

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Determine the effect of solution-Focused counseling on depression and quality of life in women after mastectomy

Protocol summary

Study aim

The effect of solution-oriented counseling on depression and quality of life in women after mastectomy

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3, on 70 patients. For randomization, block randomization method was used in 7 blocks of 10 using online software www.sealedenvelope.com.

Settings and conduct

This study will be performed in Valiasr Hospital in Arak. So that 70 female patients after mastectomy will be randomly divided into two groups of control and intervention. patients in both groups will be assessed by a pre-test and will be referred to a psychiatrist in case of severe depression and will be excluded from the study. Patients in the control group will receive routine care, and patients in the intervention group will receive solution-oriented counseling in addition to routine care. Patients are not aware of the type of counseling performed and The person who analyzes the information is blinded too, So the study will be double-blind. After the intervention, the severity of depression in patients and their quality of life will be re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 25 to 55 years, unilateral radical mastectomy during the last 2 to 5 years. exclusion criteria: Chronic physical illness, death of relatives, mental illness, related counseling, chemotherapy and radiotherapy

Intervention groups

Control group: 35 patients will receive routine post-mastectomy care after enrollment. Intervention group: 35 patients will be treated with solution-oriented psychological counseling In addition to routine care after entering the study. counseling is performed in the form of 6 sessions of 1.5 hours on women after mastectomy. Counseling in all patients will be done by a specific and single counselor on a regular and weekly basis.

Main outcome variables

Depression, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201021049103N1**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

Name

Leila Pirzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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pirzadil1378@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine the effect of solution-Focused counseling on depression and quality of life in women after mastectomy

Public title

Effect of solution-Focused counseling on depression after mastectomy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 25 to 55 years Unilateral radical mastectomy over the last 2 to 5 years

Exclusion criteria:

Chronic physical illness Death of relatives Having mental diseases Get related Consulting Radiotherapy and chemotherapy

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After admission to the study, 70 patients will be divided into control and intervention groups in 7 blocks of 10 using block randomization method with online statistical software (www.sealedenvelope.com). Then the method of sealed opaque envelopes was used to hide the sequences. In this way, a number of envelopes with aluminum wrappers (in order to obscure the contents of the envelopes) are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are not aware of the type of counseling that is done for them and the number and time of sessions and the counselor is the same for all patients in both groups and the analyzer of the obtained data is not aware of the type of groups and recognizes

the groups based on the letters A and B. Therefore, this study is a double-blind study. In this study, the counselor and the main executor of the study are aware of the study groups and the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Basij Sq., Sardasht

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.ARAKMU.REC.1398.302

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

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

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

Depression

Timepoint

Pre-intervention evaluation using pre-test, post-intervention evaluation using post-test

Method of measurement

Beck Depression Inventory

2**Description**

Quality of life

Timepoint

Before the intervention and after the intervention

Method of measurement

WHOQOL-BREF questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this group, 35 patients will be treated with solution-oriented psychological counseling In addition to routine care after entering the study. Solution-oriented counseling is a counseling approach based on the De Shazer solution-oriented counseling protocol, which in this study is performed in the form of 6 sessions of 1.5 hours on women after mastectomy. Counseling in all patients will be done by a single specific counselor on a regular and weekly basis.

Category

Rehabilitation

2**Description**

Control group: In this group, 35 patients will undergo routine care after mastectomy after entering the study, Which includes medical care and In addition, patients will receive regular (non-solution-oriented) psychological counseling, which is performed in the form of 6 1.5-hour counseling sessions for women after mastectomy. Counseling in all patients will be done by a specific and single counselor on a regular and weekly basis.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Leila Pirzadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Leila Pirzadi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available