

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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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,
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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

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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

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Faculty of Psychology & Education Mehdishahr
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City

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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

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

Name of organization / entity

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Safoora Davari

Position

PhD student of psychology

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