Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of spiritual religious psychotherapy on the self-concept and the sense of coherence in cancer Patients: Clinical trial

Protocol summary

Summary

Objective: Is to study the effect of spiritual religious psychotherapy on the self-concept and the sense of coherence in cancer patients and if effective, be used in nursing cares for these clients. Design: This study is a randomized controlled clinical trial which will be done on one hundred cancer patients at Bushehr city. By using permuted block randomization, using blocks of four, Patients will be divided into two groups of fifty case and control and then; Patients at case group will be divided into five groups of ten. Setting and conduct: The intervention and educational package are based on Richards and Bergin spiritual psychotherapy model on the basis of Islam; which will be provided at eight sessions of one hour and half; by a seminary expert. In the control group only doctor's recommendations will be implemented and a pamphlet about spirituality and its concepts will be given to them. Inclusion criteria: Cancer diagnosed by oncology doctor; suffering from the disease for more than three months; capable of taking part in classes; believe in Islam; awareness of disease; have done at least once chemotherapy; the least ability to read and write; and age range of 18 to 60. Exclusion criteria: Death while running the study; psychological diseases (for example: Schizophrenia, Bipolar disorder and other); lack of voluntary consent to participate in research or withdrawal from continued participation; and irregular participation in the classes. Main outcome measures: Changes in self-concept and sense of coherence; which will be assessed by using Beck's self-concept and Antonovsky's sense of coherence questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022322466N13**

Registration date: **2017-05-22, 1396/03/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-22, 1396/03/01

Registrant information

Name

Shahnaz Pouladi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 374 0061

Email address

sh.pooladi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Bushehr University of medical sciences

Expected recruitment start date

2017-04-08, 1396/01/19

Expected recruitment end date

2017-10-11, 1396/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual religious psychotherapy on the self-concept and the sense of coherence in cancer Patients: Clinical trial

Public title
The effect of spiritual religious psychotherapy on the self-concept and the sense of coherence in cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Cancer diagnosed by oncology doctor; suffering from the disease for more than three months; capable of taking part in classes; believe in Islam; being aware of the disease; done a course of chemotherapy; having the least ability to read and write; and ages 18 to 60 years. Exclusion criteria: Death while running the study; psychological diseases (for example: Schizophrenia, Bipolar disorder and other); lack of voluntary consent to participate in research or withdrawal from continued participation; and irregular participation in classes.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Permuted block randomization, using blocks of four, will be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bushehr University of medical sciences
Street address
School of nursing and midwifery; Bushehr University of medical sciences; Rishehr avenue; Sabzabad avenue; Bushehr
City
Bushehr
Postal code
7518759577
Approval date
2017-02-20, 1395/12/02
Ethics committee reference number
bpums.rec.1395.170

Health conditions studied

1

Description of health condition studied
Cancer
ICD-10 code
C80.9
ICD-10 code description
Malignant neoplasm, unspecified

Primary outcomes

1

Description
Self-concept
Timepoint
Before the intervention and after finishing eight educational sessions for each individual
Method of measurement
Beck's self-concept questionnaire

Secondary outcomes

1

Description
Sense of coherence
Timepoint
Before the intervention and after finishing eight educational sessions for each individual
Method of measurement
Antonovsky's sense of coherence questionnaire

Intervention groups

1

Description
In the case group, the intervention and educational package is based on Richards and Bergin's spiritual religious psychotherapy model, on the basis of Islam. This model consists of six steps, which are: First step (Multicultural spiritual sensitivity); second step (establish a spiritually open and safe relationship); third step (attend to potential ethical concerns); fourth step (conducting a religious and spiritual assessment); fifth step (set appropriate spiritual therapy goals); and the sixth step (appropriately implement spiritual interventions). Interventions which will be used are: Prayer and benediction; recitation; the rites and rituals; forgiveness; repentance; faith and trust in God; patience; and using the participants' religious supporting system. In writing the educational package some parts of Leila Hosseini's method in an article titled "The effectiveness of spiritual intervention on dopamine and serotonin

receptors gene expression in women with breast cancer" done at 2015-2016 has been used. The intervention will be done in eight sessions of one hour and half; and twice a weak (because if prolonged there is likelihood of sample loss); by a seminary expert and in the form of groups of 10. In order to approve and present the subjects an expert in psychology and a seminary expert, will be invited. Activities of each session are: 1- Checking the exercises of the previous session; 2- Giving feedback to the participants; 3- Giving a summary of the previous session, in order to make continuity between the subjects discussed and to mentally prepare the participants for a new subject; 4- Presenting each sessions' subject and exercises; 5- Giving home works for the next session; and 6-Summing up the session topic. During the intervention, the case group will not be prohibited from their medical interventions.

Category

Behavior

2

Description

In the control group only the oncologist's recommendations will run as routine and at the end of sampling; in order to comply with ethical principles, a pamphlet about spirituality and its concepts will be given to them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Blood and oncology unit of Persian Gulf Martyrs' hospital of Bushehr

Full name of responsible person

Saghar sakhamanesh, nursing student of master degree

Street address

Persian Gulf Martyrs' hospital of Bushehr, Taleghani avenue, Azadi square, Bushehr

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Bushehr University of medical sciences

Full name of responsible person

Doctor Afshin Ostovar

Street address

Vice chancellor for research, Bushehr University of medical sciences, Rishehr avenue, Sabzabad avenue, Bushehr

City

Bushehr

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, Bushehr University of medical sciences

Proportion provided by this source

100

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

Bushehr University of medical sciences

Full name of responsible person

Doctor Shahnaz Pooladi

Position

Nursing Ph.D

Other areas of specialty/work

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School of nursing and midwifery, Bushehr University of medical sciences, Rishehr avenue, Sabzabad avenue, Bushehr

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Email
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Web page address

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