

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 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

##### **Province**

Razavi Khorasan

##### **Postal code**

1377591766

##### **Phone**

+98 51 3842 6082

##### **Email**

hafezianfars@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Somayeh Hafezian Far

**Street address**

Ebne Sina St

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**Postal code**

91379 13316

**Phone**

+98 51 3854 3031

**Email**

support@rpsi.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Nahid Aghebati

**Street address**

Daneshgah Street, Ebne Sina Aven, nursing and midwifery School, Mashhad University of Medical Sciences

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**Province**

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**Postal code**

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**Phone**

+98 51 3859 1511

**Email**

aghebatin@mums.ac.ir

**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

**Street address**

Daneshgah Street, Ebne Sina Aven, Nursing and Midwifery School, Mashhad University of Medical Sciences

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**Email**

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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**

Associate professor

**Latest degree**

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**

Somayeh Hafezian Far

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

University Street, Doctor's Crossroad, Ibn Sina Street,  
Faculty of Nursing and Midwifery

**City**

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**Province**

Razavi Khorasan

**Postal code**

91375345

**Phone**

+98 51 3859 1511

**Email**

hafezianfars982@mums.ac.ir

**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**