portable spirometer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191117045462N11**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

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

2023-12-10, 1402/09/19

Expected recruitment end date

2024-04-10, 1403/01/22

Actual recruitment start date

2023-12-10, 1402/09/19

Actual recruitment end date

2024-04-10, 1403/01/22

Trial completion date

2024-06-10, 1403/03/21

Scientific title

COMPARATIVE EFFECTS OF DIAPHRAGMATIC BREATHING AND PACED BREATHING ON PULMONARY FUNCTION, HOT FLASHES AND POST-MENOPAUSAL SYNDROME IN

WOMEN

Public title

COMPARATIVE EFFECTS OF DIAPHRAGMATIC BREATHING AND PACED BREATHING ON PULMONARY FUNCTION, HOT FLASHES AND POST-MENOPAUSAL SYNDROME IN WOMEN

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Menopausal women having symptoms Hot Flashes during menopause Not currently taking hormonal replacement therapy, a psychoactive medication, and not using complementary therapy for menopausal symptoms

Exclusion criteria:

Had hormonal replacement therapy Having any cardiac and lung diseases will be excluded If they had history of breast cancer , myocardial infarction and pulmonary embolism

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Taking into account the above mentioned inclusion and exclusion criteria, patients will be recruited in the study through convenient sampling technique and then will be randomly assigned to each group through Random Sampling by lottery method. Labeled as group A and group B

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Riphah college of rehabilitation & Allied Health Sciences

Street address

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

City

Lahore

Postal code

54000

Approval date

2023-11-26, 1402/09/05

Ethics committee reference number

RCR&AHS/REC/MS-CPPT

Health conditions studied

1

Description of health condition studied

post-menopausal syndrome patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-menopausal symptoms

Timepoint

pre-post treatment

Method of measurement

Menopausal rating scale, Hot flash-related daily interference scale

Secondary outcomes

1

Description

Hot flashes

Timepoint

pre-post treatment

Method of measurement

Hot flash-related daily interference scale

Intervention groups

1

Description

Intervention group A: Diaphragmatic Breathing group : Group A will be treated with diaphragmatic breathing cycles (6breaths/min), including 5s of inhalation and 5s exhalation, for twice a day and 15 minutes per day for 3 weeks .

Category

Treatment - Other

2

Description

Intervention group B: Paced Breathing Group :Group B will be treated by Paced Breathing slowly count for four

while inhaling through the nose and feel the abdomen rise, hold breath for 1sec and slowly exhaling through lips repeat exercise 6 to 8 minutes per minutes twice a day for 3 weeks.

Category

Treatment - Other

3**Description**

Baseline intervention: Lifestyle intervention advice Each patient in both groups will instructed to follow lifestyle intervention advice. The advice included avoiding eating or drinking before going to bed , and increasing consumption of a whole diet rich in fruit, vegetables, carbohydrates, and legumes . Moreover, advice included preparing for sleep by mentally calming down at night and avoiding afternoon naps, making sure the bedroom was comfortable, warm, calm, and dark , avoiding sleeping near a light source , going to bed when feeling tired, getting up when unable to sleep, and rising at the same time every morning.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Riphah college of rehabilitation & Allied Health Sciences

Full name of responsible person

Riphah college of rehabilitation & Allied Health Sciences

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**

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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?**

No

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

Gullnaz Yousaf

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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

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Full name of responsible person

wajeeha

Position

Senior lecturer

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

student

Latest degree

Master

Other areas of specialty/work

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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

N/A

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