

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Determining the effect of continues care model on health promotion behaviors of breast cancer survivors referring to the Educational, Research, and Therapeutic Centers of Urmia in 2017

Protocol summary

Study aim

Determining the effect of continues care model on health promotion behaviors of breast cancer survivors referring to the Educational, Research, and Therapeutic Centers of Urmia in 2017

Design

Considering the criteria for entering the study, 60 patients and one of the active members of the family to take care of the patient, participate in the study, using the availability method and filling the written consent form. And by using an envelope containing odd or even numbers, the participants will be chosen randomly to be in the control group (N= 30) or in the intervention group (N= 30).

Settings and conduct

Demographic questionnaire, family support questionnaire, and health promotion lifestyle questionnaire are first filled in both groups, and then follow-up care model is provided for intervention group, whereas the control group receives routine care. Classes will be held at one of the private clinics in groups of 5 families in 6 sessions within a week interval.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes: Age range from 20 to 60, familiarity with Persian and Turkish languages, diagnosis of breast cancer, not having other types of cancer, having had mastectomy, completing breast cancer treatment (chemotherapy, radiotherapy, hormone therapy), degrees of 1, 2, 3a of breast cancer based on the pathology sheet, not having another stressful experience in the last 6 months, gaining score below 23 in public health screening (GHQ28 questionnaire), and not attending another training sessions.

Intervention groups

Classes will be held at one of the private clinics in groups of 5 families in 6 sessions, within a week interval. In each session, topics from the items of the life style health

questionnaire will be discussed.

Main outcome variables

Health promotion behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150125020778N20**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **retrospective**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

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

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the effect of continues care model on health promotion behaviors of breast cancer survivors referring to the Educational, Research, and Therapeutic Centers of Urmia in 2017

Public title
The effect of continues care model on health promotion behaviors in breast cancer survivors

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria includes: Age range from 20 to 60, familiarity with Persian and Turkish languages, diagnosis of breast cancer, not having other types of cancer, having had mastectomy, completing breast cancer treatment (chemotherapy, radiotherapy, hormone therapy), degrees of 1, 2, 3a of breast cancer based on the pathology sheet, not having another stressful experience in the last 6 months, gaining score below 23 in public health screening (GHQ28 questionnaire), and not attending another training sessions.
Exclusion criteria:

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Considering the criteria for entering the study, and having filled the consent paper, 60 patients and one of the active members of the family to take care of the patient, take part in the study, utilizing the availability method. And by using an envelope containing odd or even numbers, the participants will be chosen randomly to be in the control group (N= 30) or in the intervention group (N=30).

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

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

lr.umsu.rec1396.278

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

Health promotion behaviors

Timepoint

Before intervention and 6 weeks after the first session

Method of measurement

Health-Promoting Lifestyle Profile questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: counseling program , discussion and following up , consisting of patients and one of the active elements of the family which consist of 6 groups and in each group there are 5 families.it will be held weekly in 6 sessions that will last one or one and a half hour and in

each sessions titles will be discussed , from the items of the life style health questionnaire (mental health , physical activity , interpersonal communication , nutrition , stress management health responsibility) in which the patient and his family mention their ongoing challenges to the debate and in order to solve the problems , appropriate solutions depending on the topic will be taken. Using brochures and pamphlets by researchers for more impact will be provided. Notepads will also be provided to the patients so that they can write their daily behaviors at intervals between sessions and report the process of doing behaviors in each sessions so the researchers can evaluate the impact of skills acquired in a person and solve the problems and barriers with the help of the patient and his family and promote the positive hints as much as possible.

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

Imam khomeini hospital

Full name of responsible person

Dr. Fatemeh Mogaddam Tabrizi

Street address

Ershad street, Ayatollah Modarres blvd, Imam Khomeini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia 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

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Irajmohebbi@umsu.ac.ir

Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Moghaddam Tabrizi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Nursing and midwifery department, Nazloo

City

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West Azarbaijan

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Fatemeh Moghaddam Tabrizi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

I have not decided yet - its publication plan is still unclear

When the data will become available and for how long

I have not decided yet - its publication plan is still unclear

To whom data/document is available

I have not decided yet - its publication plan is still unclear

Under which criteria data/document could be used

I have not decided yet - its publication plan is still unclear

From where data/document is obtainable

I have not decided yet - its publication plan is still unclear

What processes are involved for a request to access data/document

I have not decided yet - its publication plan is still unclear

Comments

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Moghaddam Tabrizi

Position

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Latest degree

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Other areas of specialty/work

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