

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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, nausea and body image. this study is a randomized clinical trial on patients suffering from breast cancer who referred 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, nausea 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

Mahsa Imanian

Name of organization / entity

Ahvaz Jundishapor University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 79 1227 7642

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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 Science

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 Sciences

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 Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapor University Of Medical Sciences

Full name of responsible person

Dr Mostafa Fegghi

Street address

Golestan Autobahn, Ahvaz

City

Ahvaz

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 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

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Full name of responsible person

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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*