Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

"Investigating the Effects of Diaphragmatic Breathing Training on Anxiety and Sleep Quality in gastrointestinal Cancer Patients Undergoing Chemotherapy "

Protocol summary

Study aim

Determining the effect of diaphragmatic breathing on anxiety levels and sleep quality in patients with gastrointestinal cancer undergoing chemotherapy

Design

A controlled, double-blind, randomized, parallel-group clinical trial on 62 patients. The randomization method in this study was based on a block design with a block size of four and a 1:1 distribution of participants, using a sequence generated by RAS.

Settings and conduct

This study is a randomized controlled clinical trial study conducted to investigate the effect of diaphragmatic breathing training on anxiety levels and sleep quality in patients with gastrointestinal cancer undergoing chemotherapy. The statistical population includes all patients with gastrointestinal cancers who were referred to hospitals affiliated with Arak University of Medical Sciences in 1404 and were undergoing chemotherapy. Due to the obvious nature of the intervention (breathing training), complete blinding of participants and the instructor is not possible. However, data collectors and statistical analysts will be blinded to group allocation to minimize the risk of bias.

Participants/Inclusion and exclusion criteria

Patients aged 18–65 with confirmed gastrointestinal cancer, at least one chemotherapy session, and ability to complete questionnaires are included. Those with severe cardiac/pulmonary disease, major psychiatric disorders, addiction, or inability to perform exercises are excluded. Participants may withdraw if condition worsens or they decline.

Intervention groups

The intervention group receives face-to-face diaphragmatic breathing training plus educational materials and follow-up monitoring. The control group receives routine oncology care only.

Main outcome variables

Sleep quality: Obtained through the Pittsburgh Sleep Quality Index. Anxiety: A score obtained through the Spielberger State Anxiety Inventory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260122068638N1**
Registration date: **2026-02-25, 1404/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-25, 1404/12/06**
Update count: **0**

Registration date

2026-02-25, 1404/12/06

Registrant information

Name

Hannie Varvani

Name of organization / entity

The university of khomein

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-29, 1404/11/09

Expected recruitment end date

2026-05-30, 1405/03/09

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Investigating the Effects of Diaphragmatic Breathing Training on Anxiety and Sleep Quality in gastrointestinal Cancer Patients Undergoing Chemotherapy "

Public title
"Investigating the Effects of Diaphragmatic Breathing Training on Anxiety and Sleep Quality in gastrointestinal Cancer Patients Undergoing Chemotherapy "
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients will be eligible to enter the research if the definitive diagnosis of digestive tract cancer is registered in their medical records and confirmed by a specialist doctor The age of the patients should be between 18 and 65 years, so that they are physiologically within the range that can be expected to respond to breathing exercises Patients must have a sufficient level of consciousness and cognitive ability to understand the instructions and perform the breathing exercises correctly Fluency in Persian language is required to complete the questionnaires and answer accurately Willingness and written informed consent to cooperate in research Patients must have completed at least one course of chemotherapy so that their clinical conditions are relatively stable
Exclusion criteria:
Patients who are unable to participate in this study due to clinical conditions or individual characteristics will not be included in the inclusion group. This category includes patients who have severe heart or lung diseases, and this condition can prevent breathing exercises safely. Patients with a history of severe psychiatric disorders such as diagnosed severe depression or anxiety, or those dependent on sedatives, hypnotics, or addictive substances, will not be eligible for entry. Patients with cognitive or physical limitations that prevent them from performing exercises or completing questionnaires will not be included in the study from the beginning due to ethical and scientific considerations.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method in this study is based on block design with a block size of four and distribution of participants as 1:1 and by the sequence produced with RAS. This method ensures that the number of samples in both intervention and control groups always remains balanced during the process of recruiting patients. The random allocation sequence will be generated by an independent researcher who has no involvement in the recruitment, training, or assessment of patients, and this sequence will be placed in opaque, sealed, and numbered envelopes. When each patient enters, the envelope corresponding to the sequence number is opened and the patient is assigned to the intervention or control group based on the code inside.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the open nature of the intervention (breathing exercise), complete blinding of the participants and trainer is not possible. However, data collectors and statistical analysts will be blinded to group allocation to minimize the risk of bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name

Secondary trial Id
--
Registration date
2026-01-23, 1404/11/03

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of khomein University of Medical Sciences
Street address
Arak.,qods blvd.,banoo street.,ensaf8 alley
City
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Province
Markazi
Postal code
3818648764
Approval date
2026-01-11, 1404/10/21
Ethics committee reference number

IR.KHOMEIN.REC.1404.036

Health conditions studied

1

Description of health condition studied
gastrointestinal Cancer
ICD-10 code
C15-C26
ICD-10 code description
Malignant neoplasms of digestive organs

Primary outcomes

1

Description
Anxiety and Sleep Quality in gastrointestinal Cancer Patients Undergoing Chemotherapy
Timepoint
At the beginning of the study (before the intervention) and 14 days after the start of diaphragmatic breathing
Method of measurement
Pittsburgh Sleep Quality Index-State-Trait Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The research intervention in the experimental group includes training and implementation of diaphragmatic breathing exercises. Initial training will be conducted in person and face-to-face by the researcher, and an educational brochure, video, and audio file will be provided to the patients to reinforce learning. Each training session will last 10 minutes, and patients will be required to perform it twice a day (9 am and 9 pm) for 14 consecutive days. The first training session will be conducted under the supervision of the researcher to ensure that the patient has learned the method correctly. Then, the patients will continue the exercises independently, and their adherence will be monitored through daily records and telephone calls.
Category
N/A

2

Description
Control group: They will only receive routine oncology care and will not receive any specific breathing training or exercises.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
khansari hospital
Full name of responsible person
Hannie Varvani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of khomein
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3881743364
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Email
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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
The University of khomein
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
The University of khomein

Full name of responsible person
Hannie varvani

Position
student

Latest degree
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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