Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of a person-centered self-care educational intervention delivered through telenursing on quality of life and fatigue in women with breast cancer

Protocol summary

Study aim
Evaluating the effectiveness of a personalized self-care educational intervention delivered through telenursing on quality of life and fatigue in women with breast cancer

Design
Clinical trial, with parallel groups, open-label, randomized, on 76 patients

Settings and conduct
After allocating patients to the two groups and obtaining informed consent, the study instruments will be provided to the participants. These include three questionnaires: a demographic information questionnaire, the quality of life questionnaire for women with breast cancer, and the cancer-related fatigue assessment questionnaire. To identify patients' problems and needs, the ORMS (Assessment and Recognition of Needs) questionnaire will also be used. The intervention will consist of five sessions. Educational materials (voice-over slides) will be uploaded weekly in a virtual social media group. Participants in the intervention group will receive a telephone call every two weeks, lasting 15 to 30 minutes. Each participant will receive individualized consultation according to their needs, and their questions will be answered. Then, three months after the start of the intervention, all patients will complete the quality of life and cancer-related fatigue questionnaires again (post-test).

Participants/Inclusion and exclusion criteria
Women with breast cancer referred to the selected medical center of the Armed Forces in Tehran in the year 1404 , with a confirmed diagnosis of stage I-A breast cancer based on biopsy results, undergoing treatment (chemotherapy, chemotherapy following radiotherapy, or chemotherapy following surgery)

Intervention groups
Person-centered self-care educational intervention through telenursing

Main outcome variables
Quality of life score Fatigue score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251202068188N1**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date
2026-04-22, 1405/02/02

Registrant information

Name
Foroozan Faghihi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5328 8305

Email address
foroozan.fgh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-07-06, 1405/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of a person-centered self-care educational intervention delivered through telenursing on quality of life and fatigue in women with breast cancer

Public title
The effectiveness of a person-centered self-care educational intervention on quality of life and fatigue in women with breast cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women with breast cancer referred to the selected medical center of the armed forces (Emam Reza Hospital) in Tehran in 1404 Ability to work with software applications and mobile devices Patients undergoing chemotherapy, chemotherapy following radiation therapy, or chemotherapy following surgery
Exclusion criteria:
Unwillingness to receive the educational program Rapid disease progression or widespread metastasis
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method was purposive, and participants were selected from among patients referring to Imam Reza Hospital according to the inclusion criteria. Subsequently, in order to randomly allocate participants into two groups (intervention and control), block randomization with a block size of four was used. Accordingly, the letter A was assigned to the intervention group and the letter B to the control group. Then, six possible arrangements (AABB, BBAA, ABBA, BAAB, ABAB, BABA) were written on separate sheets of paper and placed into a container. One sheet was randomly selected, and the sequence written on it was recorded and then returned to the container. This procedure was repeated 19 times, and each time the selected sequence was recorded consecutively until the total sample size of 76 was achieved. Numbers from 1 to 76 were assigned to each letter. Each letter was placed in a separate envelope, and the envelopes were labeled with numbers from 1 to 76. Each time a participant was enrolled, the envelopes were opened sequentially, and in this manner it was determined whether the participant was allocated to the intervention or 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 Baqiyatallah University of Medical Sciences
Street address
13th Floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simaye Iran Street, between Flamk Jonoubi and Zarfshan, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2025-11-26, 1404/09/05
Ethics committee reference number
IR.BMSU.BAQ.REC.1404.112

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
Quality of life score of women with breast cancer based on the breast cancer–specific quality of life questionnaire
Timepoint
Measurement of quality of life at baseline (before the intervention) and at the end of the personalized self-care educational intervention delivered through tele-nursing
Method of measurement
Thirty-item breast cancer quality of life questionnaire

assessing functional domains, symptom subscales, and global quality of life

Secondary outcomes

1

Description
Fatigue score of women with breast cancer in physical, cognitive, and emotional dimensions
Timepoint
Measurement of fatigue at baseline (before the intervention) and at the end of the personalized self-care educational intervention delivered through telenursing
Method of measurement
A fifteen-item cancer-related fatigue questionnaire assessing fatigue in the physical, cognitive, and emotional dimensions

Intervention groups

1

Description
Intervention group: Five weekly sessions of a personalized self-care educational intervention delivered through telenursing. Educational content includes voice-over slides covering self-care strategies tailored to each participant's needs. Each participant receives a 15–30 minute telephone consultation every two weeks, providing individualized guidance and answers to questions. Total duration of the intervention: 10 weeks (including weekly educational materials and biweekly calls)
Category
Lifestyle

2

Description
Control group: Participants receive standard care provided by the medical center, without additional personalized self-care educational intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Foroozan Faghihi
Street address
Imam Reza Hospital, Etemadzadeh St
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1411718546
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Email
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Web page address
https://www.ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Abbas_Ali Imani Fouladi
Street address
Baghiatallah University of Medical Sciences, Molla Sadra St., Tehran, Iran
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Tehran
Postal code
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Phone
+98 21 8804 0060
Email
bmsusrc.research@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Foroozan Faghihi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery

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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
All above-mentioned data and documents will be available after study completion in de-identified form. They can be accessed upon written request to the research team, and eligible researchers may use them for scientific research purposes only.
When the data will become available and for how long
Access will begin six months after publication of study results and continue for five years thereafter.
To whom data/document is available
Researchers affiliated with academic and research institutions with approved scientific objectives.
Under which criteria data/document could be used
Data may only be used for scientific research purposes and statistical analyses. Commercial use or publication of data without explicit permission from the research team is not allowed.
From where data/document is obtainable
Applicants should send a written request to the research team via email at: info@baghiatallah.ac.ir
What processes are involved for a request to access data/document
1. Submit a written request to the research team via email 2. Review and approval of the request by the research team 3. Signing a data use agreement by the applicant 4. Provision of de-identified data and documents to the applicant 5. Use of data exclusively for scientific research purposes
Comments