

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effectiveness of Group Spiritual Therapy on Health Status ,Coping strategies & Serum T Lymphocyt Immune System in Women With Breast Cancer.

#### Protocol summary

##### Study aim

study the effect of Spiritual Therapy on Health Status ,Coping strategies & Serum T Lymphocytes in Breast Cancer.

##### Design

Clinical trial with case control groups .the subjects were selected and replaced with the specifies criteria in tow case control groups (30 patients ) ,then the experimental group underwent 12 sessions, 90 minute of spirituality therapy.

##### Settings and conduct

Study in Bushehr city ,before and after intervention , to investigate the levels of T cells & markers, 5 cc blood was obtained from both groups. the demographic, clinical, data , also the Ellison spiritual well-being, WHO Individual Health Status and Lazarus & Foulkman coping strategy questionnaires.were collected.

##### Participants/Inclusion and exclusion criteria

Age 30 to 59 ; at clinical stage I , II , or III ;no metastasis ;at least 8 months after diagnosis .;having literacy ; consent the study ; no history of :psychotropic drug , alcohol use or smoked during the 3 months before,and other neurosis or psychosis like DSM-V , no history of active cancers during 10 years and other chronic diseases. and psycho- spiritual education..

##### Intervention groups

only Experimental group underwent sessions of spirituality therapy and the control group would be recived any usual care from their doctor made to order with any training.. recital sessions are: 1-acquaint to another 2- introspection 3- fear & anxiety 4-dateless 5-rancor & devotion 6-meditation 7- relaxation 8- anger 9- remission 10-self regulating 11- self awareness,acceptance 12 - end of session.

##### Main outcome variables

Health Status ,Coping strategies & Serum T Lymphocytes .

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190508043520N1**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **retrospective**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

##### Registration date

2019-09-02, 1398/06/11

##### Registrant information

##### Name

Zinab Hossainy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3332 9198

##### Email address

hossaini@outlook.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-11, 1398/02/21

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effectiveness of Group Spiritual Therapy on Health Status ,Coping strategies & SerumT Lymphocyt Immune System in Women With Breast Cancer.

**Public title**

The effectiveness of Group Spiritual Therapy on Health Status ,Coping strategies & SerumT Lymphocyt Immune System in Women With Breast Cancer.

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

breast cancer diagnosis from oncologist. being at clinical stage I , II , or III no metastatic lesion. Age between 30 to 59 years At least 8 months after diagnosis and termination of acute treatment period such as surgery, chemotherapy, and radiation therapy which are effective in psycho-spiritual aspect and may have caused some bias in the study. having literacy having letter of satisfaction no history of psychotropic drug use, and no history of alcohol used or smoked during the 3 months before the study. no history of other neurosis or psychosis before diagnosis , such as depression and schizophrenia.. no history of other chronic diseases. no history of other cancer during 10 years. no history of psycho- spiritual education .

**Exclusion criteria:**

dissatisfaction to participate in research any disability to be present in sessions intervention those with history of cognitive disorder,confusion or cerebral injury.

**Age**

From **30 years** old to **59 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This was a quasi-experimental study, procedure by a pre-post-test approach with case control groups and the subjects were selected and replaced in two groups of the case (30 patients) and control (30 patients )with the specifies criteria . Randomize Allocation ,The Permuted block randomization method in clinical trial designed to randomize subjects into groups that result in equal sample sizes. Randomization ensures that each patient has an equal chance to settle in each groups (experimental or control groups). Sixty breast cancer women (30 to 59 years) refer for treatment to Shafa Clinic in Bushehr selected and placed in two groups(case-control),then the experimental group underwent twelve 90 minute sessions of spirituality therapy intervention.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features**

This was a quasi-experimental study, procedure by a pre- , post-test approach with case control groups and the subjects were selected with the specifies criteria and replaced in two groups of the case (30 patients) and control (30 patients)..60 patients with breast cancer refer for treatment to Shafa Clinic in Bushehr were selected and randomly divided into experimental and control group. ,then ,only the experimental group underwent twelve 90 minute sessions of spirituality therapy intervention and control group would be received the usual medical care.the specifies criteria :.Age between 30 to 59years ;being at clinical stage I , II , or III ;no metastatic lesion ;at least 8 months after diagnosis and termination of acute treatment period such as surgery, chemotherapy, and radiation therapy , having literacy ; no history of psychotropic drug used, and no history of alcohol or smoked used during the 3 months before the study, no history of other neurosis or psychosis before diagnosis like DSM-V,such as depression and schizophrenia, having letter of satisfaction ,no history of other cancer during 10 years, no history of other chronic diseases ;and no history of psycho- spiritual education .

