# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The Effect of Social Support Based on Group Intervention on Loneliness among Women with Mastectomies

## Protocol summary

**Summary**

Objective: present study will conduct with the aim of effect of social support based group Intervention on loneliness among women with mastectomies. The most important of inclusion criteria: having experienced mastectomy procedures within 4-24 last month; having public health based on GHQ scale and the most important of exclusion criteria: having another type of cancer. The study of population and sample size: This study will carry out on 80 Women with Mastectomies in Urmia city. Intervention: The program of intervention will be in 6 group sessions in dimensions emotional, tools and informational support. Sessions will be held with a focus on communication and make friends, communication with family and friends, coping, stress management and answer questions. The control group received no intervention. Main outcome: Social Support; Improve loneliness Variables: loneliness

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014031516564N3**
Registration date: **2015-07-16, 1394/04/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-07-16, 1394/04/25

**Registrant information**

**Name**

Molood Radfar

**Name of organization / entity**

Urmia University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Urmia University of Medical Sciences

**Expected recruitment start date**

2014-03-21, 1393/01/01

**Expected recruitment end date**

2014-05-22, 1393/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Social Support Based on Group Intervention on Loneliness among Women with Mastectomies

**Public title**

The Effect of Social Support on Loneliness

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: having experienced a mastectomy procedures within 4-24 last month, having general health based on GHQ scale; awareness of the disease Exclusion criteria: having another type of cancer, the experience of other stressful events within 6 last month; absence of more than two sessions

**Age**

From **20 years** old to **60 years** old

**Gender**

Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**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 Urmia University of Medical Sciences
**Street address**
Resalat boulevard, next to the emergency
**City**
Urmia
**Postal code**
**Approval date**
2014-07-15, 1393/04/24
**Ethics committee reference number**
Ir.umsu.rec.1393.108

## Health conditions studied

**1**

**Description of health condition studied**
Breast Cancer
**ICD-10 code**
C50.9
**ICD-10 code description**
Malignant neoplasm: Breast, unspecified

## Primary outcomes

**1**

**Description**
loneliness
**Timepoint**
Before the intervention - at the end of the intervention - two months after the end of intervention
**Method of measurement**
with UCLA questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention: The program of intervention will be in 6 group sessions in dimensions emotional, tools and informational support. Sessions will be held with a focus on communication and make friends, communication with family and friends, coping, stress management and answer questions. The control group received no intervention.
**Category**
Lifestyle

**2**

**Description**
The control group received no intervention.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Khomeini hospital
**Full name of responsible person**
Medical Documentation Center
**Street address**
Ershad avenue
**City**
Urmia

**2**

**Recruitment center**
**Name of recruitment center**
Imam Reza hospital of Urmia
**Full name of responsible person**
Medical Documentation Center
**Street address**
Molavi avenue
**City**
Urmia

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Urmia University of Medical Sciences, Vice Chancellor of Research
**Full name of responsible person**
Erag Mohebbie

**Street address**
Urmia University of Medical Sciences and Health Service, next emergency center, Resalat Blvd
**City**
Urmia
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Urmia University of Medical Sciences, Vice Chancellor of Research
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Urmia University of Medical Sciences
**Full name of responsible person**
Zeinab Taei
**Position**
Master of Nursing
**Other areas of specialty/work**
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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)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*