

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying Effect of Cognitive-Behavioural Stress Management(CBSM) program on occupational performance and adjustment women with breast cancer, attending to MRI center and Hamadan Therapeutic Facilities, 2015

Protocol summary

Summary

Breast cancer is the most common cancer among women. Short recovery times and the best possible functioning of patients after breast cancer operations should be the key interests of rehabilitation. Most studies in the field of breast cancer rehabilitation still have a major concern with impairments, although a shift of interest is gradually taking place towards broader conceptualization of the aspects of health. The International Classification of Functioning, Disability and Health (ICF), published by WHO . Many studies have reported flaws in upper limb function in these patients, however a little is known about activity limitations and participation restrictions. Diagnosis and treatment of primary breast cancer in women present a series of challenges often resulting in stress, emotional distress, difficulty in adjustment and decreased social interactions. Studies have shown effectiveness cognitive behavioral therapy in hard and chronic medical conditions due to the long-term effects of this treatment on depression, anxiety and quality of life, especially in patients with breast cancer respectively. According to the findings, the aim of this study evaluate the effect of cognitive-behavioral stress management on occupational performance and adjustment in women with breast cancer referred to medical centers in Hamedan

General information

Acronym

Cognitive-Behavioural Stress Management(CBSM)

IRCT registration information

IRCT registration number: **IRCT2016051224468N1**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Farkhondeh Jamshidi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1571

Email address

f.jamshidi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-05-06, 1395/02/17

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying Effect of Cognitive-Behavioural Stress Management(CBSM) program on occupational performance and adjustment women with breast cancer, attending to MRI center and Hamadan Therapeutic

Facilities, 2015

Public title

Studying Effect of Cognitive-Behavioural Stress Management(CBSM) program on occupational performance and adjustment women with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Age range between 20-60 years old; 2) Being married; 3) Women with breast cancer Grade 3 or lower after surgery (regardless of the type of surgery); 4) Level of Education: High School to the top; 5) Willing to participate in research and cooperate in all phases of evaluations. Exclusion criteria: 1) History of chronic physical and mental illnesses such as psychotic disorders such as schizophrenia, severe depression and ...; 2) Participate in more than one educational session; 3) The occurrence of stressful events (death of someone close, divorce, etc.) while studying; 4) The existence of mental retardation; 5) Drug abuse.

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: **104**

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

Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Pajohesh Intersection, Shahid Fahmideh Blvd., Opposite the Mardom Park

City

Hamadan

Postal code

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.UMSHA.REC.1395.32

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

Adjustment

Timepoint

Before and one week after intervention

Method of measurement

Bell adjustment questionnaire

2

Description

Occupational performance

Timepoint

Before and one week after intervention

Method of measurement

Canadian occupational performance questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: intervention does not take place.

Category

N/A

2

Description

The intervention group counseling, stress management, 4 sessions of 60 minutes each, for 4 weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Imam Khomeini Clinic
Full name of responsible person
Street address
City
Hamadan

Fax
Email
farkhondeh.jamshidi@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology
University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Hamadan University of Medical Sciences, Pajohesh
Intersection, Shahid Fahmideh Blvd., Opposite the
Mardom Park
City
Hamadan

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 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
Hamadan University of Medical Sciences
Full name of responsible person
Farkhondeh Jamshidi
Position
Faculty member
Other areas of specialty/work
Street address
Hamadan University of Medical Sciences, Pajohesh
Intersection, Shahid Fahmideh Blvd., Opposite the
Mardom Park
City
Hamadan
Postal code
Phone
+98 81 3838 1571

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Farkhondeh Jamshidi
Position
Master of sciences(MSc)
Other areas of specialty/work
Street address
Hamadan University of Medical Sciences, Pajohesh
Intersection, Shahid Fahmideh Blvd., Opposite the
Mardom Park
City
Hamadan
Postal code
Phone
+98 81 3838 1571
Fax
Email
farkhondeh.jamshidi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Farkhondeh Jamshidi
Position
Faculty member
Other areas of specialty/work
Street address
Hamadan University of Medical Sciences, Pajohesh
Intersection, Shahid Fahmideh Blvd., Opposite the
Mardom Park
City
Hamadan
Postal code
Phone
+98 81 3838 1571
Fax
Email
farkhondeh.jamshidi@yahoo.com
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