Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The effect of the implementation of the care-nursing protocol (acupuncture, nutrition and psychology) on the side effects of chemotherapy in women with breast cancer and explaining their experiences: a combined study

Protocol summary

Study aim
Determining the impact of the implementation of the care-nursing protocol (acupuncture, nutrition and psychology) on the side effects of chemotherapy in women with breast cancer and explaining their experiences: a combined study

Design
Combined research is the third wave of research methodology and is defined as a research in which the researcher collects and analyzes data with both quantitative and qualitative approaches and then integrates and discusses them during a program.

Settings and conduct
This research is a randomized clinical trial research that will be conducted at the Imam Hassan Mojtabi on female patients with breast cancer. In this study, the statistician will not know about the groups. Therefore, this study will be one-sided blind.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: participants must be between 18 and 65 years old. Does not have a history of previous surgery and also does not have a contraindication to chemotherapy. Exclusion criteria: having an underlying heart disease if EF is less than 40.

Intervention groups
The intervention group includes 1) acupuncture group, 2) psychological counseling, 3) nutritional counseling, 4) integrative medicine and 5) control group.

Main outcome variables
Nausea and vomiting; pain; fatigue; appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230616058495N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Arezoo Palizian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4252 8401

Email address
arezoo4747@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-10, 1402/08/19

Expected recruitment end date
2025-05-09, 1404/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the implementation of the care-nursing protocol (acupuncture, nutrition and psychology) on the

side effects of chemotherapy in women with breast cancer and explaining their experiences: a combined study

Public title
The effect of the implementation of the care-nursing protocol (acupuncture, nutrition and psychology) on the side effects of chemotherapy in women with breast cancer and explaining their experiences: a combined study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Participants must be between 18 and 65 years old. Confirmation of breast cancer diagnosis by pathology and non-metastatic breast cancer. The patient has undergone surgery and then underwent chemotherapy. Informed consent of the patient to accept participation in the study. The consent of the treating oncologist regarding the patient's participation in the present study. The patient does not have an underlying heart disease, does not have a history of previous surgery, and does not have any contraindications for chemotherapy.

Exclusion criteria:
Having an underlying heart disease if EF is less than 40. The patient or the treating doctor has requested to withdraw from the study. Have a cognitive disorder. Receive other parallel treatments. The organizers of the plan should diagnose the need to withdraw the patient from the study.

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
This study was conducted as a primary randomized clinical trial in 114 patients with breast cancer. The sample people who were diagnosed with breast cancer at the Imam Hassan Mojtabi Center were selected by purposive sampling and were randomly divided into the experimental group and the control group. The method of randomization is simple random method and the randomization unit is individual. In this study, the participants are randomly placed in separate groups according to the hospital's daily admission list, and the randomization tool is lottery. Random sequence is the use of random allocation. The second step, after creating a random sequence, is to hide the created sequence, and this process is called random assignment hiding.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the statistician will not know about the groups. Therefore, this study will be one-sided blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Dezful University of Medical Sciences

Street address
Dezful University of Medical Sciences, Faculty of Nursing

City
Dezfoul

Province
Khouzestan

Postal code
6461669969

Approval date
2024-01-09, 1402/10/19

Ethics committee reference number
IR.DUMS.REC.1402.013

Health conditions studied

1

Description of health condition studied
Breast cancer patients

ICD-10 code
C79.2

ICD-10 code description
Secondary malignant neoplasm of skin

Primary outcomes

1

Description
Nausea, vomiting, which score higher in the acute and delayed questionnaire

Timepoint
Before the intervention and after the intervention

Method of measurement
The CINV measurement tool is a standard questionnaire that includes 3 parts: 1. The first part is a predictive nausea and vomiting questionnaire that includes the person's previous experiences of nausea and vomiting before chemotherapy or after chemotherapy. 2. The second part of the tool is related to acute nausea and vomiting, which evaluates the patient's nausea and

vomiting during the first 24 hours after chemotherapy and 3. The third part is the questionnaire related to delayed nausea and vomiting, which It examines and evaluates the patient's nausea and vomiting in more than 24 hours since the start of chemotherapy.

2

Description

Assessing pain with the help of a visual pain scale and obtaining a score higher than 6

Timepoint

Before the intervention and after the intervention

Method of measurement

Visual scale is perhaps one of the most well-known methods forto measure mental phenomena in clinical research. This scaleIn the form of a 10 cm line, a score of zero indicates the absence of painAnd a score of ten is the maximum pain that the patient can imaginewhich was graded horizontally in this study. 2 hours afterCaesarean section, the patient was asked to rate the intensity of his pain by putting a markShow on this line. Obtaining a score of 1-3 indicates mild pain.4-7 is moderate pain and 8-10 is severe pain. Validity and reliability of thisThe tool has been validated in several studies

3

Description

Assessing the appetite status using the Short Appetite Status Questionnaire (SNAQ), a score higher than 14 indicates low appetite.

