Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2026

The effect of group counselling on health promoting lifestyle and quality of life in women who have undergone mastectomy: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of group counselling on health promoting lifestyle and quality of life in women who have undergone mastectomy. Design: Randomized controlled trial. Conduct: This study will be conducted on 76 women under the age of 60 years old who have undergone mastectomy during the last five years in state and private hospitals of Tabriz. The researcher will refer to hospital and will select eligible women through convenience sampling method and the questionnaires of HPLP-2 will be completed and the women who obtain score lower than 3 will be included in study and written consent will be obtained and also Quality of Life Questionnaire-Cancer 30 will be completed. Participants will be randomly assigned into two groups of counseling and control through block randomization. Participants: 76 women who have undergone mastectomy during the last five years. Intervention: For the intervention group (n= 38), six 60 to 90 minute group counseling once a week will be provided. The control group (n= 38) will receive routine cares. The main outcome variables include health promoting lifestyle and quality of life that will be assessed before intervention, four and eight weeks after the intervention through HPLP-2 and Quality of Life Questionnaire-Cancer 30.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062510324N40**
Registration date: **2017-08-16, 1396/05/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-16, 1396/05/25

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-12-23, 1396/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counselling on health promoting lifestyle and quality of life in women who have undergone mastectomy: a randomized controlled clinical trial

Public title

The effect of group counselling on health promoting lifestyle and quality of life in women who have undergone mastectomy

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Age less than 60 years old; Passing of at least 1 year and a maximum of 5 years from mastectomy; Obtaining HPLP-2 score less than 3. Exclusion criteria: History of severe mental illness (such as depression, bipolar, schizophrenia) according to woman’s expression; Taking psychiatric drugs or psychotropic substances; Having other cancers; Recent occurrence of tragic events; Previous participation in counseling classes for prompting lifestyle.
Age
To **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
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 Tabriz Univercity of Medical Sciences
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan
City
Tabriz
Postal code
Approval date
2017-08-07, 1396/05/16
Ethics committee reference number
IR.TBZMED.REC.1396.376

Health conditions studied

1

Description of health condition studied
Lifestyle
ICD-10 code
Y98
ICD-10 code description
Lifestyle-related condition

Primary outcomes

1

Description
Health promoting lifestyle
Timepoint
Before intervention, four and eight weeks after the intervention
Method of measurement
HPLP-2 questionnaire

2

Description
Quality of life
Timepoint
Before intervention, four and eight weeks after the intervention
Method of measurement
Quality of Life Questionnaire-Cancer 30

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, six 60 to 90 minute group counseling once a week will be provided.
Category
Lifestyle

2

Description
The control group will receive routine cares.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz state and private hospitals
Full name of responsible person
Manirah Hamed Biyabani
Street address

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research of Tabriz University of Medical Sciences

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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Monireh Hamed Biyabani

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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