Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of continuous care model on the side effect of chemotherapy in breast cancer patients

Protocol summary

Summary

this study aimed to determine the effect of continuous care model on the management of chemotherapy side effect like sleep disorder, fatigue, pain, nasea and body image.this study is a randomized clinical trial on patients suffering from breast cancer who reffered to shafa and golestan hospital (Ahvaz, Iran). after reviewing the characteristics of the samples in the research environment, among patients eligible for the study, selected couple samples among similar samples and each with a random of two groups will be assigned. then four days after chemotherapy session, demographic, sleep quality, fatigue, pain, nasea and body image questionnaires for patients completed by investigator and will be performed in all cases. then two months continuous care model in intervention group will be implemented that including four orientation stage, making sensitive, control and evaluation.there is no intervention in control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070613802N2**
Registration date: **2013-09-25, 1392/07/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-25, 1392/07/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapor University Of Medical Sciences

Expected recruitment start date

2013-07-30, 1392/05/08

Expected recruitment end date

2013-09-30, 1392/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continuous care model on the side effect of chemotherapy in breast cancer patients

Public title

decrease of side effect of chemotherapy by continuous care model

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Being aware of the time and place; The lack of a clear and well-known sleep disorders, pain, fatigue, nausea and vomiting in the patient's medical history is mentioned; Lack of mental and brain diseases in the patient's medical history is mentioned (Thease has the effect of variables);The absence of severe dyspnea in patients; Not receiving the sleep-disrupting drugs such as diuretic drugs, antidepressants, and amphetamines and inotropes at night; Age 65-25 years; known Persian

language; Patients who have a minimum of one and a maximum of 5 sessions of chemotherapy; Patients with stage II, III and IV disease. Exclusion criteria: Get an anesthetic and narcotic drugs during the study; Patient's unwillingness to continue participation in the study; Acute complications during the study; Get the sleep-disrupting drugs such as diuretic drugs, antidepressants, and amphetamines and inotropes at night; Need CPR during the intervention

Age
From **25 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

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
Ahvaz Jundishapor University Of Medical Sceince

Street address
Autobahn Golestan, Ahvaz

City
Ahvaz

Postal code

Approval date
2013-07-06, 1392/04/15

Ethics committee reference number
ajums.REC.1392.36

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50.0, C50

ICD-10 code description
Malignant neoplasm of Breast

Primary outcomes

1

Description
sleep quality

Timepoint
beginning of study, two months after intervention

Method of measurement
pittsburgh sleep quality Questionnaire

2

Description
pain

Timepoint
beginning of study, two months after intervention

Method of measurement
pain assessment questionnaire

3

Description
fatigue

Timepoint
beginning of study, two months after intervention

Method of measurement
fatigue summarized check list

4

Description
nasea

Timepoint
beginning of study, two months after intervention

Method of measurement
nasea assessment questionnaire

5

Description
body image

Timepoint
beginning of study, two months after intervention

Method of measurement
Body image scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Continuous Care Model (Including orientation, sensitization, monitoring and evaluation) in the intervention group and measurements related to sleep, fatigue, pain,nasea and body image

Category

Prevention

2

Description
control group: in the control group the patients will be received only routine cares
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Dr Nasrin Elahi
Street address
School Of Nursing And Midwifery, Ahvaz Jundishapor University Of Medical Sceinces
City
Ahvaz

2

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Dr Nasrin Elahi
Street address
School Of Nursing And Midwifery, Ahvaz Jundishapor University Of Medical Sceinces
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapor University Of Medical Sceinces
Full name of responsible person
Dr Mostafa Feghhi
Street address
Golestan Autobahn, Ahvaz
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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
Ahvaz Jundishapor University Of Medical Sceinces
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

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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