Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Theraputic 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
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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 Theraputic

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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farkhondeh Jamshidi

Position

Master of sciences(MSc)

Other areas of specialty/work

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Person responsible for updating data

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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