

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)

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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

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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

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Omid Medical Education Center., Khayyam St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Navid Nasirizade

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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

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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