

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Peer Education on Cluster Symptoms and Self-Efficacy in Patients with Breast Cancer

#### Protocol summary

##### Study aim

Determining the effect of Peer Education on Cluster Symptoms and Self-Efficacy in Patients with Breast Cancer

##### Design

A randomized clinical trial with two groups of test and control , with 100 subjects as sample size, a purpose-based sampling method and dividing subjects into two groups of test and control

##### Settings and conduct

his clinical trial study was conducted on 100 breast cancer patient. The location of the study was the Omid Medical Education Research Center in Isfahan city.

##### Participants/Inclusion and exclusion criteria

Patients diagnosed with breast cancer .patients with ability to read and write.

##### Intervention groups

In the test group, in addition to the current education by healthcare personnel, eight sessions were conducted per week and each session lasted for 60 minutes. The control group received to the current education by healthcare personnel.

##### Main outcome variables

Cluster Symptoms: Self-Efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190627044033N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **retrospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

##### Registration date

2019-07-08, 1398/04/17

#### Registrant information

##### Name

Farzaneh Kamaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3681 5611

##### Email address

it\_shahreza@phc.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-06-10, 1397/03/20

##### Expected recruitment end date

2019-01-10, 1397/10/20

##### Actual recruitment start date

2018-06-26, 1397/04/05

##### Actual recruitment end date

2019-03-06, 1397/12/15

##### Trial completion date

2019-03-06, 1397/12/15

#### Scientific title

The Effect of Peer Education on Cluster Symptoms and Self-Efficacy in Patients with Breast Cancer

#### Public title

Peer Education on Cluster Symptoms and Self-Efficacy in Breast Cancer

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients diagnosed with breast cancer patients with ability to read and write patients aged 35 and over

##### Exclusion criteria:

Patients with physical and mental disabilities Patients with known psychiatric disorders

## Age

From **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

Actual sample size reached: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization of this study is simple randomization. One hundred Patients with diagnosed of breast cancer who had inclusion criteria and tend to participate in this study. A code was assigned to each person. they were divided into intervention and control groups by applying the Random number table.

## 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

thics Committee of Islamic Azad University - Isfahan (Khorasgan) Branch

##### Street address

Islamic Azad University Isfahan (Khorasgan) Branch., University Blvd., Jey St., Isfahan town

##### City

Eefahan

##### Province

Isfahan

##### Postal code

۸۱۵۵۱۳۹۹۸

#### Approval date

2018-06-03, 1397/03/13

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1397.084

## 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

Cluster Symptoms

#### Timepoint

The measurement of mean of the cluster symptoms before the intervention and one month after the end of the intervention.

#### Method of measurement

McGill Pain, Beck Anxiety, Piper Fatigue, Pittsburgh sleep quality questionnaires

### 2

#### Description

Self-Efficacy

#### Timepoint

The measurement of mean of the self efficacy before the intervention and one month after the end of the intervention.

#### Method of measurement

Sherer General Self-Efficacy Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group held 8 peer education sessions in the field of physical, psychological, social and behavioral issues per week, and each session was 60 minutes.

#### Category

Lifestyle

### 2

#### Description

Control group: receives only current education by healthcare personnel.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Omid Medical Education Research Center

##### Full name of responsible person

Farzane Kamaee

**Street address**

Omid Medical Education Center., Khayyam St.,  
Isfahan Town

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱۸۱۷۴۶

**Phone**

+98 31 3236 8005

**Fax**

+98 31 3236 8005

**Email**

fkamaee@yahoo.com

**Web page address**

<http://omid.mui.ac.ir>

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Navid Nasirizade

**Street address**

Deputy of research and technology., Islamic Azad  
University., Alam Sq., Yazd Town

**City**

Yazd

**Province**

Yazd

**Postal code**

8915813135

**Phone**

+98 35 3821 1391

**Fax**

+98 35 3821 4810

**Email**

research@iauyazd.ac.ir

**Web page address**

<http://www.iauyazd.ac.ir/>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Masoumeh Barkhordari

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University., Alam Sq., Yazd Town

**City**

Yazd

**Province**

Yazd

**Postal code**

8915813135

**Phone**

+98 35 3821 1391

**Fax**

+98 35 3821 4810

**Email**

barkhordary\_m@yahoo.com

**Web page address**

<https://www.iauyazd.ac.ir/>

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Masoumeh Barkhordari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University., Alam Sq., Yazd Town

**City**

Yazd

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**Postal code**

8915813135

**Phone**

+98 35 3821 1391

**Fax**

+98 35 3821 4810

**Email**

barkhordary\_m@yahoo.com

**Web page address**

<http://www.iauyazd.ac.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farzane Kamaee

**Position**

Master degree in Medical Surgery Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University., Alam Sq., Yazd Town

**City**

Yazd

**Province**

Yazd

**Postal code**

8915813135

**Phone**

+98 35 3821 1391

**Fax**

+98 35 3821 4810

**Email**

fkamaee@yahoo.com

**Web page address**

<http://www.iauyazd.ac.ir/>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable