

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of midwifery- led supportive program on coping strategies and stress in breast cancer women

Protocol summary

coping strategies and stress

Study aim

determining the effect of midwifery- led supportive program on coping strategies and stress in breast cancer women

Design

this study is a controlled clinical trial and one blind experiment whose community includes women with breast cancer referring to chemotherapy sections in Imam Khomeini hospital and Baghban Specialized Clinic in the Sari city.60 patients are chosen by software and Permuted block randomization (ten sextet blocks) in two groups, that 30patients are in intervention group (3 groups of 8-12 patients as entering in to the study) and 30 patients in control groups.

Settings and conduct

Sampling is done in Imam Khomeini hospital and Baghban Specialized Clinic in the Sari city. In intervention group, the supportive program is administered in 6 sessions as one 90-minute session every week.The control group, in addition to routine care, will receive an individual training session after completing the latest post-test questionnaire.

Participants/Inclusion and exclusion criteria

inclusions: stage I to III, at most one year after diagnosis, patients under at least one session chemotherapy, at least finishing primary school; exclusions: suffering from another cancer, participating in others psychotherapy interventions, suffering from severe psychiatric disorders (panic attacks, severe depression and anxiety and...), participating in consulting courses for last 6 months

Intervention groups

intervention group: the supportive program is administered in 6 sessions as one 90-minute session every week. In sessions, they are informed about breast cancer, coping strategies, reducing stress. control group: in addition to routine care, will receive an individual training session after completing the latest post-test questionnaire.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150608022609N4**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-20, 1397/08/29**

Update count: **0**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Zohre Shahhosseini

Name of organization / entity

Mazandaran University of Medical Science, Nasibe School Of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-16, 1397/08/25

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of midwifery- led supportive program on coping strategies and stress in breast cancer women

Public title
the effect of midwifery-led supportive program on coping strategies and stress

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
stage I to III at most one year after diagnosis patients under at least one session chemotherapy at least finishing primary school
Exclusion criteria:
suffering from another cancer participating in others psychotherapy interventions suffering from severe psychiatric disorders (panic attacks, severe depression and anxiety and...) participating in consulting courses for last 6 months

Age
No age limit

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
60 patients are chosen by software and Permuted block randomization (ten sextet blocks) in two groups, that 30patients are in intervention group (3 groups of 12-8 patients as entering in to the study) and 30 patients in control groups.

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

Ethics committee of Mazandaran University of Medical

Science

Street address
Deputy of Research and Technology of Mazandaran University of medical Sciences,Moalem Square, Moalem Avenue

City
Sari

Province
Mazandaran

Postal code
4816715793

Approval date
2018-09-26, 1397/07/04

Ethics committee reference number
IR.MAZUMS.REC.1397.155

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

coping strategies

Timepoint

Pre- intervention, Immediately and one month after intervention

Method of measurement

Coping Strategies Questionnaire (Folkman and Lazarus)

Secondary outcomes

1

Description

Stress

Timepoint

Pre- intervention, Immediately and one month after intervention

Method of measurement

Depression, Anxiety and Stress questionnaire (DASS-21)

Intervention groups

1

Description

Intervention group:In intervention group, the supportive program is administered in 6 sessions as one 90-minute session every week. In sessions, they are informed about breast cancer, coping strategies, reducing stress.

Category

Behavior

2

Description

Control group: The control group, in addition to routine care, will receive an individual training session after completing the latest post-test questionnaire.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Misagh Shafizad

Street address

Imam Khomeini Hospital, Amir Mazandarani Avenue, Sari, Mazandaran

City

Sari

Province

Mazandaran

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4816633131

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Emamsarih@gmail.com

2

Recruitment center

Name of recruitment center

Baghban Specialized Clinic

Full name of responsible person

Mohammad Panbehchi

Street address

Baghban Specialized Clinic, Former Medical Faculty, Khazar Boulevard, Sari, Mazandaran

City

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Mazandaran

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4816895474

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mhpanbehchi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Akbar Hedayatizadeh Omran

Street address

Deputy of Research and Technology of Mazandaran University of medical Sciences, Moalem Square, Moalem Avenue

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akbar_hedayati@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Elahe samami

Position

masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohreh Shahhosseini

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Elahe samami

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

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

Clinical Study Report

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

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