

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effectiveness of short-term solution-oriented therapy (SBFT ) 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 (SBFT) 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)

##### Phone

+98 13 1111 1111

##### Email address

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

Ardabil

##### 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

**Street address**

Next to Tawaf Alley., Inghelab St., Rasht

**City**

Rasht

**Province**

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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

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Position**

Student

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

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دانشجو

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Bachelor

**Other areas of specialty/work**

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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