Timepoint

Before the intervention and after the intervention

Method of measurement

Short Appetite Status Questionnaire (SNAQ)Due to the sensitive conditions of the patients, the Short Appetite Questionnaire (SNAQ) of the CNAQ questionnaire will be used to evaluate the appetite. This questionnaire has 4 questions and each question has a score between 1 and 5 points. The final score of this questionnaire is between 4 and 20. Score ≤ 14 indicates low appetite and risk of significant weight loss for the next 6 months

4

Description

Fatigue score of the individual in the Multidimensional Fatigue Measurement Questionnaire (MFI)

Timepoint

Before the intervention and after the intervention

Method of measurement

Also, to evaluate and measure the fatigue of the studied patients, the standard questionnaire of Smets Multidimensional Fatigue Measurement (MFI) will be used. The multidimensional fatigue measurement questionnaire (MFI) was created by Smets (1996), which consists of 20 items and 5 subscales of general fatigue (4 questions), physical fatigue (4 questions), decreased activity (4 questions), and decreased motivation (4 questions). and mental fatigue (4 questions) is formed, which is used to measure fatigue. The MFI measures fatigue as it is felt and expressed by the individual. General fatigue related to a person's general functions during the day, physical fatigue to a physical feeling that is directly related to fatigue, mental fatigue to a decrease in cognitive skills, activity decrease to a decrease in usual and useful daily activities, and decrease in motivation to a decrease or lack. Motivation refers to starting any activityبررسی جزئیات

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nutrition intervention In the third group, intervention for people participating in the diet study and recommendations to reduce nausea and improve appetite are considered. The diet is designed in such a way that based on the current weight and taking into account the physical activity factor and the stress factor related to the chemotherapy period, the total daily energy requirement is calculated. Finally, based on the total daily energy requirement, the suitable diet of each person is adjusted. Also, in this study, in order to follow and check the diet of the patients, at the beginning of the study and at the end of the study, the patients will be reminded of their 24-hour food intake for three days about one day off and two days off, through face-to-face or telephone interviews. In order to comply more with the diet, recommendations regarding not changing the framework of the diet plan will be made by phone call every 15 days. Analysis of 24-hour food recall questionnaires will be done using Nutritionist IV (N4) nutritional software.

Category

Lifestyle

2

Description

Control group: Breast cancer patients who do not receive any intervention.

Category

N/A

3

Description

Intervention group: acupuncture In the intervention group (acupuncture receiving group), the acupuncture protocol by a respected physiotherapist (with an acupuncture certificate from the Iranian Physiotherapy Association) will be performed for the patients as follows: acupuncture points that are widely used for nausea, including PC6 (between the palmaris longus and flexor carpi radialis tendons in 2 because it is located proximal to the distal fold of the wrist) and ST36 (on the anterior lateral side of the foot, 1 because it is outside towards the crown) The anterior tibia is (38, 51). Other

acupuncture points include Ren 12, LR13, ReN6, ST25 (37), and LI4 point (between the first and second metacarpals) will be used as a general analgesic to reduce pain in this study. All these acupuncture points are manually stimulated every 10 minutes. It should be noted that single-use stainless steel acupuncture needles are used in this research design. Acupuncture treatment of patients for There will be 5 sessions such that the participants will receive acupuncture treatment at the private clinic twice on the day of the start of chemotherapy and once every 4 consecutive days.Each acupuncture session will last approximately 30 minutes. Needles of 0.25 mm diameter and 40 mm length are used for the limb and abdomen area, which are inserted at a depth of 10 to 35 mm and are manually manipulated to create a special sensation called De Qi. Treatment outcomes will include nausea and vomiting and pain, which will be evaluated before the first session and one day after the fifth session and the last day of chemotherapy. It should be noted that during the study period, participants will not undergo other acupuncture treatments or medical interventions. Using a visual pain scale, the level of perceived pain will be measured, which includes a 100 mm long line, the two ends of which indicate no pain and very severe pain, and the patient is asked to mark the average intensity of pain he felt in the past week on the line, and the validity and reliability of this pain assessment method has been evaluated in previous studies

Category

Lifestyle

4

Description

Intervention group: Psychology In the second intervention group (the group receiving psychological counseling), in the first session of the treatment, the respected clinical psychology expert will explain the treatment steps, chemotherapy side effects, drug effects and possible experienced symptoms to the clients, and then the purpose of the study will be explained and the summary of the intervention will be explained. Misconceptions about the treatment will be discussed and participants will be helped to adjust their understanding of their symptom experience, and then the individual will be given the questionnaires and explained to the individual to complete the questionnaires. And patients receive four 45-minute treatment sessions. Patients will be given a session-by-session treatment manual and an accompanying workbook to make treatment sessions more effective and efficient. The psychological treatment method that will be used to improve the psychological symptoms of breast cancer patients will be a four-session method using coping skills training methods and treatment based on acceptance and commitment.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dezful University of Medical Sciences

Full name of responsible person

Narges Majidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Research Assistant of Dezful University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dezfoul 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

Dezfoul University of Medical Sciences

Full name of responsible person

Arezoo Paliziyan

Position

PhD in psychology, mental health expert

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Position

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Latest degree

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Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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

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