

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of family intervention based on FOCUS program on cancer coping in breast cancer survivors undergoing chemotherapy

Protocol summary

2016-07-11, 1395/04/21

Summary

The family-based intervention program (FOCUS) designed to Support and cope for mastectomy patients undergoing chemotherapy and their families. The sampling method will be available at first. A total of 60 patients and an active members of the family will enroll. Inclusion criteria included: age 30-60 years, speak persian language, diagnosis breast cancer, having experienced a mastectomy procedures, pass 48 hours of chemotherapy, between two chemotherapy, do not having other cancer, do not having a history of hospitalization. Exclusion criteria: any stressful event for the patient or family members patient during the study and the absence of more than a session of meetings of family intervention. Patients will enter in the intervention and control groups. The intervention consisted of implementation the FOCUS program will be based family intervention. Intervention will happen in 6 sessions in format of the FOCUS program items. Participants will complete cancer coping questionnaire before and after intervention to assess the impact of the intervention program. Therefore aim of this study to determine that the effect of family intervention based on FOCUS program on cancer coping in breast cancer survivors undergoing chemotherapy in academic centers of Urmia in 2016.

Registrant information

Name

Fatemeh Moghaddam Tabrizi

Name of organization / entity

Uromia University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 44 3275 4964

Email address

moghaddam.f@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University Of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052820778N16**

Registration date: **2016-07-11, 1395/04/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

The effect of family intervention based on FOCUS program on cancer coping in breast cancer survivors undergoing chemotherapy

Public title

Effect of family-based intervention on cancer coping in breast cancer survivors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included: ages 30-60 years: speak the

persian language! diagnosis breast cancer! having experienced a mastectomy procedures! pass 48 hours of chemotherapy! between two chemotherapy! do not having other cancer! do not having a history of hospitalization. Exclusion criteria: any stressful event for the patient or family members during the study and the absence of more than one session of meetings.

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Based on odd or even being randomly 30 patients for control group ,and 30 patients for intervention group will select.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University Of Medical Sciences

Street address

Resalat Blv, next to the emergency center. Urmia University Of Medical Sciences

City

Urmia

Postal code

5714783734

Approval date

2016-05-18, 1395/02/29

Ethics committee reference number

Ir umsu.rec.1395.109

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Cancer coping

Timepoint

Before intervention and 6 weeks after the first session

Method of measurement

Cancer coping questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family-centered group discussion and counseling that include six meetings of the group of patients and an active member of families that includes six groups and each group will have five families in the intervention group. With titles introduce, communicate and encourage clients to express their views on their experiences in applying methods of coping before, providing effective solutions and use and interpret and to discuss any of the agenda items FOCUS in each of the meetings. The duration of each session will be about 1.5-2 hours. Researcher will use tools such as flash card, PowerPoint, pamphlets, lectures and group discussion to more effective intervention program during the intervention. Researcher will use brainstorming ways to solve the problems. Researcher will give diary to the patients. Participants will encourage to do that practice in the home between two sessions and report to express their assignment procedure at each meeting. Meetings will be weekly for 6 weeks. The first session includes of support and family involvement, optimistic attitude to have a second meeting, the third session of the impact of the deal and cope with cancer, reduce uncertainties for fourth session and the fifth session will be symptoms management.

Category

Lifestyle

2

Description

Control group: The control group will not receive the any intervention. But due to ethical norms that they were in the control group, after the intervention, one or two sessions will do for them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Dr. Fatemeh Mogaddam Tabrizi

Street address

Farhangian street, Omid hospital

City

Urmia

2

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Dr. Fatemeh Mogaddam Tabrizi

Street address

Ershad street, Ayatollah Modarres blvd, Imam Khomeini hospital

City

Urmia

3

Recruitment center

Name of recruitment center

Motahhari hospital

Full name of responsible person

Dr.Fatemeh Mogaddam tabrizi

Street address

Kashani street

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellfor research Of Urmia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Resalat blv, next to the emergency center, Urmia University Of Medical Sciences

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellfor research Of 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

Dr. Fatemeh Moghaddam Tabrizi

Position

Ph.D

Other areas of specialty/work

Street address

Nursing and midwifery department, Nazloo

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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address**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