Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 , mayocardial 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
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Riphah International University
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Pakistan
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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 , mayocardial 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 adviceEach 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
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?
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

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wajeeha

Position

Senior lecturer

Latest degree
Ph.D.

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Latest degree
Master

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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