

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of short-term solution-oriented therapy (SFBT) on psychological distress and somatization disorder in patients with breast cancer.

Protocol summary

Study aim

The purpose of this research is to determine the effectiveness of short-term solution-oriented therapy (SFBT) on reducing psychological distress and somatization disorder among breast cancer patients.

Design

The current research is conducted as a clinical trial with a control group, a blind strain, randomized using the site randomization.com on 30 patients.

Settings and conduct

The location of the research is besat Clinic in Rasht, the research method is a clinical trial with a control group, the intervention group receives 8 sessions of solution-oriented therapy, but the intervention group does not receive therapy. The research is one-sided blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: positive screening for psychological distress and moderate or greater somatization disorder; female gender; Being in the age range of 40 to 55 years; Willingness to participate in research Non-entry conditions: drug and alcohol abuse; Receiving all kinds of drug and psychological treatments in the last six months

Intervention groups

At the beginning of the research, the members of both experimental and control groups will be administered a pre-test questionnaire. After that, the members of the experimental group undergo intensive solution-oriented psychotherapy for 8 sessions of 90 minutes, which are performed twice a week. At the time of the intervention, the control group was put on the waiting list and did not receive any intervention. After the completion of the intervention sessions, a post-test will be conducted for both groups.

Main outcome variables

depression, anxiety, stress score in DASS-21 psychological distress questionnaire; PGQ-15 somatization questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230510058149N1**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **0**

Registration date

2023-06-06, 1402/03/16

Registrant information

Name

Zahra Akhlaghi navideh

Name of organization / entity

Mohaghegh Ardabili University

Country

Iran (Islamic Republic of)

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+98 13 1111 1111

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zahraakhlaghi151@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of short-term solution-oriented therapy (SFBT) on psychological distress and somatization disorder in patients with breast cancer.

Public title

Effect of SFBT on psychological distress and somatization disorder in patients with breast cancer.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All women with breast cancer referred to Rasht oncology centers Moderate or greater positive screening for psychological distress and somatization disorder

Exclusion criteria:

Abuse of drugs and alcohol Receiving all kinds of drug and psychological treatments in the last six months

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The site <http://www.randomization.com> is used to divide people into two groups randomly. Due to conducting the study on two groups, the first generation random allocation method is used. The work process is that first, each of the people included in the study is assigned a number from 1 to 30. In the online software, two blocks A and B are considered active for intervention and control groups, respectively. Then the software randomly divides the numbers from 1 to 30 between two blocks of 15 people, and in this way, 15 people belong to the intervention group and 15 people belong to the active control group. For cancellation, one person outside the research team of the intervention and active control group will be randomly divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single-blind study in which the participants in the study are blind. It should be noted that all participants are present in this study with their personal consent and knowledge of participating in the research, and this one-way blinding is only due to the reduction of error in the measurement of the outcome in the intervention and control groups.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه محقق اردبیلی

Street address

University Street, Mohaghegh Ardabili University

City

Ardabil

Province

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Postal code

5619913131

Approval date

2023-05-09, 1402/02/19

Ethics committee reference number

IR.UMA.REC.1402.002

Health conditions studied

1

Description of health condition studied

Psychological distress and somatization disorder in breast cancer patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score of depression, anxiety, stress in psychological distress questionnaire DASS-21; PGQ-15 somatization questionnaire score

Timepoint

At the beginning of the study, before the start of the intervention and after the completion of the 8-session intervention period

Method of measurement

psychological distress questionnaire DASS-21; PHQ-15 somatization questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receives short-term solution-

focused therapy (SFBT). This treatment is performed in a brief and short-term manner on subjects who are patients with breast cancer. This intervention is non-diagnostic and focuses on the patient's strengths and internal resources.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Clinic

Full name of responsible person

Fateme Najati far

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mohaghegh Ardabili University

Full name of responsible person

Mahdi Moini Kia

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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

Mohaghegh Ardabili University

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

Mohaghegh Ardabili University

Full name of responsible person

Zahra Akhlaghi Navideh

Position

Student

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

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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