

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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

###### Name

Afsaneh Malekpour Tehrani

###### Name of organization / entity

Community medicine department of Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 31 1627 3708

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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

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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*