

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 Mahdiah 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

Arezo 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, unspecific

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 group 2: 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 Mahdijeh, Hamadan.
City
Hamadan

Email
arezoo.shayan2012@yahoo.com
Web page address
-

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
--

**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
-

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
-

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