Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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, 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
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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
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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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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