Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Diaphragmatic Respiratory Exercise Training on Clinical Symptoms, Quality of Life and Referral to physician in The Gastro-esophageal Reflux Patients (GERD)

Protocol summary

Study aim

Determining the effect of diaphragmatic breathing training on clinical symptoms, quality of life and re-seeing a physician in patients with gastroesophageal reflux disease

Design

patients will be randomly assigned to one of the intervention or control groups based on a table of random numbers. no intervention will be done in the control group and diaphragmatic breathing exercises will be taught and performed in the intervention group. The sample of the present study is based on the sample size formula of 146 people.

Settings and conduct

In this study, the research community included patients with GERD in the gastrointestinal clinic of Shariati Hospital affiliated to Tehran University of Medical Sciences.The purpose of diaphragmatic breathing exercises in this study is to change chest breathing to abdominal breathing along with contraction of the patient's diaphragmatic muscles. The educational content in the form of a booklet will also be provided to patients at the end of the training.

Participants/Inclusion and exclusion criteria

Entry Criteria: In this study, patients with gastroesophageal reflux disease will enter the study with grade 2 esophagus, a tendency to participate in the study and age 20-60 years. Criteria for not entering the study: There is another chronic disease that affects the quality of life, Pregnancy, History of upper gastrointestinal surgery, BMI above 35 and below 18 Dissatisfaction with studying.

Intervention groups

No intervention will be performed in the control group and diaphragmatic breathing exercises will be taught and performed in the intervention group.

Main outcome variables

Prerequisite: Recurrence, quality of life and clinical signs that will be measured before, one month later and six months later with the above questionnaires. Secondary outcome: frequency of symptoms and duration of symptoms

General information

Reason for update

Acronym

GERD

IRCT registration information

IRCT registration number: **IRCT20190727044341N2**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **prospective**

Last update: **2020-05-01, 1399/02/12**
Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Amin Hosseini Sooreh Bargh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7701 1942

Email address

ahosseinis@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-21, 1399/05/31

Expected recruitment end date

2022-02-28, 1400/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Diaphragmatic Respiratory Exercise Training on Clinical Symptoms, Quality of Life and Referral to physician in The Gastro-esophageal Reflux Patients (GERD)

Public title

The Effect of Diaphragmatic Respiratory Exercise Training on Clinical Symptoms, Quality of Life and Referral to physician in The Gastro-esophageal Reflux Patients (GERD)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Criteria for entering the study: Patients with second-degree gastroesophageal reflux disease who need medication in addition to lifestyle changes. The desire to participate in the study Age 20-60

Exclusion criteria:

Criteria for not entering the study: the presence of other chronic diseases that affect quality of life (cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, cirrhosis, rheumatoid disease, a history of malignancy, scleroderma, diabetes and a history of stroke Brain) Pregnancy History of upper gastrointestinal surgery BMI above 35 and below 18 Dissatisfaction with studying

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

After the pre-test, patients will be randomly assigned to one of the intervention or control groups based on a table of random numbers. For this purpose, a list of patients with entry criteria will be prepared and no intervention will be done in the control group and diaphragmatic breathing exercises will be taught and performed in the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs- Tehran University of Medical Sciences

Street address

Deputy of Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

81633698

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

IR.TUMS.VCR.REC.1399.249

Health conditions studied

1

Description of health condition studied

Gastro-esophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Clinical Symptoms: In this study, clinical symptoms will be measured using the Reflux Disease (RDQ) questionnaire. The Reflux Disease (RDQ) questionnaire includes questions about heartburn, regurgitation, and dyspnea based on the frequency and severity of symptoms. The scores of each question are in the Likert range from zero to five for the frequency and severity of the symptoms, and the higher the score of the questionnaire, the greater the severity of the symptoms or the greater the frequency of symptoms.

Timepoint

Before the study, one and six months later

Method of measurement

Reflux Disease Questionnaire (RDQ)

2

Description
Quality of life: In this study, GERD-HRQL questionnaire is used to measure this variable. This questionnaire includes ten questions about the symptoms of the disease from 0 (asymptomatic) to 5 (inability to perform daily activities). The score from these ten questions ranges from zero (best) to 45 (worst).

Timepoint
Before the study, one and six months later

Method of measurement
GERD-HRQL Questionnaire

3

Description
Re-visit to the doctor: In this study, re-referral to the doctor will be reported using patients' self-report after the intervention and follow-up.

Timepoint
Before the study, one and six months later

Method of measurement
Self-report

Secondary outcomes

empty

Intervention groups

1

Description
Control group: No intervention will be made in this group.

Category
N/A

2

Description
Intervention group: Diaphragmatic breathing exercises will be taught and performed in the intervention group. The purpose of diaphragmatic breathing exercises in this study is to change chest breathing to abdominal breathing along with contraction of the patient's diaphragmatic muscles. The training includes the following: Explaining the purpose of diaphragmatic breathing exercises to the patient - The patient will be asked to be in an open position and place one hand on the chest and the other hand above the navel in the abdomen. - Teach the patient He will be able to breathe through the nose and exhale with his mouth open while only the abdomen moving up and down (the goal is for the abdomen to go up and down, while the shoulders and chest without The patient will be taught to perform the tail operation slowly by counting the numbers one to four and the exhalation operation by counting the numbers five to eight slowly. do it. If the patient has difficulty breathing, he or she will be taught how to breathe with the help of inhaled lips. Sit down and then stand up. The patient will be instructed to do the exercises three times a day, 30 breaths or five minutes at home each time.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Dr. Saeed Reza Mehrpour

Street address
Dr. Shariati Research and Medical Training Center, in front of the Faculty of Economics, Jalal Al-Ahmad Highway, North Kargar St, Tehran

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 0008 4901

Fax
+98 21 8863 3039

Email
shariatihosp@tums.ac.ir

Web page address
http://shariati.tums.ac.ir/Show/Item/2

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraeian

Street address
Deputy of Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
81633686

Phone
+98 21 8163 3685

Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Public

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
Tehran University of Medical Sciences

Full name of responsible person
Amin Hosseini Sooreh Bargh

Position
Master of Medical surgical Nursing Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
School of nursing and midwifery, Tohid square, Tehran

City
Tehtan

Province
Tehran

Postal code
1419733171

Phone
+98 21 6692 7171

Email
aminhosseini835@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Amin Hosseini Sooreh Bargh

Position
Master of Medical surgical Nursing Student

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Other areas of specialty/work
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Postal code
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Phone
+98 21 6692 7171

Email
aminhosseini835@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Email
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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