Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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.

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

2016-07-11, 1395/04/21

Registrant information

Name
Fatemeh Moghaddam Tabrizi

Name of organization / entity
Uromia University of Medical sciences

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Iran (Islamic Republic of)

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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

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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Postal code
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+98 44332754963
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fmtabrizi@gmail.com
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Person responsible for scientific inquiries

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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