Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of implementation of self-management five-A model versus no implementation on quality of life patients with breast cancer: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of implementation of self-management five-A model versus no implementation on quality of life patients with breast cancer Design: A randomized clinical trial. Setting and conduct: The eligible patients with breast cancer who will refer to Tohid Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 35 to 65 years; breast cancer; under chemotherapy with a history of mastectomy. Exclusion criteria: Mental disease; participating in similar study; deterioration of the patient's situation during study period. Intervention group: Routine treatment plus implementation of self-management five-A model in five stage and two educational session 1.5 hours with a week interval. Control group: Just routine treatment. Primary outcome: Assessing the quality of life before intervention and 3 months after intervention using QLQ-C30 and QLQ-BR23 questionnaires. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710159014N196**
Registration date: **2017-10-18, 1396/07/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-18, 1396/07/26

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Kurdistan University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementation of self-management five-A model versus no implementation on quality of life patients with breast cancer: a randomized clinical trial

Public title

Effect of implementation of self-management five-A model versus no implementation on quality of life patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 35 to 65 years; breast cancer; under chemotherapy with a history of mastectomy. Exclusion criteria: Mental disease; participating in similar study; deterioration of the patient's situation during study period.

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Kurdistan University of Medical Sciences, Pasdaran Ave

City

Sanadaj

Postal code

Approval date

2017-09-09, 1396/06/18

Ethics committee reference number

IR.MUK.REC.1396/193

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Assessing the quality of life

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Using QLQ-C30 and QLQ-BR23 questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus implementation of self-management five-A model in five stage and two educational session 1.5 hours with a week interval.

Category

Other

2

Description

Control group: Just routine treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Mayar Karhor

Street address

Tohid Hospital, Gariashan Ave.

City

Sanadaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Kurdistan University of Medical Sciences

Full name of responsible person

Dr Farzin Rezaei

Street address
Kurdistan University of Medical Sciences, Pasdaran Ave
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Sanadaj
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 and Technology, Kurdistan 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
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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