

# 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

zare.fatemeh7575@gmail.com

##### 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

**City**

ahvaz

**Province**

Khuzestan

**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**

Ahvaz 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**

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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Khadige Hekmat

**Position**

Lecturer In Midwifery Department

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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shiraz

**Province**

Fars

**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