

# 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

+98 11 3336 7342

##### Email address

z.shahhosseini@mazums.ac.ir

##### 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

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Sari

**Province**

Mazandaran

**Postal code**

4816633131

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**Email**

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

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**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

**Street address**

Nasibeh Nursing and Midwifery Faculty, Vesal Shirazi Avenue

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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

**Street address**

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**Province**

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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