

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The effect of religious/spiritual psychotherapy on improvement of illness perception, inner strength promotion and serum level of CA15-3 among women patients with breast cancer

#### Protocol summary

##### Summary

The main objective of this study is to investigate the effect of religious/spiritual psychotherapy on improvement of illness perception, inner strength promotion and serum level of CA15-3 among women patients with breast cancer. Other objectives of this study include investigation of the effect of spiritual-religious psychotherapy on spiritual health, anxiety, and stress among these patients with social protection control. The samples include 45 female patients with non-metastatic breast cancer, who are randomly divided into three 15-member groups, namely intervention, placebo, and control using drawing a lot and Without blinding . Inclusion criteria : female; pathology report of malignant neoplasm of breast; breast surgery; Completion of chemotherapy and radiation therapy; Having informed consent exclusion criteria: age under 25 or over 60; Metastatic disease; Having serious or chronic medical conditions. The intervention group undergoes 10 individual spiritual-religious psychotherapy sessions including God consciousness, prayer, endeavor, kindness and forgiveness, hope, Islamic meaning and illness perception, and the placebo group undergoes a few neutral individual consultation sessions, and the control group receives no intervention. Illness perception, inner strength, spiritual health , depression and anxiety are measured by a questionnaire and serum tumor marker CA 15-3 level is measured using a blood test in all three stages (before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016090529715N1**

Registration date: **2017-08-11, 1396/05/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-11, 1396/05/20

##### Registrant information

###### Name

Safoora Davari

###### Name of organization / entity

Semnan University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3362 3300

###### Email address

sdavari@semnan.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

researcher

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of religious/spiritual psychotherapy on improvement of illness perception, inner strength

promotion and serum level of CA15-3 among women patients with breast cancer

#### Public title

The effect of religious/spiritual psychotherapy on the Physical and Psychological health among women patients with breast cancer

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: female; pathology report of malignant neoplasm of breast; breast surgery; Completion of chemotherapy and radiation therapy; Having informed consent exclusion criteria: age under 25 or over 60; Metastatic disease; Having serious or chronic medical conditions

#### Age

From **25 years** old to **60 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **45**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

##### Street address

Shahid Mohammadi Hospital east side, Vice Chancellor for Research & Technology, Jomhoori-e Eslami Boulevar, Bandar Abbas

##### City

Bandar Abbas

##### Postal code

7919915519

#### Approval date

2017-05-15, 1396/02/25

#### Ethics committee reference number

HUMS.REC.1396.23

## Health conditions studied

### 1

#### Description of health condition studied

Breast cancer

#### ICD-10 code

C50

#### ICD-10 code description

Malignant neoplasm of breast

### 2

#### Description of health condition studied

Depression

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

### 3

#### Description of health condition studied

anxiety

#### ICD-10 code

F41

#### ICD-10 code description

Other anxiety disorders

## Primary outcomes

### 1

#### Description

illness perception

#### Timepoint

Before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period

#### Method of measurement

illness perception questionnaire

### 2

#### Description

inner strength

#### Timepoint

Before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period

#### Method of measurement

inner strength questionnaire

### 3

#### Description

serum level of CA 15-3 tumor marker

#### Timepoint

Before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period

#### Method of measurement

blood test

## Secondary outcomes

### 1

#### Description

Anxiety and depression

#### Timepoint

Before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period

#### Method of measurement

dss questionnaire

### 2

#### Description

spiritual health

#### Timepoint

Before intervention, Immediately after the end of the intervention, and Four months after the end of the intervention in the follow-up period

#### Method of measurement

spiritual health questionnaire

## Intervention groups

### 1

#### Description

intervention group: undergoes ten 90-minute sessions of individual spiritual-religious psychotherapy including God consciousness, prayer, endeavor, kindness and forgiveness, hope, Islamic meaning and illness perception

#### Category

Lifestyle

### 2

#### Description

placebo group: undergoes a few neutral individual consultation sessions

#### Category

Lifestyle

### 3

#### Description

Control group: routine care

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Omid Center For Radiotherapy Chemotherapy

##### Full name of responsible person

Najme Abvassani

##### Street address

Omid Center For Radiotherapy Chemotherapy,  
Jomhoori-e Eslami Boulevar, Bandar Abbas

##### City

Bandar Abbas

### 2

#### Recruitment center

##### Name of recruitment center

Dr.Mohammad Reza Evazy Clinic

##### Full name of responsible person

Zahra Khalafai

##### Street address

Building of Physicians of Noor, Moradi Street, Bandar  
Abbas

##### City

Bandar Abbas

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology of  
Semnan University

##### Full name of responsible person

Dr.Ali Haghighi Asl

##### Street address

Central Administration of Semnan University, Campus  
1, Semnan, I. R. of Iran

##### City

Semnan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research and Technology of Semnan  
University

#### Proportion provided by this source

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

### 2

#### Sponsor

##### Name of organization / entity

researcher

##### Full name of responsible person

Safoora Davari

##### Street address

Faculty of Psychology & Education Mehdishahr  
Semnan University , Darband, Mehdishahr, Semnan,

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**City**

Mehdishahr

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

researcher

**Proportion provided by this source**

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

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Safoora Davari

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**Position**

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**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty