Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study on the Effect of stress management consulting on the sexual Function in women suffering from breast cancer

Protocol summary

Summary

(1) Objectives: Study on the Effect of stress management consulting on the sexual Function in women suffering from breast cancer (2) Design: The study in women with women with breast cancer referred to Mahdieh MRI Center Hamadan, with a sample content of 104, randomized, clinical trial, single-center (3)How do: patients with breast cancer referring to the MRI center of Hamadan, after obtaining informed consent, 104 cases who met the inclusion criteria were selected as convenience sampling. Using permutation blocks, they were randomly divided into two experimental and control groups (n= 52). The experimental group Participation 4 sixty-minute sessions over consecutive weeks in stress management training classes of 12 persons. The control group received no psychological intervention and only received medical treatments. Before starting therapy, test and control groups were tested by a questionnaire and two groups were post-tested after completion of sessions and two weeks later in order to follow up. The therapist specified some assignments each session to be done during the interval of the sessions by the patients. (4) Inclusion criteria: age range of 20-45 years; married; women with breast cancer of grade 3 and below after mastectomy surgery and under chemotherapy; lack of other chronic illnesses; and having passed at least one month of operating period. Exclusion criteria: included a history of important mental and physical illness such as psychosis including schizophrenia and severe depression and so on which required special medicine or diet; not participating in more than one educational session; the occurrence of stressful events(death of close relatives/friends, divorce, and drug abuse. (5) interventions: Participation 4 sixty-minute sessions over consecutive weeks in stress management training classes for experimental group and in control group not intervention. (6) The main outcome: Improve sexual function

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030623350N2**
Registration date: **2016-04-08, 1395/01/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-08, 1395/01/20

Registrant information

Name
Arezoo Shayan
Name of organization / entity
Hamadan University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 0551
Email address
a.shayan@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Hamadan University of Medical Sciences

Expected recruitment start date

2015-12-31, 1394/10/10

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study on the Effect of stress management consulting on the sexual Function in women suffering from breast cancer

Public title
The impact of stress management consulting on sexual function and stress in women with breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age range of 20-45 years; married; women with breast cancer of grade 3 and below after mastectomy surgery and under chemotherapy; lack of other chronic illnesses; and having passed at least one month of operating period. Exclusion criteria: included a history of important mental and physical illness such as psychosis including schizophrenia and severe depression and so on which required special medicine or diet; not participating in more than one educational session; the occurrence of stressful events (death of close relatives/friends, divorce), and drug abuse.
Age
From **20 years** old to **45 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
Ethics committee of Hamadan University of Medical Sciences
Street address
Front of Mardom park, Shahid Fahmideh Street, Hamadan University Of Medical Sciences, Hamadan
City
Hamadan
Postal code
-
Approval date
2016-02-27, 1394/12/08
Ethics committee reference number
IR.UMSHA.REC.1394.497

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50.1, C50
ICD-10 code description
Central portion of breast, Upper-inner quadrant of breast, Lower-inner quadrant of breast, Upper-outer quadrant of breast, Lower-outer quadrant of breast, Axillary tail of breast, Overlapping lesion of breast, Breast, unspecifie

Primary outcomes

1

Description
sexual function
Timepoint
Before,2 weeks after intervention
Method of measurement
Sexual function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1:stress management consulting 4 sessions in 60 minutes, for 4 weeks
Category
Behavior

2

Description
In intervention group2: Without intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
MRI Center Hamadan
Full name of responsible person
Vahid Tahmasebi
Street address

Nurse Street, MRI Center Mahdiyeh, Hamadan.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Mohammad Yosef Alikhani

Street address

Front of Mardom park, Shahid Fahmideh Street, Hamadan University Of Medical Sciences, Hamadan

City

Hamadan

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research, Hamadan 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 Science

Full name of responsible person

Arezoo Shayan

Position

Masters, Lecturer Faculty

Other areas of specialty/work

Street address

Front of Mardom park, Shahid Fahmideh Street, Hamadan University Of Medical Sciences, Hamadan

City

Hamadan

Postal code

-

Phone

+98 81 3838 0551

Fax

-

Email

arezoo.shayan2012@yahoo.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University Of Medical Science

Full name of responsible person

Arezoo Shayan

Position

Masters, Lecturer Faculty

Other areas of specialty/work

Street address

Front of Mardom park, Shahid Fahmideh Street, Hamadan University Of Medical Sciences, Hamadan

City

Hamadan

Postal code

-

Phone

+98 81 3838 0551

Fax

-

Email

arezoo.shayan2012@yahoo.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University Of Medical Science

Full name of responsible person

Arezoo Shayan

Position

Master degree, Lecturer faculty

Other areas of specialty/work

Street address

Front of Mardom park, Shahid Fahmideh Street, Hamadan University Of Medical Sciences, Hamadan

City

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0551

Fax

Email

arezoo.shayan2012@yahoo.com

Web page address

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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