

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of transitional care program from hospital to home on the quality of life of women with breast cancer their family caregiver's burden

Protocol summary

Quality of life, caregiver burden

Study aim

Investigation and impact of transitional care program from hospital to home on the quality of life of women with breast cancer and the care burden of their caregivers in two intervention and control groups.

Design

A clinical trial with a control group, with parallel groups, not blinded, randomized based on a block of four on 60 patients, due to the lack of drug use, the phase is not valid.

Settings and conduct

This study is a randomized controlled clinical trial that will be conducted on women undergoing mastectomy surgery in selected military centers (Baqiyatallah Hospital and Chamran Hospital). Sampling will be done using a four-way block method and will be randomly divided into two intervention and control groups. A transitional care program will be implemented for the intervention group. So that the patients will be provided with educational intervention during four sessions (the first session, before discharge in person and three sessions once a week for up to three weeks after discharge by telephone for 45 minutes).

Participants/Inclusion and exclusion criteria

Inclusion criteria Hospitalized patients who are on postoperative days 1 to 3 following mastectomy surgery. Having the age of eighteen to seventy years Breast cancer identified by pathology and treated by surgery Ability to complete the questionnaire independently Access to a home phone and mobile phone Not suffering from mental illnesses Exclusion criteria History of chronic diseases Not living in Tehran Women over seventy years old

Intervention groups

Women with breast cancer who are candidates for mastectomy and meet the inclusion criteria.

Main outcome variables

General information

Reason for update

Minor errors in some parts that were entered during incomplete registration

Acronym

IRCT registration information

IRCT registration number: **IRCT20231203060248N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**

Update count: **1**

Registration date

2023-12-23, 1402/10/02

Registrant information

Name

Marzie sadat Seyed alighadr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6552 7557

Email address

marziealighadr25@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of transitional care program from hospital to home on the quality of life of women with breast cancer their family caregiver's burden

Public title

The effectiveness of transitional care program on the quality of life of women with breast cancer and the care burden of their caregivers

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized patients who are on postoperative days 1 to 3 following mastectomy surgery. Breast cancer identified by pathology and treated by surgery Ability to complete the questionnaire independently Access to home and mobile phones Residence in Tehran and its suburbs within one month after discharge for the possibility of home visits No mental illness

Exclusion criteria:

History of chronic diseases Women over seventy years old Non-residence of the person in Tehran

AgeFrom **18 years** old to **70 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

This study is a randomized controlled clinical trial that will be conducted on women undergoing mastectomy in selected military centers. At first, the samples will be randomly divided into intervention and control groups based on the inclusion criteria and selected in a purposeful way and by the quadruple block method. The method of random assignment with blocks of four will be such that letter A will be assigned to the intervention group and letter B will be assigned to the control group, and in blocks of four with letters A and B, six states AABB, BBAA, ABAB, BABA, ABBA, BAAB will be written on separate sheets and thrown in a container. Randomly, one of these sheets will be taken out of the container and the composition written on it will be noted and that sheet will be thrown into the container again. Since the sample size is 60 patients, this procedure will be repeated fifteen times and each time the composition written on the sheet will be noted down after the composition written on the previous sheet. Then, each letter will be assigned a number from one to sixty in the order of the letters written down one after the other.

Each of the letters will be placed in an envelope and numbers from one to sixty will be written on the envelope. Each time a patient is selected, one of these envelopes will be opened in order of the number written on the envelope, and it will be determined in which group the patient will be placed.

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**

Ethics and Research Committee of Baqiyatullah Azam Educational-Therapeutic Center

Street address

South Bahai Sheikh, Nosrati Alley, Baqiyatullah Aj University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-10-24, 1402/08/02

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.082

Health conditions studied**1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes**1****Description**

Quality of Life

Timepoint

before the start of the intervention and three months after the intervention

Method of measurement

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Breast Cancer Module (EORTC QLQ-BR30)

Secondary outcomes

1

Description

The care burden of the caregivers

Timepoint

before the start of the intervention and three months after the intervention

Method of measurement

Zarit Care Burden Assessment Questionnaire

Intervention groups

1

Description

For the intervention group, a structured transitional care program based on these principles will be developed. The program will include four components: 1. Preparation for transition: Pre-discharge education on the discharge process, expectations for home care, differences between hospital and home care, and the psychological and physical preparation of patients and caregivers. 2. Support and independence: Aims to reduce dependency and increase caregiver and patient self-efficacy through structured education, emotional support, and caregiver participation in providing care. 3. How to communicate with the care team. 4. Integrated and needs-based care: Includes a comprehensive assessment of patient and caregiver needs, personalized care planning, ongoing follow-up, targeted education, and access to support services. The educational content will be delivered by a trained nurse with experience in oncology (researcher) in four sessions (one in person before discharge and three weekly sessions by telephone after discharge, for 45 minutes). In addition to the educational sessions, participants will receive two home visits (at weeks 4 and 8) and weekly telephone follow-ups to assess clinical symptoms, psychosocial status, caregiver needs, and provide tailored counseling. During the home visits, the patients' clinical status (vital signs, blood glucose, weight, mobility, respiratory and mental status) will be monitored and recorded.

Category

Other

2

Description

The control group will receive routine postoperative care as directed

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah AJ Hospital, Chamran Hospital

Full name of responsible person

Dr. Akram Parandeh

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Sheikh Bahai South, Nosrati Street, Baqiyatullah AJ University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Abul Qasimi

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South Sheikh Baha'i, Nosrati Street, Baqiyatullah AJ University

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Marzieh Sadat Seyyed Aliqader

Position

Nursing master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is shared after de-identifying individuals

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Everyone will have access to educational content

Under which criteria data/document could be used

Access to the outcomes and results of this study will help others to use transitional care to choose the most effective work on the quality of life of women with breast cancer and the care burden of their caregivers.

From where data/document is obtainable

To receive the data, send an email to the address below
marziealighadr25@gmail.com

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

Correspond by email

Comments