

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Determining the Effect of Health Promotion Educational Support Program on the Quality of Life, Hope and Family Support of Women with Breast Cancer in the Stage of Surgery and Chemotherapy

Protocol summary

Study aim

Determining the Effect of a Supportive Educational Program to Promote the Health of Women with Breast Cancer on the Quality of Life, Hope and Family Support during Surgery and Chemotherapy

Design

A clinical trial with a control group, non-parallel groups, single-blind, non-randomized, phase 3 on 304 patients with breast cancer in the stages of chemotherapy and surgery

Settings and conduct

The research environment will be Omid Hospital in Mashhad. The intervention includes the implementation of the health promotion program, which includes educational, support and follow-up sessions. First, sampling of the control group will be done, then the program will be implemented for the intervention group and the questionnaires will be completed by the implementation group

Participants/Inclusion and exclusion criteria

The patient is a new case of breast cancer; He is a candidate for mastectomy surgery or a candidate for a chemotherapy protocol; Be a woman; Be between the ages of 25 and 65; Be Iranian; Ability to read and write in Farsi language.

Intervention groups

First, the sampling of the control group will be done independently until a sufficient sample size is reached for both surgery and chemotherapy groups. Control groups will receive only routine care. Then the intervention, which consists of the implementation of an educational support program for health promotion, will be implemented for two groups of surgery and chemotherapy. For both chemotherapy groups (intervention and control) questionnaires related to quality of life, hope and family support on dates 0, 1 and 3 months after the start of treatment and for both

surgery groups (intervention and control) questionnaires related to Quality of life, hope and family support will be completed on the day of discharge and 8 weeks after surgery.

Main outcome variables

Quality of life, hope and family support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230510058141N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

samane raffe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3890 9438

Email address

rafes991@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-04-20, 1403/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the Effect of Health Promotion Educational Support Program on the Quality of Life, Hope and Family Support of Women with Breast Cancer in the Stage of Surgery and Chemotherapy

Public title
Determining the Impact of the Health Promotion Program for Women with Breast Cancer on the Quality of Life, Hope and Family Support During Surgery and Chemotherapy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a new case of breast cancer. She is a candidate for mastectomy surgery or a candidate for a chemotherapy protocol. The patient is female. The patient must be between 25 and 65 years old. Be an Iranian patient. The patient should be able to read and write in Persian language.
Exclusion criteria:
Does not Agree to Participate in the Research.

Age
From **25 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **304**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, the research participants will include breast cancer patients and will be blinded. In this way, while providing full explanations of the research, the patient will be told that the patient will be placed in one of the two control or intervention groups. It will also be explained that if the patient is placed in the control group, he will receive routine interventions and care. Then informed consent will be obtained.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing & Midwifery; Mashhad University of Medical Sciences

Street address

No. 5, Ceraghchi 17 St., Saremi 52 Ave., VakilAbad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9178835442

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.112

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

The score obtained from the EORCT QLQ30 quality of life questionnaire

Timepoint

In surgery patients: at times (discharge day) 0 and 6 weeks after surgery and in chemotherapy patients at times 0 (first session of chemotherapy), one week later and 3 months later

Method of measurement

EORCT quality of life QLQ c30 questionnaire

2

Description

Hope: the score obtained from the Hearth Hope Index tool

Timepoint

In surgery patients: at times (discharge day) 0 and 6 weeks after surgery and in chemotherapy patients at times 0 (first session of chemotherapy), one week later and 3 months later

Method of measurement

Hearth Hope Index tool

3

Description

Family support: score obtained from the ICE-FPSQ
Perceived Family Support Questionnaire

Timepoint

In surgery patients: at times (discharge day) 0 and 6 weeks after surgery and in chemotherapy patients at times 0 (first session of chemotherapy), one week later and 3 months later

Method of measurement

ICE-FPSQ Perceived Family Support Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes the implementation of the health promotion program. This program consists of: Holding at least one training session for 30 minutes to justify the laboratory staff to refer the patient to the medical clinic in order to provide the appointment of the doctor to the patient. Holding at least one training session for 30 minutes to justify the reception staff of the clinic to facilitate the doctor's visit to the patient. Telephone follow-up by making at least 2 phone calls to the patient by the nurse working in the health education nursing clinic according to the defined process up to 48 hours after receiving the pathology answer and answering the patient's questions in the form of telephone consultation to follow up the referral and start the treatment. Development of electronic education by updating the website of Omid Hospital by providing up-to-date scientific content, education through smart phones by making it possible to access up-to-date and scientific educational content by scanning the QR code on the educational content. Development of scientific and up-to-date educational content in the application available in Omid Hospital. Making it possible to access educational content through Bluetooth. Holding a face-to-face training session for 15 minutes for the patient and family on how to access the educational materials available on the Omid Hospital website and training the patient and family on how to receive the educational materials by scanning the QR code.

Category

Lifestyle

2

Description

Control group: Providing routine and usual educational, care and treatment interventions

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Dr Seyed Amir Aledavood

Street address

Omid Hospital, Kohsangi Ave,

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aledavoodA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Talat khadivzade

Street address

Faculty of Nursing and Midwifery, Ebne Sina Street,

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vcresraech@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Samane Raffae

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fateme Heshmati Nabavi

Position

Associate Professor

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samane Raffae

Position

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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)

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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Health and treatment centers

From where data/document is obtainable

Applicants can refer to the library of Mashhad College of Nursing and Midwifery located on Ebne Sina Street to receive documents. Or call 05138591511 ext. 253 Mrs. Nowrozi.

What processes are involved for a request to access data/document

Immediately by visiting the Mashhad Nursing and

Midwifery Faculty library in person or online

Comments