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National Medical Ethics Committee

**Street address**

Moalem Avn -Bushehr province university of medical science

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7514633341

**Approval date**

2019-04-22, 1398/02/02

**Ethics committee reference number**

IR.BPUMS.REC.1398.020

**Health conditions studied****1****Description of health condition studied**

Breast cancer

**ICD-10 code****ICD-10 code description**

## Primary outcomes

### 1

#### Description

Health Status

#### Timepoint

Study of Health Status at the beginning ,before intervention and after 12 weekly session( 3 month after Intervention) .

#### Method of measurement

WHO Individual Questionnaire 2016.

### 2

#### Description

Coping strategies

#### Timepoint

Study of Coping strategies at the beginning ,before intervention and after 12 weekly session( 3 month after Intervention) .

#### Method of measurement

Lazarus & Folkman coping strategy questionnaire 1988.

### 3

#### Description

Serum T Lymphocyte Immune System.

#### Timepoint

Measure Serum T Lymphocyte Immune System at the beginning ,before intervention and after 12 weekly session( 3 month after Intervention).

#### Method of measurement

5 cc blood was obtained from participants & test analyzed by flow cytometry.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: experimental group : The 30 breast cancer patients(30 to 59 years) refer for treatment to SHafa Clinic in Bushehr in the experimental group underwent twelve weekly 90 minute sessions of spirituality therapy intervention.The purpose of spirituality therapy: additional awareness ,Coping & problem solving ,assurance,self regulation,buoyancy,review the purposeful and meaningful life. session 1: acquaint to another & explanation experience of spirituality. session 2: introspection . session 3: recognition the source of fear & anxiety ,distress and own strategies for coping with them. session 4: understand the concept of dateless & unending concept . session 5: understand the concept of rancor & devotion. session 6: understand the concept of meditation & compute . session 7: meditation & relaxation . session 8: understand the concept of remission and solving conflict & anger. session 9:

remission and solving conflict & anger focus on self,others & world. session 10: enhanced self regulating. session 11:self care in alarm protection ,hope,self expectation, acceptance ,patience and move responsible. session 12: to look together,settle self monitoring & self controlling and end of session.

#### Category

Behavior

### 2

#### Description

Control group: The control group (C) was asked to stay for a period of 3 months on the waiting list and would be received the usual care from their doctor on treatment plan. after end of session. intervention , a 4 hour psycho-education meeting concerning readjustment with cancer were executed for control group in one day..

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

SHafa Clinic in Bushehr

##### Full name of responsible person

Zinab Hoossaini

##### Street address

sangy Avn, near the Transfusion of Blood Organization

##### City

Bushehr

##### Province

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##### Phone

+98 77 3332 9198

##### Email

RKb.seyed@gmail.com

##### Web page address

<http://bpums.ac.ir/fa/default.aspx>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Boushehr University of Medical Sciences

##### Full name of responsible person

Gholamreza Khamisipour Hematology & Blood Bank,PhD

##### Street address

Bahmany. Salman Farsy Avn, pardis , Bushehr Province University Of Medical.near Salman Farsy Hospital. Sciences

##### City

Bushehr

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Pkarshenasan@yahoo.com

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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**  
Boushehr University of Medical Sciences

**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**  
Boushehr University of Medical Sciences

**Full name of responsible person**  
Zinab Hoossaini

**Position**  
employee of manager area

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Psychology

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Moalem Avn, Bushehr Province University Of Medical Science-manager area-layer 2

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not 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

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The part of information related to consequences variables

### When the data will become available and for how long

6 month after edition the results

### To whom data/document is available

The researchers of academic & scientific center

### Under which criteria data/document could be used

for another researches

### From where data/document is obtainable

hossaini@outlook.com

### What processes are involved for a request to access data/document

If you have more information contact email

hossaini@outlook.com

### Comments