

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative effects of diaphragmatic myofascial release versus diaphragmatic breathing in post operative patients diagnosed with Gastroesophageal reflux disease (GERD)

Protocol summary

Study aim

To determine the comparative effects of Diaphragmatic breathing exercises and diaphragmatic myofascial release in post-operative patients diagnosed with GERD.

Design

Randomized clinical trial

Settings and conduct

Following hospitals of FAISALABAD Allied hospital DHQ hospital Madina Teaching Hospital Aziz Fatima hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria □ Both genders . □ Age 25 to 45 years, □ Participants with a confirmed diagnosis of GERD after 1 week of surgery. □ Willingness to participate □ Participants who have not responded well to conventional treatments for GERD □ Patients with stable cardiovascular and respiratory system. Exclusion criteria: □ Participants with significant comorbidities that may confound the study results or interfere with the ability to perform diaphragmatic interventions. For example, serious cardiovascular or respiratory diseases. □ Diagnosed febrile condition □ Individuals who have undergone recent abdominal or thoracic surgeries, as these may affect diaphragmatic function and introduce variability in the study population . □ Diagnosed malignancy □ Diagnosed psychiatric disorder. □ Unwillingness to Participate in Physiotherapy □ Osteoporosis □ Participants with Smoking and excessive alcohol intake history will be excluded because it can impact GERD symptoms and may influence the study outcomes. □ Pregnancy □ Diagnosed dermatological condition □ Participants who are currently enrolled in other clinical trials to avoid potential confounding factors. □ Underline stomach conditions

Intervention groups

Diaphragmatic group (DB group) Diaphragmatic Myofascial release group (MFR group)

Main outcome variables

Gastrointestinal symptom rating score(GSRS) Reflux Disease Questionnaire (RDQ)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240731062603N1**

Registration date: **2024-08-09, 1403/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-09, 1403/05/19**

Update count: **0**

Registration date

2024-08-09, 1403/05/19

Registrant information

Name

Fizzah Tahir

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 318 7411248

Email address

fizzahtahir2k19@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-08, 1403/05/18

Expected recruitment end date

2024-10-08, 1403/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of diaphragmatic myofascial release versus diaphragmatic breathing in post operative patients diagnosed with Gastroesophageal reflux disease (GERD)

Public title

Comparative effects of diaphragmatic myofascial release versus diaphragmatic breathing in post operative patients diagnosed with Gastroesophageal reflux disease (GERD)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both genders, age 25 to 45 years Willingness to participate Participants with stable cardiovascular and respiratory system Confirmed diagnosis of GERD 1 week after surgery

Exclusion criteria:

Diagnosed Febrile illness Diagnosed malignancy Diagnosed psychiatric disorder

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method was used. subjects were distributed in the groups randomly. The lottery method of randomization is a technique used to randomly assign participants or items to different groups or conditions. Here's a step-by-step description of the process: 1. Identification of participants or items: Identify the individuals or items that need to be randomized. 2. Assignment of unique identifiers: Assign a unique identifier (e.g., number, code, or name) to each participant or item. 3. Creation of a lottery pool: Create a pool of unique identifiers, similar to a lottery drawing. 4. Random drawing: Randomly draw identifiers from the pool, using a method such as a random number generator or a physical drawing. 5. Assignment to groups: Assign the drawn identifiers to different groups or conditions, based on the random order in which they were drawn. 6. Repeat the process: Continue drawing and assigning identifiers until all participants or items have been assigned to a group. The lottery method ensures that: - Each participant or item has an equal

chance of being assigned to any group. - The assignment is random and unbiased. - The process is transparent.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were unaware of the intervention which was applied. Assessor was unaware of the group of interventions

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The University of Faisalabad

Street address

Sargodha road Faisalabad

City

Faisalabad

Postal code

1234

Approval date

2024-02-19, 1402/11/30

Ethics committee reference number

TUF/PB/15/14/2

Health conditions studied**1****Description of health condition studied**

Gastroesophageal reflux disease

ICD-10 code

Gastroesop

ICD-10 code description

Gastroesophageal reflux disease

Primary outcomes**1****Description**

It was measured by reflux disease questionnaire that is self-administered questionnaire comprising 12 items which will measure the frequency and severity of heart burn, regurgitation and dyspeptic complaints which was experienced in early weeks after surgery.

Timepoint

15 days

Method of measurement

Reflux disease Questionnaire (RDQ)

Secondary outcomes

1

Description

It had brought changes in health related quality of life through Gastrointestinal symptom rating scale (GSRS).

Timepoint

15 days

Method of measurement

Gastrointestinal symptom rating score GSRS

Intervention groups

1

Description

Group 1: DB Group Number of participants: [14]- Gender: [Both]-Intervention:Type: Diaphragmatic breathing exercises- Frequency: 2 times a week- Duration: 2 weeks- Number of repetitions: 25 repetitions per session- Exercise Protocol:1. Participants sit comfortably with their backs straight, feet planted firmly on the ground, and hands placed gently on their stomach.2. Inhale deeply through the nose, allowing the diaphragm to drop and the stomach to rise as the lungs fill with air (count of 4).3. Hold the breath for a brief moment (count of 2).4. Exhale slowly through the mouth, allowing the diaphragm to rise and the stomach to fall as the lungs empty (count of 4).5. Repeat for 25 repetitions.Instructions:Participants are instructed to focus on the sensation of their diaphragm expanding and contracting.- Encourage participants to breathe naturally and avoid forcing their breathing.- Monitor participants for proper technique and provide feedback as needed.

Category

Treatment - Other

2

Description

Group 2 : Diaphragmatic Myofascial release group: Group Characteristics: - Number of participants: [14]- Age range: [25 to 45 yrs]- Gender: [both] Health status: Diagnosed with Gastroesophageal Reflux Disease (GERD)_Intervention:Type: Diaphragmatic myofascial release- Frequency: 2 times a week- Duration: 2 weeks- Number of repetitions: 10 repetitions per session- Technique:_1. Participants lie on their back with knees bent and feet flat on the floor.2. The practitioner applies gentle, sustained pressure to the diaphragm using their fingers or a tool.3. Pressure is held for 3-5 minutes to release tension in the diaphragm and surrounding fascia.4. Participants breathe deeply and naturally during the release.5. Repeat for 10 repetitions.Goals:Reduce the severity of GERD symptoms- Improve diaphragmatic function and mobility- Enhance digestion and reduce discomfort_Outcome Measures:_ GERD symptom severity (e.g., frequency, duration, intensity)- Quality of life questionnaires (e.g., GERD-QOL)_Theoretical Rationale:Diaphragmatic tension can contribute to GERD symptoms by increasing intra-abdominal pressure and

impairing esophageal function.- Myofascial release can help relax the diaphragm, improve its function, and reduce GERD symptoms.This description provides a clear outline of the group's characteristics, the intervention, and the technique used to reduce the severity of GERD symptoms.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied hospital

Full name of responsible person

Fizzah Tahir

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self

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

Self

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Faisalabad
Full name of responsible person
Fizzah Tahir
Position
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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