Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Orem's self-care program on the anxiety and sleep quality of women with breast cancer that reffring chemotherapy

Protocol summary

Study aim
Determining the effect of Orem's self-care program on the anxiety and sleep quality of women with breast cancer under chemotherapy

Design
In this study, 70 patients with chemotherapy-induced breast cancer who were admitted to study were available in 35 intervention groups from KhatamAnbia Hospital and 35 controls from Imam Ali Hospital in Zahedan.Apart from routine care, they will not receive special care

Settings and conduct
In this study, 70 patients with chemotherapy-induced breast cancer who were enrolled in the study were available in 35 cases of intervention group from Khatamanbia Hospital and 35 controls from Imam Ali Hospital in Zahedan. The group Controls other than routine care do not receive special care, but the intervention group falls under 3 individual training sessions

Participants/Inclusion and exclusion criteria
Start the first chemotherapy course Age over 18 years old. Able to communicate and collaborate No metastasis The absence of psychiatric illness and the use of psychosocial drugs Gain a sleep quality score of 5 or more from the Pittsburgh Sleep Quality index Anxiety score ranges from 32 to 75 Have at least reading and writing skills

Intervention groups
35 women with breast cancer who are chemotherapeutic and who have been admitted to the study are selected in an accessible manner.that The research units received three 30-minute training sessions, which take place individually and weekly before chemotherapy sessions.

Main outcome variables
Anxiety; Sleep quality

General information

Reason for update

Acronym
مصداق ندارد

IRCT registration information
IRCT registration number: **IRCT20171009036675N3**
Registration date: **2018-09-01, 1397/06/10**
Registration timing: **retrospective**

Last update: **2018-09-01, 1397/06/10**
Update count: **0**

Registration date
2018-09-01, 1397/06/10

Registrant information

Name
Fatemeh Kiani

Name of organization / entity
Faculty member, Zahedan University of Medical Scienses

Country
Iran (Islamic Republic of)

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+98 54 3329 5715

Email address
f.kiani@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-30, 1396/11/10

Expected recruitment end date
2018-04-29, 1397/02/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Orem's self-care program on the anxiety and sleep quality of women with breast cancer that reffring chemotherapy

Public title
The effect of Orem's self-care program on the anxiety and sleep quality of women with breast cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Start the first chemotherapy course Be over 18 years of age Be able to communicate and collaborate Lack of metastasis The presence of psychiatric illness and the use of neurology and psychiatry Quality score sleep rating of 5 or more From the Pittsburgh Sleep Quality Index Anxiety scores ranged from 32 to 75 At least reading and writing literacy
Exclusion criteria:
A session of absence from educational sessions Metastasis of the disease Patient death
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Dr Hesabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2018-02-05, 1396/11/16
Ethics committee reference number
IR.ZAUMS.REC1396.334

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
Anxiety
Timepoint
At the beginning of the study, 6 weeks after the intervention
Method of measurement
Spielberger Anxiety Inventory (trait and state)

2

Description
Sleep quality
Timepoint
At the beginning of the study, 6 weeks after the intervention
Method of measurement
Pittsburgh sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description
Self-care education programs, with the assistance of a female educator who has a bachelor's degree in nursing, have also seen the necessary training in this regard, based on common nursing diagnosis in the stage of screening for breast cancer patients about self-care behaviors In connection with potential and Actually problems, based on the standard protocol of patient education, during the 3 weekly 25-30 non-group sessions with an emphasis on self-care in a separate department that has appropriate training conditions before starting chemotherapy and by questioning and responding And face-to-face learning and the use of pamphlets and instructional books The scholarly content of the subject

will be approved by an oncologist

Category

Behavior

2

Description

Control group: Except for routine care and treatment, no intervention is given

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al anbia hospital

Full name of responsible person

Fatemeh Kiani

Street address

Zahedan, Jamejam Avenue

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khatamhospital_zah@yahoo.com

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2

Recruitment center

Name of recruitment center

Ali bin abe taleb hospital

Full name of responsible person

Fatemeh Kiani

Street address

Persian gulf highway.Salamat Avenue-Supplemental Hospital Ali Ibn Abi Talib

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Fkiani2011@yahoo.com

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Deputy of Research and Technology , Medical Sciences Campus , Dr. Hesabi Square, Zahedan, Iran

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Email

taheri@zaums.ac.ir

Web page address

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fatemeh Kiani

Position

Instructor،faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

faculty of nursing and midwifery, Mashahir sq

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Instructor, Faculty member

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only the original outcome data will be available

When the data will become available and for how long

After publishing the article in 2018

To whom data/document is available

all people

Under which criteria data/document could be used

Improve treatment conditions

From where data/document is obtainable

Zahedan University of Medical Sciences

What processes are involved for a request to access data/document

Applying from the university research vice president

Comments