

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Investigating the Impact Of Orem's Supportive-Educative System On Depression, Body Image And Self-Esteem Of Women Underwent a Mastectomy

#### Protocol summary

##### Study aim

Determining The Impact Of Orem's Supportive-Educative System On Depression, Body Image And Self-Esteem Of Women Underwent A Mastectomy, West Azerbaijan, 2022

##### Design

Clinical trial with a control group, with parallel-group, single-blind, randomized. Random.org (Random Integer Set Generator) was used for randomization

##### Settings and conduct

According to Orem's theory of nursing systems, it will be held as a support-educational system in 4 stages (diagnostic, prescriptive, regulatory, and control operations) and 7 training sessions will be held twice a week. The content of the sessions will be prepared based on the texts and form of Orem's self-care needs. For 2 months after the end of the intervention, the necessary training will be followed. The questionnaires will be completed in 4 stages after the end of the intervention (immediately, 1, 3, and 6 months later).

##### Participants/Inclusion and exclusion criteria

- Age 35-65 years
- Women who have started at least one session of chemotherapy.
- Women whose chemotherapy sessions will continue for at least another 3 months.
- Women whose mastectomy surgery (total or partial) within the last 5 months.
- No history of other malignancies
- Not suffering from chronic diseases
- Absence of other stressful events in the last 6 months
- Absence of hearing, vision, and cognitive disorders
- speak Persian or Turkish
- Ability to complete the questionnaire
- Willingness to participate in the study
- Not suffering from specific psychological disorders like MDD
- Not using narcotics or Psychedelic drugs
- Not taking drugs that affect the physical and mental state
- Access to smartphone and internet

##### Intervention groups

7 sessions of 60-90 minutes will be conducted on the

intervention group based on Orem's educational support system. The control group will receive usual care.

##### Main outcome variables

depression; self-esteem; body image

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016564N16**

Registration date: **2022-09-07, 1401/06/16**

Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

##### Registration date

2022-09-07, 1401/06/16

##### Registrant information

##### Name

Molood Radfar

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1275 4961

##### Email address

radfar.m@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the Impact Of Orem's Supportive-Educative System On Depression, Body Image And Self-Esteem Of Women Underwent a Mastectomy

**Public title**

Impact Of Orem's Supportive-Educative System in mastectomized women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women who have started at least one session of chemotherapy. Women whose chemotherapy sessions will continue for at least another 3 months. Women who have undergone mastectomy surgery (total or partial) within the last 5 months. No history of other malignancies (according to the patient's statement and medical record) Not suffering from chronic diseases (according to the patient's statement and medical record) Absence of other stressful events such as the death of a first degree relative in the last 6 months according to the patient statement Not suffering from hearing, vision and cognitive disorders (according to the statement of the patient and companion) Ability to speak Persian or Turkish Ability to complete the questionnaire Willingness to participate in the study Not having specific psychological disorders such as major depression (according to the patient's statement and medical record) Not using drugs or psychotropic substances (according to the patient's statement and medical record) Not taking drugs that affect the physical and mental state (according to the patient's statement and medical record) Access to smart phone and internet

**Exclusion criteria:****Age**

From **35 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

With the Convenience Sampling method and taking into account the loss of samples, 80 people who meet the criteria for entering the study will be selected. Then, by coding the participants as integers and using the random integer generation feature by Random.org (Random Integer Set Generator), people will be randomly assigned

to two groups of 40 people, control and intervention.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Data will be collected in 4 steps. After collecting the data, the intervention group will be named as group B and the control group as group A and will be provided to the analyst. In all 4 stages, the names of the groups will be the same and will not change.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Urmia University of Medical Sciences

**Street address**

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

**City**

اروميه

**Province**

West Azarbaijan

**Postal code**

5756115335

**Approval date**

2022-07-27, 1401/05/05

**Ethics committee reference number**

IR.UMSU.REC.1401.201

**Health conditions studied****1****Description of health condition studied**

Breast cancer, mastectomy

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

**Primary outcomes****1****Description**

Depression score in Beck questionnaire

**Timepoint**

At the beginning of the study, immediately after the end of the intervention, one month, three months and six after the Imam of the intervention

**Method of measurement**

**2**

**Description**

Body image score of women with breast cancer in Hopwood questionnaire

**Timepoint**

At the beginning of the study, immediately after the end of the intervention, one month, three months and six after the Imam of the intervention

**Method of measurement**

Hopwood body image scale (BIS) of women with breast cancer

**3**

**Description**

Self-esteem score in the Rosenberg questionnaire

**Timepoint**

At the beginning of the study, immediately after the end of the intervention, one month, three months and six after the Imam of the intervention

**Method of measurement**

Rosenberg's Self-Esteem Scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: According to the theory of Orem nursing systems, it will be held as a support-educational system in 4 stages (diagnostic, PRESCRIPTIVE, regulatory, and control operations) and 7 training sessions will be held in two sessions in one week. The content of the sessions will include familiarization with the nature of breast cancer, familiarization with the concept of body image and its causes and ways to improve it, familiarizing the participants with the concept of depression and managing its causes, and familiarizing the participants with the concept of self-esteem and offering ways to improve it. For 2 months after the end of the intervention, the necessary training will be followed. The questionnaires will be completed in 4 stages after the end of the intervention (immediately, 1, 3 and 6 months later).

**Category**

Other

**2**

**Description**

Control group: They do not receive any intervention

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Educational and Medical Center of Urmia

**Full name of responsible person**

Nima Sadeghzadeh

**Street address**

No. 61, Tamayol Ave., Sardaran 1 Blvd

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Urmia

**Province**

West Azarbaijan

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**Phone**

+98 936 991 4582

**Email**

Nima.sadeghzadeh97@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saber Gholizadeh

**Street address**

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

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**Email**

Nima.sadeghzadeh97@gmail.com

**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**

Moloud Radfar

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Latest degree**

Ph.D.

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Documentation will be published in the form of an article.

**When the data will become available and for how long**

Access starts 3 months after the results are published

**To whom data/document is available**

Available to all researchers in the field of psychiatry

**Under which criteria data/document could be used**

Compare demographic characteristics with body image, self-esteem, Depression or two groups with each other

**From where data/document is obtainable**

Moloud Radfar: Associate Professor

Mradfar1343@gmail.com Nima Sadeghzadeh: Master of science in psychiatric nursing

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

Send e-mail and in case of no response after one day by phone and coordination with research members and if you agree to provide information for about a week

**Comments**