Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 71 3273 8397

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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 committeee of Ahvaz University of Medical Sciences
Street address
Ahvaz University of Medical sciences, Golestan Blvd,Ahvaz
City
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

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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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Midwifery

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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