

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

City

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****Name of organization / entity**

Tohid Hospital

Full name of responsible person

Mayar Karhor

Position

Master of Nursing

Other areas of specialty/work**Street address**

Tohid Hospital, Gariashan Ave.

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

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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