Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title
Comparative effects of diaphragmatic myofascial release versus diaphragmatic breathing in post operative patients diagnosed with Gastroesophaegeal 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.Assesor 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
Gastroesophaegeal reflux disease
ICD-10 code
Gastroesop
ICD-10 code description
Gastroesophaegeal 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 Questionaire (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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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

Researcher

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Position

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Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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