

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of peer groups on life quality and treatment adherence in patients affected by breast cancer

Protocol summary

Summary

Introduction: Breast cancer is the most common cancer in women. It seems that patients who have contact with a former cancer patient can benefit from meeting someone who had a similar experience. This study evaluated the effect of two kinds of intervention (peer support and educational program) on quality of life in breast cancer patients. Methods: This study is a controlled clinical trial on women diagnosed with breast cancer of stage II or III. The patients took part in peer support group as experimental group or educational group as control group during 3 months and in 6 sessions. The studied sample consisted of 68 patients with breast cancer selected through convenience sampling method considering inclusion and exclusion criteria. Inclusion criteria included women with breast cancer with 20 to 65 years of age who have had mastectomy 6 months to 2 years before and at the time of study were receiving therapy. Patients should have been in stage II or III of non-metastatic breast cancer, who had no chronic disabling underlying condition. Exclusion criteria were patients who would discontinue voluntarily, patients developing any mental or physical disease which would prevent them from continuing the study, those who were absent 2 consecutive sessions and those who got aware of the other group and had meanwhile took part in their sessions. The authors administered SF-36 for evaluating the quality of life pre- and post intervention. Also patient's adherence was assessed by means of a simple checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102055766N1**

Registration date: **2011-03-19, 1389/12/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-03-19, 1389/12/28

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of peer groups on life quality and treatment adherence in patients affected by breast cancer

Public title

Effect of peer groups on life quality and treatment adherence in patients affected by breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria included women with breast cancer with 20 to 65 years of age who have had mastectomy 6 months to 2 years before and at the time of study were receiving therapy – whether radiotherapy or medical treatment. Patients should have been in stage II and III of non-metastatic breast cancer, who had no chronic disabling underlying condition (such as major depression or any other condition which would prevent them from participating in sessions). Also the patients should meet the literacy needed to fill in the questionnaires and have never had participated in such supportive programs before. Exclusion criteria were patients who would discontinue voluntarily, patients developing any mental or physical disease which would prevent them from continuing the study, those who were absent 2 consecutive sessions and those who got aware of the other group and had meanwhile took part in their sessions.

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **61**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Isfahan university of medical sciences

Street address
Isfahan University of Medical Sciences, Hezarjerib Avenue

City
Isfahan

Postal code

Approval date
2010-07-04, 1389/04/13

Ethics committee reference number

389164

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

Timepoint

3 months

Method of measurement

questionnaire

2

Description

treatment adherence

Timepoint

3 months

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The Control group: Also in the control group the patients participated in 6 educational sessions held on their disease, its treatment and complications and similar subjects. Each educational session lasted about an hour and a half and was presented by the associated specialist.

Category

Other

2

Description

In experimental group, patients were divided into two groups of 17 in order to participate in peer groups. In each group, two of the leaders were in charge of holding and conducting the sessions. The meetings were held twice-monthly (total number of 6 sessions during intervention) and in each session, the patients would have share their experiences from the disease, worries, cons and pros of the disease and their hopes with other

members and would take others experiences. In some of the sessions, the project executor also took part in order to ensure the sessions are held in correct manner and that none of control groups would take part in these sessions. Each session lasted between an hour and half to 2 hours. The patients were encouraged to contact each other out of sessions too, and support each other.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast Diseases Research Center

Full name of responsible person

Afsaneh Malekpour Tehrani

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr.Taleb Azarm

Street address

Vice chancellor for research of Isfahan University of Medical Sciences, Hezarjerib Avenue

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Afsaneh Malekpour Tehrani

Position

Doctorate/Resident

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty