

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

City

Urmia

Province

West Azarbaijan

Postal code

۵۷۱۳۹۵۹۳۵۶

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

City

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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115335

Phone

+98 44 3275 4962

Email

radfar.m@umsu.ac.ir

Person responsible for scientific 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

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115335

Phone

+98 44 3275 4962

Email

radfar.m@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Moloud Radfar

Position

دانشیار

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115335

Phone

+98 44 3275 4962

Email

radfar.m@umsu.ac.ir

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