Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Design, Implementation and Evaluation of Nurse Navigator Program (NNP) for Patients with Breast Cancer

Protocol summary

Study aim

Determining and comparing the effectiveness of the nurse navigator program on reducing care needs in the treatment of breast cancer patients in the control and intervention groups The effect of the nurse navigator program on satisfaction with breast cancer related care in the intervention group

Design

The present study is a clinical trial with an intervention and control group, which is performed using random block allocation on 60 patients.

Settings and conduct

The present study is conducted on patients with positive pathology of breast cancer who refer to the cancer research center of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Women referring to the Cancer Research Center with positive breast cancer pathology are screened for inclusion criteria at their first physician visit. Inclusion criteria included: women over 18 years of age, no previous history of cancer, no dementia, and access to telephone and internet.

Intervention groups

The care program provided by the nurse navigator includes a support package (educational and psycho-emotional) as well as telephone and online follow-up. The support package includes education related to the nature of cancer, types of treatment and complications, and how to manage complications. Psychological support includes talking to the patient and teaching stress reduction techniques based on mindfulness. At least two phone calls are made until the end of the surgery.

Main outcome variables

Supportive care needs of patients, satisfaction with cancer-related care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240610062078N1**
Registration date: **2024-06-17, 1403/03/28**
Registration timing: **prospective**

Last update: **2024-06-17, 1403/03/28**
Update count: **0**

Registration date

2024-06-17, 1403/03/28

Registrant information

Name

Mahboubeh Sadat Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

Email address

msyousefi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-29, 1403/04/09

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of Nurse Navigator Program (NNP) for Patients with Breast Cancer

Public title
effect of nurse navigator program in breast cancer care
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with positive breast cancer pathology who have referred to the Cancer Research Center. Willingness to participate in the study. Patients who are over 18 years old. Patients who have no previous history of cancer. Patients who do not have dementia. Patients who do not have advanced breast cancer. Have access to telephone and internet.
Exclusion criteria:
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to balance the number of samples allocated to each of the study groups, the block randomization method is used. According to the final sample size in this study, 10 blocks of 6 are used to allocate the participants in each group, and the intervention and control groups will be randomly assigned to the letters A and B according to the predetermined blocks. People are divided into two intervention and control groups according to the inclusion criteria for the study and according to randomly designed blocks (in each block, 3 people for the intervention group and 3 people for the control group).
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 Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran,
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-05-26, 1401/03/05
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.105

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50.9
ICD-10 code description
Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description
The mean of supportive care needs in the care needs survey questionnaire
Timepoint
Before and after the intervention
Method of measurement
supportive care needs survey

Secondary outcomes

1

Description
patient satisfaction related to cancer care
Timepoint
After the intervention
Method of measurement
The item was scored on a 10-point scale (response options ranged from 1 = Not at all to 10 = Very satisfied).

Intervention groups

1

Description
Intervention group: It includes a support package, telephone follow-up and online follow-up. The support package includes education related to breast cancer, types of treatment and side effects of treatments, types of surgery, side effects of surgery and post-surgery care.

Also, psycho-emotional care includes listening to the patient's words and stress reduction techniques based on mindfulness. These items are sent in the form of educational videos on virtual networks. In addition, telephone follow-up is done for timely treatment.

Category

Other

2

Description

Control group: Patients in the control group do not receive the services of a nurse navigator and only receive routine medical care as determined by the center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Research Center, Shahid Beheshti University of Medical Sciences,

Full name of responsible person

Mohammad-Esmaeil Akbari

Street address

Tajrish Square, ShohadayeTajrish hospital, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

5th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran,

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4631- 19395

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+98 21 2243 9781

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahboubeh Sadat Yousefi

Position

Phd student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran

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Email

msyousefi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahnaz Ilkhani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahboubeh Sadat Yousefi

Position
PhD student in nursing

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
SBMU School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
It can be shared after de-identifying people

When the data will become available and for how long
Access starts one year after results are published

To whom data/document is available
People working in academic and scientific institutions

Under which criteria data/document could be used
Subject to the agreement of Shahid Beheshti University of Medical Sciences

From where data/document is obtainable
Faculty of Nursing, Shahid Beheshti University of Medical Sciences, office of Dr. Mahnaz Ilkhani

What processes are involved for a request to access data/document
A written and official request to the research vice-chancellor of the Faculty of Nursing

Comments