Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of pranayama breathing exercise and conventional treatment on symptom burden in women with breast cancer undergoing chemotherapy

Protocol summary

Study aim
The impact of pranayama breathing exercises on symptom burden in breast cancer patients undergoing chemotherapy

Design
The current study is a single blind, parallel group clinical trial with a pre- and post-intervention design, which will be conducted on women with breast cancer undergoing chemotherapy referred to the educational center of the Velaiat.

Settings and conduct
This study will be carried out at the cancer department of the Qazvin City Health Center, focusing on breast cancer patients undergoing chemotherapy. To ensure blinding, a researcher other than the principal investigator will complete the questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of breast cancer (new cases), Women aged 18 years and older, Undergoing at least one cycle of chemotherapy Patients with stage one to three breast cancer, Patients who have undergone chemotherapy after breast surgery, Reading and writing literacy, Willingness to participate in the study, Performance scale of 0 to 2 Exclusion criteria: Suffering from other diseases concurrently (heart diseases, respiratory diseases, liver diseases, etc.), Undergoing radiotherapy concurrently, Being pregnant or breastfeeding concurrently, Having a history of mental illnesses or taking psychiatric drugs

Intervention groups
The intervention group will undergo pranayama breathing exercises. The intervention comprises Kapalabhati and Nadi Shudana breathing exercises, including a warm-up, Kapalabhati breathing, and Nadi Shodhana. Each training set involves four sets with 30-second rests, totaling four minutes. The control group will receive routine treatment only.

Main outcome variables
Functional status; symptom severity; dysfunction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231212060343N1**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date
2024-01-23, 1402/11/03

Registrant information

Name
Sima Mohebbi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pranayama breathing exercise and conventional treatment on symptom burden in women with breast cancer undergoing chemotherapy

Public title

The impact of pranayama breathing exercises on the symptom burden of breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of breast cancer (new cases) Women 18 years and older Passing at least one cycle of chemotherapy Patients with stage one to three breast cancer Patients who have undergone chemotherapy after breast surgery Being literate in reading and writing Willingness to participate in the study Having a performance scale of 0 to 2

Exclusion criteria:

Simultaneously suffering from other diseases (heart diseases, respiratory diseases, liver diseases, etc.) Radiotherapy at the same time Concomitant pregnancy or breastfeeding History of mental illness or psychotropic drug use

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be divided into two groups: test and control. This allocation will be achieved through random block allocation. Blocking and sequencing of samples will be conducted using random allocation software (Random Allocation Software, Version 1.0.0). To maintain the confidentiality of the random allocation process, group names will be placed inside numbered envelopes. These envelopes will be numbered in sequence by the software and organized in a box. The researcher responsible for random allocation will remain unaware of the envelope contents. Each envelope will denote the assigned study group (intervention or control). Once the sample is confirmed to have entered the research and written consent is obtained, the first envelope will be numbered. Based on its contents, the envelope will assign the participant to one of the study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

To maintain blinding, a collaborating researcher, unaware of patient allocation to control and intervention groups, will complete the questionnaires.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Qazvin University of Medical Sciences

Street address

University of Medical Sciences Headquarters, Building No. 1, Office Complex, Shahid Salmani St., North Nawab St., Qazvin.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.QUMS.REC.1402.262

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

symptom burden

Timepoint

Before and after intervention

Method of measurement

Eastern cooperative oncology group performance status rating (ECOG) and (M. D. Anderson Symptom Inventory (MDASI)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, the researcher will guide patients through pranayama breathing exercises step by step during the initial face-to-face meeting in the clinic, which occurs before the commencement of chemotherapy. Group interventions, involving 3 to 5 participants, will take place for 15 to 20 minutes in a quiet and peaceful room within the chemotherapy department. Patients, and any accompanying companions, will be instructed, and video materials will be provided for additional support. Participants are expected to practice breathing exercises at home for 10 minutes twice a day over 21 days, starting one week before the initiation of chemotherapy until the 14th day after its commencement. The researcher will conduct daily phone calls to ensure participants are adhering to the home-based exercises and to monitor their health status. A diary will be designed in table format to record the time of each patient's breathing exercise, along with the frequency and type performed during the 21 days. Kapalabati and Nadi Shavana breathing exercises will be implemented in this study.

Category
Rehabilitation

2

Description
Control group: Breast cancer patients undergoing chemotherapy will receive routine treatment.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
The educational and therapeutic center of the Velaiat affiliated to Qazvin University of Medical Sc

Full name of responsible person
Sima Mohebbi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Seyed Mehdi Mirhashmi

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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Sima Mohebbi

Position
Masters student

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available

When the data will become available and for how long
Undecided - It is not yet known if there will be a plan to make this available

To whom data/document is available
Undecided - It is not yet known if there will be a plan to make this available

Under which criteria data/document could be used
Undecided - It is not yet known if there will be a plan to make this available

From where data/document is obtainable
Undecided - It is not yet known if there will be a plan to make this available

What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to make this available

Comments
Undecided - It is not yet known if there will be a plan to make this available