Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

the Effect of a Supportive-Participator Intervention on the Health-Promoting Behaviors of Breast Cancer Patients Undergoing Chemotherapy

Protocol summary

Study aim

Determining the effect of implementing a supportive–participatory intervention on health-promoting behaviors of breast cancer patients undergoing chemotherapy

Design

A randomized, controlled clinical trial with parallel groups, non-blinded, phase 2–3, including 60 patients. Randomization was performed using block timing via Random Allocation

Settings and conduct

The study will be conducted in the chemotherapy wards of Omid and Imam Reza hospitals, Mashhad. The intervention group receives a supportive–participatory program covering health-promoting behaviors (2 face-to-face and 4 virtual sessions), while the control group receives routine care. Both groups are assessed using the HPLP and PPQ questionnaires at three time points. The study is non-blinded, and data will be analyzed using appropriate statistical tests.

Participants/Inclusion and exclusion criteria

inclusion criteria: age 20–60 years, confirmed diagnosis of breast cancer (grades 1, 2, 3a), no history of other cancers, no stressful events within the past 6 months, willingness to participate, and ability to communicate in Persian. Exclusion criteria: unwillingness to continue, occurrence of stressful events during the study, absence from more than two sessions, receiving other cancer treatments, and clinical instability or death of the patient.

Intervention groups

In the intervention group, patients receive a supportive–participatory intervention from the researcher. This includes training on health-promoting behaviors. Sessions consist of 2 face-to-face and 4 virtual meetings. The content is standardized but adapted to individual patient needs. Consent and a needs assessment are completed at the first session, and a summary with patient feedback is collected at the end. The control group receives no educational intervention and only routine care.

Main outcome variables

Health-promoting lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250901067082N1**
Registration date: **2025-09-19, 1404/06/28**
Registration timing: **prospective**

Last update: **2025-09-19, 1404/06/28**
Update count: **0**

Registration date

2025-09-19, 1404/06/28

Registrant information

Name

zahra Amadeh

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

2025-09-23, 1404/07/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the Effect of a Supportive-Participator Intervention on the Health-Promoting Behaviors of Breast Cancer Patients Undergoing Chemotherapy

Public title

the Effect of a Supportive-Participator Intervention on the Health-Promoting Behaviors of Breast Cancer Patients Undergoing Chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 60 years Confirmed diagnosis of breast cancer (grades 1, 2, and 3a based on pathology report) No history of other cancers No experience of other stressful life events in the past 6 months Willingness to participate in the study (informed consent) Ability to communicate verbally and fluency in the Persian language

Exclusion criteria:

Unwillingness to continue participation in the study Occurrence of a stressful event during the study for the patient or their family Absence from more than two sessions Receiving other cancer treatments (such as radiotherapy or immunotherapy) Clinical instability of the patient’s condition or patient’s death

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a block randomization method was applied. Patients were recruited through non-probability convenience sampling, and subsequently assigned to either the intervention or control group using randomized allocation. To ensure proper allocation and reduce selection bias, random sequences were generated using the Random Allocation software with block timing. A randomization sequence was prepared in advance for an 8-week period. The sequence was placed in sealed opaque envelopes to maintain allocation concealment. At the beginning of each week, one envelope was opened, and based on the code inside, all patients recruited during that week were assigned to either the intervention (Group A) or the control group (Group B). This approach minimized the possibility of foreknowledge of group assignment by the allocator, since the assignment sequence was concealed until the time of allocation. No blinding was implemented in this study; however, allocation concealment was maintained to prevent information leakage and ensure methodological rigor.

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

Research Ethics Committee of School of Nursing & Midwifery - Mashhad University of Medical Sciences

Street address

East Gate, Ferdowsi University of Mashhad Campus, Dr. Kharazmi Educational Complex, Azadi Square, Mashhad, Khorasan Razavi, Iran

City

Mashhad

Province

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Postal code

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Approval date

2025-08-26, 1404/06/04

Ethics committee reference number

IR.MUMS.NURSE.REC.1404.059

Health conditions studied

1

Description of health condition studied

Malignant neoplasm of breast

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Health-promoting lifestyle (as assessed by Walker et al.’s questionnaire)

Timepoint

Before the intervention (pre-test), after the intervention (completion of 6 sessions), and one month post-intervention

Method of measurement

Walker et al.'s questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients receive a supportive–participatory intervention delivered by the researcher. This intervention follows a predefined framework and covers key topics related to health-promoting behaviors in breast cancer patients undergoing chemotherapy. Considering the patients' clinical conditions and the challenges of travel and side effects during chemotherapy, sessions are conducted as 2 face-to-face and 4 virtual meetings. Virtual sessions are held according to patient preference via phone call or their chosen messaging platform (e.g., Eitaa, Rubika, Gap, WhatsApp, etc.).In the first session, in addition to obtaining informed consent and demographic information, patients complete a standardized needs assessment form to identify individual priorities and requirements. While the overall content is fixed, the emphasis and delivery method for each topic are tailored to individual patient needs. If no specific needs are identified, sessions proceed according to the predetermined educational program to cover all essential aspects. This structure allows the researcher to maintain the scientific integrity of the intervention while responding to each patient's specific needs (Appendix 4).After introducing themselves, establishing rapport, and listening to the patients' experiences and concerns, the researcher provides explanations about breast cancer and the chemotherapy process, and presents the intervention content—including stress management, physical activity, healthy nutrition, positive interpersonal relationships, spiritual growth, and health responsibility—via pamphlets and written materials. Additionally, the researcher conducts a 15-minute audio phone session for each session to explain the content and answer patient questions. If a patient's condition is not suitable, the session is conducted over two calls.At the beginning of each session, the researcher listens to the patient's challenges and attempts to establish a supportive relationship. Through a question-and-answer approach, patients are actively engaged in the learning process. The researcher's contact information is provided to patients for any questions or further discussions. In each session, patient feedback is collected regarding the topics discussed, and necessary adjustments are made to optimize alignment with educational and clinical needs. In the final face-to-face session, educational content is summarized, and additional feedback is collected from patients.To evaluate the intervention, the Health-Promoting Lifestyle Questionnaire by Walker et al. and the Patient Participation Questionnaire (PPQ) by Berg et al. are used for both groups at three time points: before the intervention (pre-test), after completion of the 6 sessions, and one month post-intervention. Data will ultimately be analyzed using appropriate statistical tests.

Category

Lifestyle

2

Description

Control group: The control group will receive routine chemotherapy care provided by nurses and the treatment team, including general counseling and dietary recommendations delivered face-to-face. To assess the control group, the Health-Promoting Lifestyle Questionnaire by Walker et al. and the Patient Participation Questionnaire (PPQ) by Berg et al. will be administered at three time points for both groups: before the intervention (pre-test), after completion of the 6 sessions, and one month post-intervention. Data will then be analyzed using appropriate statistical tests.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Salman Soltani

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n Sina Street, Imam Reza Hospital Square, Imam Reza Educational, Research and Treatment Center, Mashhad, Khorasan Razavi, Iran

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2

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Soudabeh Shahid Thaleth

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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The decision not to share individual participant data is due to the sensitivity of patient information and the ethical considerations regarding confidentiality and privacy. Sharing the data could potentially risk identifying participants despite anonymization, and therefore, to protect their rights and maintain trust, the data will remain confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available