

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The Effect Of Education And Telephone Counseling On The Self- Efficacy Of Women With Breast Cancer Undergoing Radiotherapy

Protocol summary

Summary

The purpose of the study: determine the effect of education and telephone counseling on the self-efficacy of women with breast cancer undergoing radiotherapy. Design of the study: clinical trial. The study Population: All women with breast cancer referring to the radiotherapy of cancer institute of Imam Khomeini. Inclusion criteria: Aged of 18 to 64 years, the definitive diagnosis of breast cancer, the first ever radiation therapy experience, at the same time you do not receive chemotherapy, Having a landline and cell phone, Proficiency in Persian. Exclusion criteria: Unwillingness to continue cooperation, Disconnect the phone for 2 weeks in the first month of intervention and for 3 weeks in the second and third months of intervention, Hospitalization during the period of the research. Sample size: 32 patients in the experimental group and 32 patients in the control group. Interventions studied and intervention time: The intervention method in the intervention group is through training via SMS and consultation through a telephone call for 3 months, A training short message sent for patients daily, Telephone counseling will be done by making 2 calls per week in the first month and one call per week in the second and third months. Chronic Disease Self-Efficacy Scale Before, one month and three months after the intervention will be completed for both groups. Primary outcome or study outcome : If the impact of education and telephone counseling on the self-efficacy of women with breast cancer undergoing radiotherapy is identified, telephone counseling centers in radiation therapy centers can be established.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082835955N1**

Registration date: **2017-10-03, 1396/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name

Asma Satiyarvand

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3226 6174

Email address

a-satiyarvand@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Education And Telephone Counseling On The Self- Efficacy Of Women With Breast Cancer Undergoing Radiotherapy

Public title

Effect Of Education And Telephone Counseling On The Self-Efficacy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: aged of 18 to 64 years , definitive diagnosis of breast cancer, first radiation therapy experience, lack of simultaneous chemotherapy, fixed and mobile phone numbers, fluency in Farsi, lack of familial communication with other participants in the study, lack of speech and hearing problems , Lack of dementia and cognitive impairment. Exclusion criteria: reluctance to continue cooperation, disconnect for 2 weeks in the first month of intervention and for 3 weeks in the second and third month of intervention, hospitalization during the study period, metastasis And died

Age

From **18 years** old to **64 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the random allocation of binary blocks is used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Myrkhani Street, Towhid Square, Tehran

City

Tehran

Postal code

1419733171

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

IR.TUMS.FNM.REC.1395.1655

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Self-efficacy score

Timepoint

Before, one month and three months after educaion and telephone counseling

Method of measurement

- Chronic Disease Self-Efficacy Scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: The intervention method in the intervention group is through training via SMS service and consultation by phone call for 3 months. Daily an educational short message sent to patients about radiotherapy, skin changes, laryngeal disorders, nausea and vomiting, diarrhea, fatigue, psychosocial issues, immune deficiency, fertility and lactation, lymphedema, and cardiovascular and pulmonary complications. Telephone counseling is also done by making 2 calls per week in the first month and 1 call per week in the second and third months. The content of the first 12 conversations that took place during 2 months included radiation therapy, skin changes, laryngeal disorders , nausea and vomiting, diarrhea, fatigue, psychosocial issues, immune deficiency , fertility and lactation, lymphatic edema, and cardiovascular and pulmonary complications of radiation therapy. And the last 4 conversations that take place in the third month to follow the patients' status and respond to patient questions.

Category

Behavior

2

Description

The control group receives routine training at Imam Khomeini Cancer Center, which includes a one-on-one training session with the presentation of the pamphlet, but will not receive any training from the researcher.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Imam Khomeini Cancer Institute

Full name of responsible person

Asma Satiyarvand

Street address

Tehran Faculty of Nursing and Midwifery, Mirkhani Street, Towhid Square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Asma Satiyarvand

Street address

Tehran Faculty of Nursing and Midwifery, Mirkhani Street, Towhid Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Asma Satiyarvand

Position

MSc student of Medical-Surgical Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty