

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effectiveness of Group education to the partners on social adaptation of women with breast cancer undergoing chemotherapy

Protocol summary

Summary

This study examined the effect of group education to partners on the social adaptation of women with breast cancer undergoing chemotherapy. In this study, 56 women with breast cancer undergoing chemotherapy were included. This study was designed as pretest-posttest with a control group. Patients eligible to participate in the study were randomly assigned into two intervention (28 = n) and control (28 = n) groups. For spouses of patients in the intervention group, six 2-hour sessions were held. Spouses of patients in the control group didn't receive any intervention. Social Adjustment Scale (SAS-m) was completed by patients before and after intervention. Social adjustment in both groups are compared before and after the intervention and with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111420778N7**

Registration date: **2016-06-16, 1395/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-16, 1395/03/27

Registrant information

Name

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4964

Email address

moghaddam.f@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University of Medical Sciences

Expected recruitment start date

2016-01-15, 1394/10/25

Expected recruitment end date

2016-04-13, 1395/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Group education to the partners on social adaptation of women with breast cancer undergoing chemotherapy

Public title

The effect of group education to the partners on social adaptation

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: aged 20-60 years, understanding Persian language, afflicting with breast cancer, not affected by another cancer, not experienced stressful events in previous 6 months. Exclusion criteria included any stressful event for the patient or the patient's first-degree family and being absent in more than two training sessions.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 56

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was performed using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Postal code

571478334

Approval date

2015-12-09, 1394/09/18

Ethics committee reference number

IR.UMSU.REC.1394.299

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

c50.9

ICD-10 code description

z60.0

Primary outcomes

1

Description

Social adjustment

Timepoint

Before and after the intervention.

Method of measurement

Social Adjustment Scale (SAS-M)

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

In the intervention group educational sessions for partners of women with breast cancer are held as 2-hour sessions once a week for six weeks (six 2-hour sessions)

Category

N/A

2

Description

The control group received no intervention whatsoever.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Support Community of Saba in Bukan

Full name of responsible person

Hesam Soltany

Street address

Farhang Town, Uromia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Doctor Fatemeh Moghadam Tabrizi

Street address

Urmia University of Medical Sciences, next to the emergency center, Resalat bolvar

City
Urmia

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, Urmia 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
Urmia University of Medical Sciences

Full name of responsible person
F. Moghaddam Tabrizi

Position
Assistant Professor

Other areas of specialty/work

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F Moghadam Tabrizi doctor

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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