

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effectiveness of cognitive-behavioral stress management on fear of disease progression in women with breast cancer

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral stress management on fear of disease progression in women with breast cancer

Design

Clinical trial with control group, randomized, on 54 patients Random allocation using block design method (4 blocks) in two groups of intervention and control

Settings and conduct

The statistical population of women with breast cancer referred to the accelerator ward of Golestan Hospital in ahvaz. 54 women with a high fear of disease progression score who meet the inclusion criteria are selected. And fall into two groups of intervention (27) and control (27). Behavioral cognitive stress management training is performed on the intervention group during 10 weekly sessions. The Fear of Progress of Hersbach's disease questionnaire is completed in two stages: pre-test and post-test.

Participants/Inclusion and exclusion criteria

Having a cancer diagnosis by a specialist Score above 85 of the Fear of Disease Progression Questionnaire Be literate Willingness to participate in research Written consent to participate in the research Reluctance to continue participating in research Incomplete completion of the questionnaire Having medical disorders at the same time Under psychotherapy simultaneously Having serious illnesses or cancer Having any signs of metastatic disease

Intervention groups

cognitive-behavioral therapy in 10 sessions of 90 minutes, one day a week, for the interventional group in the study . no training and advice is given in the control group

Main outcome variables

fear of disease progression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220122053798N1**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Fatemeh zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3273 8397

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral stress management on fear of disease progression in women with breast cancer

Public title

The effectiveness of cognitive-behavioral stress management on fear of breast cancer progression

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a cancer diagnosis by a specialist Score above 85 of the Fear of Disease Progression Questionnaire Be literate Willingness to participate in research Written consent to participate in the research

Exclusion criteria:

Reluctance to continue participating in research Incomplete completion of the questionnaire Having medical disorders at the same time Under psychotherapy simultaneously Having serious illnesses or cancer Having any signs of metastatic disease

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 54

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning individuals in control and test groups is random and quadruple blocks (using the table related to random permutations). After determining the volume of blocks, which in this study is 4, a list of blocks is prepared and a number is assigned to them. Then random numbers between 1 and 6 will be selected. (4)AABB(1), ABAB(2), ABBA(3), BBAA BABA(5), BAAB(6) There will be a total of 24 opportunities for random selection.

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 Ahvaz University of Medical Sciences

Street address

Ahvaz University of Medical sciences, Golestan Blvd, Ahvaz

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ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2022-01-15, 1400/10/25

Ethics committee reference number

IR.AJUMS.REC.1400.611

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**

Fear of disease progression score in the fear of disease progression questionnaire of Hersbach

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

fear of disease progression questionnaire of Hersbach

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention group (27 people), group stress management training (cognitive-behavioral) is done during 10 weekly sessions. Each 90-minute training session will include 45 minutes of training and 45 minutes of practical work. Based on Anthony, Ironson, Schneiderman's training package. Behaviorally cognitively stress management is a multifaceted approach in which techniques such as relaxation, diaphragmatic breathing, meditation, detection of negative automatic thoughts, cognitive distortions and its reconstruction by replacing logical thoughts, effective coping training, management Anger and expression are taught to people. Hersbach Fear of

disease progression questionnaire is completed in two stages: pre-test and post-test

Category

Behavior

2**Description**

Control group:No psychological training is applied for the control group of 27 people, but the questionnaire is administered in two stages of pre-test and post-test and together with the intervention group for the control group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Fatemeh Zare

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Ahvaz, Golestan Blvd., Farvardin St., Golestan Hospital

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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**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Zare

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Lecturer In Midwifery Department

Latest degree

Master

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Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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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