

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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

+98 44 1275 4961

Email address

radfar.m@umsu.ac.ir

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

lr.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

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Web page address**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