

# 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, Having 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**

Isfahan

**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

Isfahan

##### 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.

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##### Province

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## 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

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##### Province

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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

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**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

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Masoud Bahrami

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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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**

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 ( bahrani@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**