Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Investigating The Effect Of Continuous Care Model On The Quality Of Life And Adherence To Treatment In Breast Cancer Patients Undergoing Chemotherapy

Protocol summary

Study aim
Determining and comparing the average score of quality of life and adherence to treatment in patients with breast cancer, before, one and three months after the implementation of the continuous care model in the intervention and control groups.

Design
The clinical trial is in the intervention and control group, which is determined by randomization by card and is performed on 62 patients.

Settings and conduct
The above project is carried out in Bahar and Kausar hospitals. The continuous care model will be taught individually to the people of the intervention group in the training class located in the hospital by the researcher.

Participants/Inclusion and exclusion criteria
Women over 18 years of age referring to Kausar hospitals in Semnan and Bahar hospitals in Shahrood, who are natives of Semnan and at least 1 year has passed since they were diagnosed with breast cancer, were considered as inclusion criteria, and people who do not want to participate in the study. And other than the stated cases, they are considered as exit criteria

Intervention groups
First, the mentioned questionnaires are completed in both groups. Then, during 6 sessions that are held three times a week with the presence of the patient and family, in the time period of 45 to 60 minutes in each session, the necessary information about breast cancer is provided to the patients of the intervention group. At the end of this stage, the training booklet will be provided to them. For 3 months, follow-up care will be carried out by telephone (once a week), repeatedly with the aim of checking the process of care continuously and continuously. At the end of the first and third month after the end of the intervention, the questionnaires will be distributed again in both groups. And it will be completed.

Main outcome variables
Adherence to treatment, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200926048842N3**
Registration date: **2023-03-21, 1402/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-21, 1402/01/01**
Update count: **0**

Registration date
2023-03-21, 1402/01/01

Registrant information

Name
Sajad Salehipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-13, 1401/12/22

Expected recruitment end date
2023-07-13, 1402/04/22

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating The Effect Of Continuous Care Model On The Quality Of Life And Adherence To Treatment In Breast Cancer Patients Undergoing Chemotherapy

Public title
The Effect Of Continuous Care Model On The Quality Of Life And Adherence To Treatment In Breast Cancer Patients Undergoing Chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Not having problems such as mental retardation, mental behavioral disorder and hearing according to the patients medical record Failure to participate in similar training courses Having minimum literacy to read and write and use of a continuing care program Having breast cancer for at least 1 year Female gender Having a mobile phone personally or in the family or having a fixed phone in the place of residence A native of Semnan province Complete consent of the patient and family to refer and follow up a phone number, a purpose of treatment and continuing training and counseling required by the researcher
Exclusion criteria:
The occurrence of severe physical complications caused by the disease Death of the patient Metastasis to other parts and organs of the body Unwillingness to continue cooperation Absence of more than two sessions
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done by available methods. Every female patient with breast cancer referring to Kausar (Semnan city) and Bahar (Shahroud city) hospitals who meet the inclusion criteria will be included in the study. Then the selected patients are randomly divided into two groups of intervention and control. In this way, first, an envelope containing the group name is prepared for the total number of people studied and randomly arranged, and with the gradual referral and selection of individuals, one of the cards will be assigned to them, respectively; Which will determine the individual group in the intervention or control group. Due to random sampling, the samples will have an equal chance of being selected in both intervention and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
After selection, in order to standardize the research conditions for both intervention and control groups, the random allocation method will be used. If the patient is in the intervention group, Continuous Care Model will be performed, but no intervention will be performed for the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
headquarters of Semnan University of Medical Sciences and Health Services-Basij Blvd
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Province
Semnan
Postal code
3514799442
Approval date
2023-03-13, 1401/12/22
Ethics committee reference number
IR.SEMUMS.REC.1401.322

Health conditions studied

1

Description of health condition studied
The Effect Of Continuous Care Model On The Quality Of Life And Adherence To Treatment In Breast Cancer Patients Undergoing Chemotherapy
ICD-10 code
C50.9
ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
The score that the patient receives from the specific quality of life questionnaire for cancer patients (EORTC QLQ-C30) ranges from 30 to 126.

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention.

Method of measurement

The score obtained by the patient from the questionnaire (EORTC QLQ-C30) which is specific for cancer patients and includes 9 subscales and mostly 30 questions in the range of 126-30. This questionnaire includes 5 functional domains, 9 symptom domains and one general domain of quality of life. This questionnaire is based on a four-point Likert scale. Not at all (score 1), a little (score 2), a bit (score 3), very much (score 4). To calculate the score of each subscale, the score of each item related to that subscale is added together. The minimum and maximum score of this questionnaire is 30 and 126. The higher the score obtained from this questionnaire, the higher the quality of life and vice versa.

