Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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

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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
ارومیه
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

Beck's Depression Inventory-II

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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Phone
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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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Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
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

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Person responsible for updating data

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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