Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,
City
Mashhad
Province
Razavi Khorasan
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9176613775
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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,
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
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 Raffe

Position
Ph.D student

Latest degree
Master

Other areas of specialty/work
Nursery

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No. 5, Saremi 52 Ave., Cheraghchi 17., Vakilabad Blvd.

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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

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Samene Raffe

Position
Ph.D student

Latest degree
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Other areas of specialty/work
Nursery

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Faculty of Nursing and Midwifery, Ebne Sina Street

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Rafes991@mums.ac.ir

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**