

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of using supportive-educative self-care program with the approach of telenursing on hope and body image in women with breast cancer undergoing mastectomy

Protocol summary

Study aim

Determining the the effect of using supportive-educative self-care program with the approach of telenursing on hope and body image of women with breast cancer undergoing mastectomy

Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 108 patients. The website <https://www.sealedenvelope.com> was used for randomization.

Settings and conduct

Women undergoing mastectomy surgery are hospitalized in educational hospitals of Mashhad, and after discharge, they are trained in self-care with a telenursing approach. Then, Hope Index and Body Image will be completed by the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with breast cancer undergoing mastectomy are admitted to the ward three days after surgery. At least one month has passed since the diagnosis of cancer. Literacy for reading and writing. Having an Android mobile phone. 18 to 60years old. Absence of metastatic cancer so that the patient has not metastasized to other parts of the body in the pathology report or Positron emission tomography scan Exclusion criteria: Not using the application for more than ten consecutive days or less than 20% of referrals to the application. Failure to provide feedback in WhatsApp consultations for more than four sessions. Sudden hospitalization due to life-threatening problems

Intervention groups

The intervention group includes women with breast cancer undergoing mastectomy in the hospital. An educational support self-care application will be installed on their cell phone upon discharge and they will be monitored remotely based on their learning needs and preferences.

Main outcome variables

Improving self-care in women undergoing mastectomy surgery by using training with a telenursing approach and helping to improve the body image and improve hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150607022592N2**

Registration date: **2022-09-16, 1401/06/25**

Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**

Update count: **0**

Registration date

2022-09-16, 1401/06/25

Registrant information

Name

nahid aghebati

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

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-21, 1401/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using supportive-educative self-care program with the approach of telenursing on hope and body image in women with breast cancer undergoing mastectomy

Public title

The effect of using supportive-educative self-care program with the approach of telenursing on hope and body image in women with breast cancer undergoing mastectomy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

At least three days have passed since the surgery At least one month has passed since the diagnosis of cancer Be literate in reading and writing have access to a smartphone The age of patients should be in the range of 18 to 60 years old Absence of metastatic cancer so that the patient has not metastasized to other parts of the body in the pathology report or Positron emission tomography scan

Exclusion criteria:

Not using the application for more than ten consecutive days or less than 20% of referrals to the application Failure to provide feedback in WhatsApp consultations for more than four sessions Sudden hospitalization due to life-threatening problems

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, for randomization, permutation blocks of 4 will be retrieved using Excel software. with the explanation that each of the blocks has 4 members and the shape of the blocks can be as follows: [ABAB4],[BB4AA],[BABA4], ... Codes A and B are assigned to the accident related to the intervention and control groups. The aforementioned site randomly selects 18 blocks out of all the four possible blocks so that all patients are included in the study. Allocation Concealment method: At first, replacement blocks will be provided by the statistics professor. Each block is placed separately in sealed envelopes and all envelopes are provided to a research assistant. Then, at the beginning

of sampling, the researcher asks the researcher to open the first envelope and tell the researcher based on random letters which group the first patient will be in, and the sampling will be done in the same way until the end of the research.

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 committee of Mashhad University of Medical Sciences

Street address

Daneshgah St, Ebn Sina Ave, Nursing and Midwifery School, Mashhad University of Medical Sciences

City

Mashhad

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Razavi Khorasan

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9137913199

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.049

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

Body Image disturbance in Patients undergoing mastectomy surgery

ICD-10 code

Code C50

ICD-10 code description

Malignant neoplasm of breast

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

Hope score in Herth Hope Index

Timepoint

When entering the study and one month after entering the study

Method of measurement

Herth Hope Index (HHI)

2

Description

The body image score based on the Body Image after Breast Cancer Questionnaire (BIBCQ)

Timepoint

When entering the study and one month after entering the study

Method of measurement

Body Image after Breast Cancer Questionnaire (BIBCQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this research includes firstly designing, construction and validation of a supportive-educative self-care application for breast cancer patients and secondly implementing a self-care educational support program through telenursing using the application and remote communication with the patient through the WhatsApp virtual network during a clinical trial research. the intervention group, after obtaining informed consent from the patient and having the code of ethics at the beginning of the researcher's acquaintance with the patient in the surgical department, demographic and disease data, mental body image questionnaire and Herth hope index will be given to the patient for preliminary examination. At this stage, the effort to create a suitable relationship between the nurse and the patient by using active listening, using appropriate sentences to prove professional competence and having up-to-date information of the nurse to gain trust and encourage the patient to cooperate in the process of care and education, which is Virtualization will continue, then the self-care application will be provided to the patients in person undergoing mastectomy surgery, and the researcher will teach the patients how to install the application on the smart phone, and the researcher will explain how to work with the application. is given and after installing the application, the patient uses it in the presence of the researcher and asks his questions. Then the researcher will establish the first message through WhatsApp with the patient. During the period of one month, by communicating daily with the patient (4 days a week) through WhatsApp, he is asked to gradually use the app based on his preferences and learning needs, and at the same time, the researcher provides related support, such as further explanations in the field of activities. Self-care needed by the patient and responding to his care needs, and emotional support such as calming the patient using various counseling and sedation techniques. Use of WhatsApp group: The purpose of forming groups is to interact with similar patients in a group and share daily problems caused by the disease in the field of quality of life, including:

nutritional needs and daily activities and mental problems, and to share mental concerns about the side effects of drugs and Also, examining similar challenges and answering questions in the presence of the researcher. In general, sharing the experiences of different people and taking role models from them to increase awareness will be done according to the need for training in self-care. These sessions will be twice a week with a duration of at least 30 to 45 minutes, and the number of sessions will increase depending on the needs of the patients.

Category

Lifestyle

2

Description

Control group: The control group consists of women with breast cancer undergoing mastectomy hospitalized in the surgery departments of Omid and Imam Reza Hospitals. At the time of discharge, after filling out the consent questionnaire to participate in the research, the usual procedures of the department are performed for these patients, which includes face-to-face training of nurses. to these patients during discharge and providing them with educational pamphlets. In the following, the contact number of the researcher will be provided to these patients so that they can raise any questions and problems with the researcher. Phone calls are optional in this group of patients and the researcher does not communicate with this group in a targeted manner like the intervention group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Somayeh Hafezian Far

Street address

Koh Sangi St., El Nandasht Square

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Nahid Aghebati

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice President of Research and Technology of Mashhad University of Medical Sciences and Health Services

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

Nahid Aghebati

Position

Associate professor

Latest degree

Ph.D.

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

Nahid Aghebati

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Bachelor

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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

There are no plans to release it

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as information related to the main outcome, can be shared.

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

Data will not be made available.

Under which criteria data/document could be used

Data will not be made available.

From where data/document is obtainable

Data will not be made available.

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

Data will not be made available.

Comments