Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The impact of remote human caring on the comfort of breast cancer patients undergoing radiation therapy: a clinical trial based on «Watson» and «Kolkaba» theoretical frameworks

Protocol summary

Study aim

Determining the Impact of Human Remote Care on the Comfort of Breast Cancer Patients Undergoing Radiation Therapy Based on «Watson» and «Kolcaba» Theories Determining the mean comfort score of breast cancer patients undergoing radiotherapy in comparison and intervention groups, before and after remote human care Determining the difference between the mean comfort scores of breast cancer patients undergoing radiotherapy in comparison and intervention groups, before and after the implementation of remote human care

Design

Clinical trial with control and intervention group, factorial, without blinding, randomized, one phase on 58 patients. For randomization, 4 random blocks were used using a random number table.

Settings and conduct

Khorramabad Rain Radiotherapy Center, remote human care in the form of at least 7 absentee sessions and two face-to-face sessions

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definite onset of primary breast cancer Stages 2 and 3 of the disease Chemotherapy and surgery before radiation therapy Stability of the patient's physical and mental Age between 20 to 60 years Criteria for not entering: Lack of patient awareness of breast cancer diagnosis Exacerbation or spread of the disease to other parts of the body Primary cancer in other areas Existence of crises affecting life during the last 6 months or during illness The patient's unwillingness to continue participating in the study Change of center and treatment process Death

Intervention groups

Both groups received comparison and routine care intervention. However, in the intervention group, the effect of remote human care on the comfort of breast cancer patients undergoing radiation therapy was evaluated in the form of at least 7 absentee sessions and two face-to-face sessions of care.

Main outcome variables

comfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210118050076N1**
Registration date: **2022-01-30, 1400/11/10**
Registration timing: **retrospective**

Last update: **2022-01-30, 1400/11/10**
Update count: **0**

Registration date

2022-01-30, 1400/11/10

Registrant information

Name

Zeinab yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3330 3370

Email address

yousefi1598@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-29, 1399/11/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

2021-02-03, 1399/11/15

Actual recruitment end date

2021-10-22, 1400/07/30

Trial completion date

2021-10-22, 1400/07/30

Scientific title

The impact of remote human caring on the comfort of breast cancer patients undergoing radiation therapy: a clinical trial based on «Watson» and «Kolkaba» theoretical frameworks

Public title

The impact of remote human caring on the comfort of breast cancer patients undergoing radiation therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definite onset of primary breast cancer by inclusion in a medical record by a specialist Stages 2 and 3 of the disease Chemotherapy and surgery before radiation therapy Candidate for radiation therapy for the first time Number of radiation therapy sessions in total 28 to 35 sessions Six million electron volts radiation therapy with a compact six-megavolt device manufactured by the British company "Elekta" Breast surgery in the form of complete breast removal or breast retention surgery Stability of the patient's physical, mental and psychological condition, according to the patient and approved by the doctor Age between 20 to 60 years Not participating in similar studies or research Ability to communicate verbally in Persian or a comprehensible local dialect

Exclusion criteria:

Patient's lack of knowledge about breast cancer diagnosis Exacerbation or spread of the disease to other parts of the body Primary cancer in other areas Existence of crises affecting life during the last 6 months or during illness (death of a loved one, divorce, etc.) The patient's unwillingness to continue participating in the study

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were divided into two groups of intervention and comparison using stratified random blocking method. The samples were matched in two groups based on the "disease stage" (stages 2 and 3) and this variable was considered as a class in random allocation. Within each floor, the method of 4 random blocks was used to assign patients to two groups A (intervention) and group B (comparison). To do this, a list of blocks was first written and the numbers assigned to them (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)). Then, using a random number table, the numbers between one to 6 were randomly selected and finally the treatment allocation list was formed based on a sequence of letters A and B.

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

Ethics committee of Lorestan University of Medical Sciences

Street address

Esmatollah Yousefi House, Baharestan 9, Baharestan Blvd, Khorramabad, Lorestan

City

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Province

Lorestan

Postal code

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Approval date

2021-01-18, 1399/10/29

Ethics committee reference number

IR.LUMS.REC.1399.267

Health conditions studied

1

Description of health condition studied

human caring, remote care, comfort, breast cancer, radiation therapy, Jean Watson's Theory, Katharine Kolcaba's Theory

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Comfort score in radiotherapy comfort questionnaire or percentage of people whose comfort questionnaire score

is above 4

Timepoint

Measure comfort 2 to 3 weeks before the start of radiation therapy and at the end of radiation therapy

Method of measurement

How to measure the comfort variable is the "Radiation Therapy Comfort Questionnaire".

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Human care was performed in the form of ten Watson romantic care processes during 2 face-to-face sessions during radiation therapy and at least 7 absentee sessions from 2 to 3 weeks before the start of radiation therapy until the end of radiation therapy. The duration of the sessions was free and according to the patient's needs.

Category

Treatment - Other

2

Description

Control group: For this group, only routine care was provided by the radiation therapy center. And was not intervened by the researcher during radiation therapy.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baran radiationtherapy center

Full name of responsible person

Zeinab Yousefi

Street address

Baran radiation therapy center, Basij 3 Street, Basij Alley, Khorramabad, Lorestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Zeinab Yousefi

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because the study of participants' personal data is not one of the goals of the study. And only the comfort score of people is measured.
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 information about the main outcome can be shared.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
The use of data is permissible only descriptively and with the permission of the principal investigator.
From where data/document is obtainable
Esmatollah Yousefi House, Baharestan 9, Baharestan Blvrd, Khorramabad, Lorestan. Name of researcher Zeinab Yousefi yousefi1598@gmail.com First priority 09168586532 Second priority
What processes are involved for a request to access data/document
About a month after receiving the email, their request will be answered.
Comments