Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effect of telephone support on supportive care needs of women with breast cancer

Protocol summary

Summary

(1)Objectives: To determine the effect of telephone support on different dimensions of supportive care needs of women with breast cancer (2) Design: This study is randomized trials with control and intervention group. A total of 62 women with breast cancer who are referred for treatment (chemotherapy, radiotherapy, surgery) to tertiary hospitals in Kashan and randomly placed in one of the intervention or control groups. (3)Setting and conduct: Telephone intervention will be performed for a month in intervention group. Data will be collected at three phases (baseline, two weeks and one month after intervention) in both groups. (4) Participants including major eligibility criteria: Eligibility to participate was restricted to people diagnosed with cancer who are treated for first round and the exclusion criteria are unwillingness to participate in the study and death. (5) Interventions: The researcher will call patients in the intervention group twice a week, and they can also get in touch with the researcher if they have any problem or question. The length of each call will be between 20-15 minutes. Researcher will talk about their issues and problems and patients' questions will be answered as well. The control group will only receive usual care. (6)Main outcome: The primary outcome is supportive care needs and the secondary outcomes are different dimensions of supportive care need that will be compared between two groups of participant using the supportive care needs survey (SCNS- SF 34).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102430465N1**
Registration date: **2016-12-18, 1395/09/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name
Nazi Nejat
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3417 3524
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n.nejat@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of telephone support on supportive care needs of women with breast cancer

Public title

Effect of telephone intervention on supportive care needs of patients with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Eligibility to participate was restricted to people diagnosed with cancer; aged between 18-80 years; aware of their diagnosis; are treathed for first round; physically and mentally capable of participating in the study (the ability to read and write and lack of hearing loss and speech problems), telephone access at home, and living in Kashan. Exclusion criteria: The the exclusion criteria are unwillingness to participate in the study and death

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

using randomized block design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij Sq, Payambar Azam University complex, Emam Mosa Kazem building, Arak

City

arak

Postal code

38481-7-6941

Approval date

2016-09-05, 1395/06/15

Ethics committee reference number

IR.ARAKMU.REC.1395.229

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

supportive care needs

Timepoint

Baseline, 2 weeks after the intervention, one month after intervention

Method of measurement

Supportive care needs survey short form 34(SCNS-SF34)

Secondary outcomes

1

Description

Psychological needs

Timepoint

baseline, two weeks and one month after intervention

Method of measurement

Psychological dimension of SCNS-SF34

2

Description

Health system & information needs

Timepoint

baseline, two weeks and one month after intervention

Method of measurement

Health system & information dimension of SCNS-SF34

3

Description

Physical & daily living

Timepoint

Baseline, two weeks and one month after intervention

Method of measurement

Physical & daily living dimension of SCNS-SF34

4

Description

Patient care & support

Timepoint

Baseline, two weeks and one month after intervention

Method of measurement

Patient care & support dimension of SCNS-SF34

5

Description

Sexual needs

Timepoint
Baseline, two weeks and one month after intervention
Method of measurement
Sexual dimension of SCNS-SF34

Intervention groups

1

Description
Intervention group: Telephone intervention will be performed for a month. The first contact with participants will be done during a week after the first meeting. The researcher will call patients in the intervention group twice a week, and they can also get in touch with the researcher if they have any problems or questions. The length of each call will be between 20-15 minutes. The researcher will talk about their issues and problems, and patients' questions will be answered as well. The content of telephone conversations will be written based on the results of new researches and using scientific resources in the field of breast cancer and will be approved by the Department of Oncology in Kashan University of Medical Sciences. In addition, patients' questions in specialized areas will be answered after consultation with an oncologist. The contacts time will be set based on patients' willingness. A phone number will be provided by the researcher for the intervention group so they can get in touch with the researcher if they have any problems or questions during the weeks in determined hours every day (9 am to 12 noon and 4 pm to 9 pm).
Category
Other

2

Description
Control group: The control group will only receive usual care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Mehran Sharifie
Street address
ghotb Ravandie Boulevard , Parastar Boulevard
City
Kashan

2

Recruitment center
Name of recruitment center
Matinie hospital
Full name of responsible person
Dr Mehran Sharifie
Street address
Amir Kabir Street
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research ofArak University of Medical Sciences
Full name of responsible person
Dr.Mohammad Rafiei
Street address
Basij Sq, Payambar Azam University complex, Emam Mosa Kazem building, Arak
City
Arak
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 ofArak 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
Arak Medical Sciences University
Full name of responsible person
Parisa Javadie
Position
Master Student in Nursing
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor/ Doctor of Philosophy in Nursing

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Aistant Proffessor/ Doctor of Philosophy in Nursing

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00

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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