Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

aghebatin@mums.ac.ir

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
Province
Razavi Khorasan
Postal code
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 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

City
mashhad

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Razavi Khorasan

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1377591766

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2

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Somayeh Hafezian Far
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nahid Aghebati
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Daneshgah Street, Ebne Sina Aven, nursing and midwifery School, Mashhad University of Medical Sciences
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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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Daneshgah Street, Ebne Sina Aven, Nursing and Midwifery School, Mashhad University of Medical Sciences
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Person responsible for scientific inquiries

Contact
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Position
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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
Somayeh Hafezian Far
Position
student

Latest degree
Bachelor
Other areas of specialty/work
Nursery
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University Street, Doctor's Crossroad, Ibn Sina Street, Faculty of Nursing and Midwifery
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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