

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 previous 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

Name of organization / entity

Riphah

Country

Pakistan

Phone

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Email address

khazimaasif73@gmail.com

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 previous 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 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

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

R03.0

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 Sphygmomanometer

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 : Patient 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

Khazima Asif

Street address

13-14-C- civic center 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

Wajeeha

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International university

Full name of responsible person

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Latest degree

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Punjab
Postal code

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