Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of the program based on the common-sense model on illness perception and health-promoting behaviors of women with breast cancer

Protocol summary

Study aim
Determining the impact of the program based on the common sense model on illness perception and health promoting behaviors of women with breast cancer

Design
The clinical trial study has a control group, with parallel groups, without blinding, randomized on 72 patients, and the block method will be used for randomization.

Settings and conduct
The research population in this research includes all breast cancer patients referred to Omid Hospital and Al-Zahra Clinic in Isfahan and the office of oncology specialists in these centers who meet the inclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: confirmation of breast cancer diagnosis for the patient, awareness of the disease,وHaving at least 18 years of age, the ability to communicate verbally, at least literate in reading and writing in Farsi, at least two months and at most one year have passed since the treatment of the disease, diagnosis of the disease in stages I to IIIA, no history of psychiatric disease, no Family history of breast cancer in the patient's first degree family Exclusion criteria: unwillingness to cooperate in the study, death or progression of the disease or severe physical and mental illnesses during the study, absence in a quarter of face-to-face meetings

Intervention groups
The intervention will be conducted by a nurse, a nutritionist and a psychologist for four consecutive weeks in 60 minutes, and in the fifth to seventh weeks, weekly question and answer sessions will be held with the intervention group via social media. The control group will receive routine care. At the end of the study, the people of the control group will be given pamphlets related to the training sessions of the intervention group, and for those who wish, the first training session will be held similar to the intervention group.

Main outcome variables
Illness perception, Health-promoting behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230904059360N1**
Registration date: **2023-09-23, 1402/07/01**
Registration timing: **prospective**

Last update: **2023-09-23, 1402/07/01**
Update count: **0**

Registration date
2023-09-23, 1402/07/01

Registrant information

Name
Fatemeh Alidoosti

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3777 0968

Email address
fatemealidoosti@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-02, 1402/07/10

Expected recruitment end date
2023-12-31, 1402/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of the program based on the common-sense model on illness perception and health-promoting behaviors of women with breast cancer

Public title
Investigating the effect of the program based on the common-sense model on breast cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
According to the pathology sheet, the diagnosis of breast cancer has been established for the patient. The patient should be aware of the diagnosis of her disease. The patient must be at least 18 years old. The patient has the ability to speak and communicate verbally. The patient must be able to read and write in Farsi at least to complete the questionnaire. At least two months and a maximum of one year have passed since the active treatment of breast cancer. According to pathology documentation, the disease was diagnosed in stages I to IIIA.
Exclusion criteria:
According to the medical file documentation, the patient has a history of psychiatric illness requiring hospitalization or drug treatment. There is a family history of breast cancer in the patient's first degree family (mother, sister, father and brother) based on the question of the patient. The patient does not consent to participate in the research.
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study the randomization will be done using block randomization method. In order to allocate the patients randomly into Intervention and control groups, at first 18 blocks of size 4 with C and T letters (The letters indicate the intervention and control groups) are created. Then the blocks are randomly selected and arranged to obtain a sequential combination of 72 letters. Each letter will be placed in a sealed packet according to the obtained sequence.
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
Research Ethics Committees of Nursing, Rehabilitation and Management schools - Isfahan University of
Street address
Building No. 4, Vice-Chancellor for Research & Technology, Isfahan University of Medical Sciences, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-09-17, 1402/06/26
Ethics committee reference number
IR.MUI.NUREMA.REC.1402.102

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 score of illness perception in the Brief Illness Perception Questionnaire (Brief IPQ)
Timepoint
Illness perception is checked before the start of the study and eight weeks after the start of the study
Method of measurement
Brief Illness Perception Questionnaire (Brief IPQ)

2

Description
The score of health promoting behaviors from the Health Promoting Behaviors Questionnaire (HPLPII)

Timepoint
Health-promoting behaviors before the intervention and eight weeks after the start of the intervention are measured through a questionnaire.
Method of measurement
Health Promoting Lifestyle Profile-II (HPLP-II) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, the intervention will be held in the form of four face-to-face sessions for 60 minutes based on the common sense model during four consecutive weeks, with the main content of the sessions being the same for all patients and including six concepts of illness perception (including identity, cause, timeline, consequences , treatment and control).The time of the meetings will be determined in coordination with the research units. Related to the disease control dimension, from the second session, nutrition, physical activity, health responsibility, spiritual growth, interpersonal relationships and stress management are taught to the units of the intervention group with the cooperation of nutrition expert and psychologist. This training will be in the form of showing clips, lectures and discussions, and presenting booklets and pamphlets, and patients will be grouped in groups of four based on the time priority of entering the study. From the fifth to the seventh weeks, in the Eitaa and Bale social media groups, question and answer sessions and discussions will be held on a weekly basis, and in the eighth week, the members of the intervention group will be asked to answer the questionnaires on Brief Illness Perception and Health Promoting Lifestyle Profile-II .
Category
Lifestyle

2

Description
Control group: Participants in the control group received no advice to attend training sessions and received routine care and were only asked to complete questionnaires. After collecting the questions, the people of the control group will be given the booklet of the training sessions of the intervention group, and the first training session will be held for the group that has the same training session as the intervention.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed-al-Shohada Hospital in Isfahan
Full name of responsible person
Fatemeh Alidousti
Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 7565
Email
fatemealidoosti@nm.mui.ac.ir

2

Recruitment center
Name of recruitment center
Al- Zahra Special Clinic
Full name of responsible person
Fatemeh Alidousti
Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 7565
Email
fatemealidoosti@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Askari
Street address
Building No. 4, Vice-Chancellor for Research & Technology, Isfahan University of Medical Sciences, Hezar Jerib St
City
Isfahan
Province
Isfehan
Postal code
81746-73461

Phone
+98 31 3668 7898
Email
askari@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Alidousti
Position
Master of Science in Medical Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 7153
Email
fatemealidoosti@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Bahrami
Position
Professor of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 7565
Email
bahrami@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Bahrami
Position
Professor of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Department of Adult Health Nursing, Nursing and Midwifery School, Isfahan University of Medical Sciences, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 7565
Email
bahrami@nm.mui.ac.ir

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

Clinical Study Report
Not applicable

Analytic Code
Undecided - It is not yet known if there will be 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

By maintaining the confidentiality of the individual characteristics of the participants, the results of the study will be shared based on the objectives of the study.

When the data will become available and for how long

The access period will start 1 month after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions are allowed to send requests to receive non-identifiable personal data or other documents. The use of documents and data will be only to improve the understanding of the disease and the health-promoting behaviors of cancer patients.

From where data/document is obtainable

In order to receive the documents, it is necessary to refer to the main executive of the project and the relevant student. Based on this, applicants can send their requests to the responsible executive (bahrami@nm.mui.ac.ir) or the student (fatemealidoosti@nm.mui.ac.ir) via email.

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

The application is sent via email and the response or sending of documents to the applicant (after the necessary checks to prevent violation of the confidentiality of the participants' information) will be after 2 weeks at most.

Comments