

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 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

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Fax

Email

pshora2014@gmail.com

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

City

Jahram

Province

Fars

Postal code

7414846199

Phone

+98 71 5433 6085

Email

pshora2014@gmail.com

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

Street address

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

City

Jahram

Province

Fars

Postal code

7414846199

Phone

+98 71 5433 6085

Email

mohsenhojjat.mh@gmail.com

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City

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Province

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Postal code

7414846199

Phone

+98 71 5433 6085

Email

mohsenhojat.mh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Saeede Raisi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Jahrom University of Medical Sciences , the end of

Ostad Motahari Boulevard,Jahrom

City

Jahram

Province

Fars

Postal code

7414846199

Phone

0715433608

Email

saedehraiese@gmail.com

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