Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the impact of a comprehensive nurse support program on death anxiety and compliance with hormone therapy in women with breast cancer

Protocol summary

Study aim
Investigating the impact of a comprehensive nurse support program on death anxiety and compliance with hormone therapy in women with breast cancer

Design
This randomized clinical trial study with parallel groups will be conducted on 70 patients with breast cancer referring to the breast clinic of Shahid Motahari Hospital of Shiraz University of Medical Sciences. Patients participating in the study will be divided into two groups using a table of random numbers.

Settings and conduct
Patients with breast cancer referred to the breast clinic of Shahid Motahari Hospital of Shiraz University of Medical Sciences will be included in the study. Patients participating in the study are randomly assigned to two groups using a random number table.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients referred to the breast clinic of Shahid Motahari Clinic of Shiraz University of Medical Sciences in the past 5 years who have breast cancer and have completed the course of treatment (surgery-chemotherapy-radiotherapy) and at least 1 year has passed since the start of hormone therapy be and express consent to participate in the study.Exclusion criteria: It includes patients who have a history of participating in similar courses and do not respond to follow-up calls.

Intervention groups
Intervention group 6 sessions (small group of 5 to 7 people) face-to-face for 45-60 minutes (in breast clinic training classes) and non-face-to-face (the same program online and of course offline in Eta, Soroush and Instagram) comprehensive nurse support program receives. Control group: will receive their usual care (including regular medical visits and periodical follow-ups).

Main outcome variables
Death anxiety and compliance with hormone therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240120060738N1**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date
2024-01-28, 1402/11/08

Registrant information

Name
Mohsen Hojat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5426 0608

Email address
mohsenhojat.mh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-09, 1402/11/20

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of a comprehensive nurse support program on death anxiety and compliance with hormone therapy in women with breast cancer

Public title

Investigating the impact of a comprehensive nurse support program on death anxiety and compliance with hormone therapy in women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with primary breast cancer Completing the course of surgery, chemotherapy and radiotherapy be under hormone therapy (any hormone medication) for at least one year In the last six months, she did not undergo any intervention regarding medication compliance or anxiety reduction Access to a mobile phone and the ability to use it Ability to perform physical activity

Exclusion criteria:

Failure to respond to follow-up calls or unwillingness to continue studying Discontinuation of medication due to side effects Recurrence of the disease in one of the organs Severe crisis in life

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Generation of random numbers from the table of random numbers: Considering that 70 patients are needed in this study, a number was randomly selected from the table of random numbers and the digit on the right side of it was taken into account. If this digit was an even number, the patient was assigned to intervention group A. And if it was an individual, it will be assigned to control group B. For example, if the number 63 is selected in the table of random numbers, since 63 is an odd number, the first sample will be assigned to the control group. Allocation of people into two groups is determined.

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 Jahrom University of Medical Sciences

Street address

Jahrom University of Medical Sciences , the end of Ostad Motahari Boulevard

City

Jahram

Province

Fars

Postal code

7414846199

Approval date

2024-01-13, 1402/10/23

Ethics committee reference number

IR.JUMS.REC.1402.108

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Adherence to drug treatment

Timepoint

Before and after the intervention

Method of measurement

Questionnaire of compliance with Moriski's drug treatment

2

Description

anxiety

Timepoint

Before and after the intervention

Method of measurement

Templer Death Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intervention group 6 sessions (small group of 5 to 7 people) face-to-face for 45 to 60 minutes (in the training classes of the Breast Clinic) and non-face-to-face (the same program online and of course offline in Ita, Soroush and Instagram) program Jame receives support from the nurse.
Category
Other

2

Description
Control group: will receive their usual care (including regular medical visits and periodical follow-ups).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Breast Clinic, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mani Ramzi
Street address
Motahari Clinic, next to Namazi Hospital, Namazi Square
City
Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Solh joo Cavus
Street address
Jahrom University of Medical Sciences , the end of Ostad Motahari Boulevard,Jahrom
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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
Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
Mohsen Hojjat
Position
science Committee
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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