Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of diaphragmatic breathing exercise and active cycle of breathing technique on heart rate and blood pressure in patients with hypertension

Protocol summary

Study aim
The aim of this study will be to compare the effects of diaphragmatic breathing exercise and active cycle of breathing technique in lowering heart rate and blood pressure measured in hypertensive patients at 24 hour and 7 days interval.

Design
Two parallel groups, single blinded, randomized clinical trial with pre and post assessment

Settings and conduct
DHQ hospital Sahiwal and privately at Sahiwal Diabetes Care Center and Polyclinic (Sahiwal), Participant will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria • Patients with age range 45-65 years • Patients clinically diagnosed with hypertension • Patients who will give consent to abide by treatment for 4 weeks. Exclusion criteria • History of precious surgery • History of rib fracture • Any neurological problem • Pregnant females • Patients with respiratory disease • Patients with coronary artery disease

Intervention groups
Interventional Group1 : Diaphragmatic breathing exercise. Interventional Group 2 : Active cycle of breathing technique.

Main outcome variables
• Heart rate • Systolic and diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201024049129N1**
Registration date: **2021-08-18, 1400/05/27**
Registration timing: **retrospective**
Last update: **2021-08-18, 1400/05/27**
Update count: **0**

Registration date
2021-08-18, 1400/05/27

Registrant information
Name
Khazima Asif
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Riphah
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Pakistan
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-14, 1399/12/24

Expected recruitment end date
2021-06-13, 1400/03/23

Actual recruitment start date
2021-04-20, 1400/01/31

Actual recruitment end date
2021-07-18, 1400/04/27

Trial completion date
2021-07-18, 1400/04/27

Scientific title
Comparison of diaphragmatic breathing exercise and active cycle of breathing technique on heart rate and blood pressure in patients with hypertension

Public title
Effect of diaphragmatic breathing exercise on heart rate and blood pressure

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with age range 45-65 years Patients clinically diagnosed with hypertension Patients who will give consent to abide by treatment for 4 weeks.
Exclusion criteria:
History of precious surgery History of rib fracture Any neurological problem Patients with respiratory disease Patients with coronary artery disease Pregnant females
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **44**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be recruited in the study through convenient sampling technique and then will be randomly assigned to each group by simple lottery method. Odd and even numbers will be given to group A and B respectively. if a patient gets odd no he/she will be allocated in Group A. If a patient gets Even number he/she will be allocated in Group B. Total sample size will be 40. So, 20 patients will get even number and 20 will get odd number.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will be blinded in terms of group allocation. Written Consent will be taken from patients but they will not be informed about the group in which they will be treated and the effects of treatment in each groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Name of ethics commitee: 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
2021-01-04, 1399/10/15
Ethics committee reference number
RCRS-RE-MS-PT/Fall20/061

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
RO3.0
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic and Diastolic Blood Pressure
Timepoint
Pre Intervention and Post Intervention for all 4 weeks
Method of measurement
Mercury Spygmomanometer

Secondary outcomes

1

Description
Heart rate
Timepoint
Pre intervention and post intervention at the end of each day for 4 weeks.
Method of measurement
By pulse oximeter in minutes

Intervention groups

1

Description
Intervention group 1: Diaphragmatic Breathing Exercise : Patiemt will be in semi fowler position. Therapist will place one hand on rectus abdominis below anterior costal.margin. After patient understand and is able to breath using diaphragmatic pattern,suggest the patient to breath nose and through mouth. Control expiration for 4 or 5 times per session. Each session will be given for 7 days per week (4 weeks).
Category
Treatment - Other

2

Description
Intervention group 2: Active cycle of breathing technique: This technique involves 3 parts. Breathing control in which patient will breath out gently and will be 3 to 5 deeper breaths with 2 second hold at the end of breath in before breath out. Second part is thoracic expansion exn exercise in which patient will keep hia shoulder and chest relaxed and will take a long slow deep breath in through nose. Patient will hold air in lungs for 2-3 seconds before breathing out. And the 3rd part huffing exhaling through open mouth . The session will last for 15 minutes for 7 days per week(4weeks).

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Riphah college of rehabilitation and Allied Health Sciences

Full name of responsible person
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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
15

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
Khazima Asif

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Rehabilitation and research

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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