

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of illness perception educational intervention's on sexual satisfaction of women with breast cancer

Protocol summary

Study aim

Determining the effect of educational intervention based on illness perception on the sexual satisfaction of women with breast cancer

Design

In this study, 80 patients with breast cancer who are eligible for inclusion in the study are selected and randomly divided in to control and intervention groups.

Settings and conduct

This clinical trial study was conducted on the sexual satisfaction of patients with breast cancer referred to the Qazvin Velayat hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married; 18-53 y; treatment has finished; ability for responsive Exclusion criteria: History of physical & sexual & psychological disorders; unwillingness; presence in another consultation treatment.

Intervention groups

The Intervention group includes women with breast cancer who have sexual unsatisfaction and receive illness perception education. Control group: Just stages of follow-up after therapy, such as the experimental group send and no training not receive.

Main outcome variables

Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037903N1**

Registration date: **2018-05-03, 1397/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-03, 1397/02/13**

Update count: **0**

Registration date

2018-05-03, 1397/02/13

Registrant information

Name

Seyyedeh Maryam Abedini Gilani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3333 7267

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of illness perception educational intervention's on sexual satisfaction of women with breast cancer

Public title

Effect of illness perception on sexual satisfaction in breast cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of breast cancer Check out stages of therapeutic Married Physical& mental appropriate to

responsive

Exclusion criteria:
 History of sexual dysfunction before breast cancer
 History of psychological disorder before breast cancer
 History of any disorder before breast cancer
 The presence in an other consultative treatment
 Unwillingness

Age
 From **18 years** old to **53 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The allocation of random groups with quadruple block's in two groups(control& intervention)

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 Qazvin University of Medical Science

Street address

Golha SQ, Minoodar Ave., 22 Bahman Blvd., Qazvin Town., Velayat Hospital

City

Qazvin

Province

Qazvin

Postal code

34174

Approval date

2018-01-04, 1396/10/14

Ethics committee reference number

IR.QUMS.REC.1396.360

Health conditions studied

1

Description of health condition studied

Sexual satisfaction in breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual satisfaction measured by the Larsson questionnaire

Timepoint

Before intervention and just after intervention

Method of measurement

Larsson sexual satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention-based illness perception individual (education face-to-face) in 3 sessions 30 minutes every 3 weeks will run among the morning shift. First session: meeting of the first after its contact primary with the patient and ask questions about understanding the disease current and their implications, then content of the desired to see the will be. This session based on 5 of illness perception and effects of psychology its Foundation is. This dimensions includes; the nature of the disease (labels and symptoms) due to the beginning disease, understanding one of the disease (time inform the person of the disease), outcome and findings of the expected one of the disease, effective control and treatment and improve disease will be. For intervention illness perception exercises self-control and encouragement verbal and design of objective (like improve sexual satisfaction) feedback and evaluation of experiences successful people will be used. The second session; after reviewing the training previous patient want the uncertainties and questions possible about your disease raise. In this session interventions unique based on the need patient set will was training in order to change misunderstanding and negative patients to see the will be. At the end of the second session manual training, including detect and definition of disease, training exercises different physical (such as Kegel) and recommendations psychological plain language and understandable and based on the latest reference scientific world to see the will be. Third session; includes evaluation and closing that the previous session at this meeting to the patient information will be notified first meeting includes review training session previous. Then the patient information impact of training and experience new questions will be. Finally, problems and obstacles for any patients will be.

Category

Treatment - Other

2**Description**

Control group: Just stages of follow-up after therapy, such as the experimental group send and no training not receive.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Maryam Abedini Gilani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available