Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of diaphragmatic breathing exercise and progressive relaxation technique in patient having preeclampsia.

Protocol summary

Study aim
To evaluate the effectiveness of diaphragmatic breathing exercises and progressive relaxation techniques in patients having preeclampsia.

Design
The design of this study is Randomized, parallel Controlled Trial. Randomization is done by lottery method. In this method, the researcher gives each participant of the trial a number. Researchers draw numbers from the box randomly to allocate participants in two groups

Settings and conduct
This study is conducted at Arif Memorial Hospital. In this trial participants are blinded through concealment to avoid biasness.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Systolic BP ≥135 mmHg or diastolic BP ≥85 mmHg Preeclampsia female diagnosed by a physician Age group 25-40 Exclusion criteria: Chronic hypertension Contraction or leakage of fluid during the study Bleeding , heart disease, and renal diseases

Intervention groups
All the subjects of the sample will be allocated to two groups randomly. Group A: Diaphragmatic breathing exercise , progressive relaxation technique and routine hypertensive medication Group B: only receive routine hypertensive medication

Main outcome variables
Arterial blood pressure, Oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220626055280N2**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **registered_while_recruiting**
Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
Nazeer Ahmad

Name of organization / entity
Rashid Latif medical college

Country
Pakistan

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+92 333 8054247

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-19, 1401/10/29

Expected recruitment end date
2023-05-19, 1402/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of diaphragmatic breathing exercise and progressive relaxation technique in patient having preeclampsia.

Public title
Effect of diaphragmatic breathing exercise and progressive relaxation technique in patient having preeclampsia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systolic BP ≥135 mmHg or diastolic BP ≥85 mmHg Preeclampsia female diagnosed by physician

Exclusion criteria:

Chronic hypertension Contraction or leakage of fluid during study Bleeding ,heart disease and renal diseases

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated into two groups i.e.; Group A and Group B, by lottery method. Lottery method is a type of simple random sampling. In this method, each participant of the trial is assigned a unique number. In the next step these numbers are written on separate cards which are physically similar in shape, size, color etc. 30 cards were used. Then they are placed in a basket and thoroughly mixed. In the last step the slips are taken out randomly without looking at them and are placed into two sets randomly. Total of 26 cards were taken out, 13 participants in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The blinding is achieved by concealment in which the treatment allocation for each patient is not revealed to the patient. This is done to avoid biasness.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of Rashid Latif Medical College

Street address

35-Km Ferozepur road Lahore

City

Lahore

Postal code

54600

Approval date

2022-10-05, 1401/07/13

Ethics committee reference number

IRB/2022/053

Health conditions studied

1

Description of health condition studied

Pre-eclampsia

ICD-10 code

O14.00

ICD-10 code description

Mild to moderate pre-eclampsia, unspecified trimester

Primary outcomes

1

Description

Blood Pressure

Timepoint

Pre and Post 1 Month

Method of measurement

Manual sphygmomanometer was used to evaluate blood pressure

2

Description

Oxygen Saturation

Timepoint

Pre and Post 1 Month

Method of measurement

Pulse oximeter is used to measure oxygen saturation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive Diaphragmatic breathing exercise , progressive relaxation technique and routine hypertensive medication. Progressive muscular relaxation technique will be performed by Conscious removal of tension from the muscles: Contractions start from the hands to the sole muscles (each muscle group was contracted for 5–7 sand then relaxed for 30–40 s). Then make Fist and tighten your hand, then relax. Now Push the elbow down on the chair and then relax arm. Raise your eyebrows and wrinkle your forehead, then relax your forehead. Furthermore, Close your eyes tightly, then open slowly. For Muscles of the central part of the face, Cross your eyes and pull the nose upwards. Moreover, to relax the lower part of face, jaw and neck,

Tie your teeth and tighten the corners of your mouth, then relax. For Shoulders, Raise your shoulders as if you want to touch the ears, then relax. Chest and abdomen muscles can be relaxed by taking a deep breath and hold it, then exhale (Abdominal muscle contraction was avoided due to avoiding preterm labor contractions in this study). For Legs muscles, Pull your toes down, away from your body, and then relax. Furthermore, for anterior thighs, Contract the muscles above and below the thigh and then relax. For Hamstrings muscle Push heels down into floor ,tighten hamstrings muscles and relax. Lastly For Calves, Points toes toward head and relax. Curl toes toward the bottom of feet and relax. At the Completion, Check the whole body for the remaining tension, If you experience tension or pressure in certain muscles, repeat the muscle contraction and relaxation for that group of muscles. Diaphragmatic Breathing will be done by Getting comfortable. You can lie on your back in bed or plinth with a pillow under your head and knees. Or you can sit in a chair with your shoulders, head, and neck supported against the back of the chair and Breathe in through your nose. Let your belly fill with air. Then Breathe out through your nose. Now, Place one hand on your belly and the other hand on your chest. As you breathe in, feel your belly rise. As you breathe out, feel your belly lower. The hand on your belly should move more than the one that's on your chest. Take three more full, deep breaths. Breathe fully into your belly as it rises and falls with your breath. The technique will be applied for 3 days a week, and a single session will be 20 minutes. 5 minutes for diaphragmatic breathing exercise and 15 minutes for progressive relaxation technique

Category

Treatment - Other

2

Description

Control group: The control group only receive routine hypertensive medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arif Memorial Hospital

Full name of responsible person

Kalsoom

Street address

35-Km Ferozepur road Lahore

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54600

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Email

kalsoomkanwal51@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rashid Latif Medical College

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rashid Latif Medical College

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

Rashid Latif Medical College

Full name of responsible person

Kalsoom

Position

Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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