2

Description

The score that a person gets from the 8-item treatment adherence questionnaire (MMAS-8) and the range of total scores is between 0 and 8.

Timepoint

It is before the start of the intervention and one month and three months after the end of the intervention.

Method of measurement

The drug treatment compliance questionnaire has 8 questions and measures drug treatment compliance. MMAS-8 drug treatment compliance questionnaire includes seven two-choice questions (with yes and no answers) and one Likert-type question, and question number 5 is scored in contrast to other questions. The range of total scores is between 0 and 8. The lower the score, the more people will adhere to medication. Scoring: In questions 1 to 7, yes answers are given a score of 1 and no answers are given a zero score. Question 5 is scored in reverse. In question 8, a score of 1, sometimes a score of 0.75, usually a score of 0.5, usually a score of 0.25, and always a score of zero is given for the answer of never.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before implementing the intervention with therapeutic communication techniques, the researcher will explain the intervention to the patient. This care technique includes 4 stages (familiarity - sensitization - control - evaluation). . 1- Familiarization stage: It is considered as the starting point and the first meeting will be held in order to justify and encourage the patient and his family and to feel the necessity of the follow-up process of the patients within 30-45 minutes with the presence of the patient and his family. At this stage, the researcher and the patient and his family will get to know each other. He will express his expectations and make recommendations on the necessity of continuing and even if possible not interrupting the therapeutic care relationship between the parties until the end of the appointed time. The actions of this stage of interventions include: introducing the researcher to the patient and family, completing the demographic information questionnaire and quality of life and compliance with the patient's treatment by the researcher, determining and agreeing on the time of the patient's visit to the relevant medical centers (this time is based on the wishes of the patient and the family) will be determined) and the time of phone calls and how to communicate (according to the patient and family) will also be discussed. A follow-up will be held in the implementation of the research (chemotherapy department of Kausar and Bahar hospitals) face-to-face and with the coordination of the clinic officials, the patient and their family for 45-60 minutes and according to the level of tolerance. Also, during the individual interaction between the researcher and the patient, preliminary questions will be asked to identify their level of awareness (about breast cancer and its complications, self-care behaviors and treatment recommendations). The content of the educational program will be adjusted according to the latest articles and consultation with expert professors. The number of sessions for each sample will depend on the patient's level of awareness and knowledge. On average, 6 sessions and three times a week with the presence of the patient and family based on the time set in the familiarization phase, according to the request of the patient and family, will be held face to face and individually in the relevant department, and at the end of the sessions, an educational platform including an educational booklet will be provided. The patient and family will be placed. 3- Control stage: The purpose of this stage is to continue the process of continuous care implementation. There is no doubt that the most appropriate programs without control and follow-up will be forgotten with the passage of time or lose their desired effect. Therefore, considering that the model used is called continuous care, the researcher communicates with the patient and family once a week through a telephone call (the day, week and time of the call are coordinated with the patient and family during the sensitization phase) and through the checklist. Care and education ensures that the interventions are carried out, in addition to that, he asks questions from the patient in relation to the training given to ensure that he has learned the content of the training sessions. If the patient had a problem in doing and learning the given training, a reminder training session will be given to him again. Also, the researcher made an appointment with the patients and their families to call the researcher's mobile phone and solve their problem if they face any question or problem at home. For 3 months, follow-up care by phone (once a week) will be carried out repeatedly with the aim of checking the care process (through the care checklist and asking questions). 4- Evaluation stage: The fourth and final step of the model. Evaluation is presented as the final stage of the continuous care model, but it is considered and ongoing

in all stages of the study. In this study, the evaluation will be done in two stages. The first stage after one month and the second stage after three months of the implementation of the model, the researcher coordinates the time and place during the phone call with the patient and the quality of life and treatment compliance questionnaires are completed again. The duration of the intervention is 4 months.

Category
Rehabilitation

2

Description
Control group: If the patient is assigned to the control group, first, to start the pre-test, the demographic information questionnaire, the standard questionnaire of quality of life and compliance with the treatment was completed by the researcher, and this group received no intervention except for routine care that is applicable in medical centers for patients with Breast cancer, including blood samples and chemotherapy, etc. are not received. Then the test will be completed simultaneously with the intervention group during a phone call by the researcher, the time of which is based on the wishes of the patient and his family, one and three months later. At the end of the intervention, the educational booklet containing the educational materials will be provided to the patient and the family of the control group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan University of Medical Sciences, Kausar Hospital
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Phone
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Sajad Salehipour
Position
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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