

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of continuing care program on self_efficacy of women with breast cancer.

Protocol summary

Study aim

Helping to increase the self-efficacy of breast cancer patients by continuing the educational program according to the importance of the topic.

Design

This research will be a randomized clinical trial. The research sample is women from the research community who meet the entry criteria. The initial sampling was done by the available method and the total sample size was determined to be 80 people, of which 40 people will be in the intervention group and 40 people will be in the control group.

Settings and conduct

This research will be conducted in Imam Khomeini Hospital Institute Cancer Center and the participants will be assigned to two intervention and control groups according to the entry criteria by random block method using the Randomizer.org site. In the first session, the intervention group receives the videocassettes and then for three weeks, they receive SMS reminders and calls for advice. But the control group only receives the programs of the clinic.

Participants/Inclusion and exclusion criteria

suffering from breast cancer in one of the stages 2, 3, 4, undergoing at least 3 stages of chemotherapy, women aged 20 to 60 years.

Intervention groups

In the first session, which is held face-to-face, the intervention group receives educational videos with specific topics and determines which one to watch each week, and then a weekly reminder SMS and then a call to answer questions.

Main outcome variables

The continuation of the care program after the patient's discharge may affect the self-efficacy of breast cancer patients and after that it can be suggested as a program to improve the health of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230629058617N1**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **prospective**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

Registrant information

Name

Mina Moafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6683 5700

Email address

mina.moafi.nurse@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continuing care program on self_efficacy of women with breast cancer.

Public title

The effect of continuing care program on self_efficacy of women with breast cancer.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmation of breast cancer diagnosis by an oncologist and diagnostic tests in the last 6 months. Having breast cancer in one of the stages 2, 3, 4 Ability to speak Persian Willingness to participate in the study Passing at least three stages of chemotherapy The age of women is between 20-60 years Full awareness and alertness and sign the consent form knowingly

Exclusion criteria:

Unwillingness to continue participating in research Hospitalization during the intervention period The occurrence of events unrelated to the disease during the study Attending other educational and counseling programs during the intervention Suffering from other chronic diseases

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Then they will be assigned to two intervention and control groups by random block method using Randomizer.org. Concealment of the created sequence will be done using sealed dark envelopes. For this purpose, 20 groups are divided into four groups, A is the intervention group and B is the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, for the intervention group, training is done through educational videocasts with the main problems of the patients, then reminders through SMS and finally counseling through phone calls.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Imam Khomeini Hospital.

Street address

Vali Asr Square - the end of Keshavarz Boulevard, Imam Khomeini Hospital Complex.

City

Tehran

Province

Tehran

Postal code

3314114197

Approval date

2023-08-10, 1402/05/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.182

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

breast cancer

ICD-10 code

Z85.8

ICD-10 code description

Personal history of malignant neoplasms of other organs and systems

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

Continuity of care plan

Timepoint

The effect of the continuation of the care program on the self-efficacy of women with breast cancer is measured on the first day and then 4 weeks after the intervention.

Method of measurement

Specific breast cancer self-efficacy questionnaire

Secondary outcomes**1****Description**

self_efficacy

Timepoint

The effect of the continuation of the care program on the self-efficacy of women with breast cancer is measured on the first day and then 4 weeks after the intervention.

Method of measurement

Specific breast cancer self-efficacy questionnaire

Intervention groups

1

Description

Intervention group: they will receive educational videos in the face-to-face meeting and watch them at the appointed time for three weeks, and counseling will be done through weekly SMS reminders and phone calls.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

imam khomeini hospital

Full name of responsible person

Mina moafi

Street address

Rodaki ave, khamse ave, 22 bahman street, 1

City

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1346645413

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Email

mina.moafi.nurse@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

doctor sarie portaghi

Street address

Faculty of Nursing and Midwifery, Tawheed Square,
Dr. Mirkhani Street, (Nusrat East), Tehran

City

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1419733171

Phone

+98 21 6105 4124

Email

Higher_education@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

doctor sarie portaghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Tawheed Square,
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61054124

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

sarieh portaghi

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

Tehran University of Medical Sciences

Full name of responsible person

Mina moafi

Position

Student

Latest degree

Bachelor

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No. 1, Rudaki St., Khamse Street, 22 Bahman St

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Phone

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Email

mina.moafi.nurse@gmail.com

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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Relationship between continuity of care program and self-efficacy

When the data will become available and for how long

Almost 6 months after the end of the intervention

To whom data/document is available

All researchers of Tehran University

Under which criteria data/document could be used

Researches that examine the relationship between self-efficacy and continuity of care program in chronic diseases.

From where data/document is obtainable

Researchers can communicate with the administrator: Mina moafi, through email. email: mina.moafi.nurse@gmail.com

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

The applicant receives the required information less than a month after sending the application via email.

Comments