Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Public title
The effectivness 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 Commitee

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 recived 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
Boushehr
Postal code
7514633341
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

Province
Boushehr
Postal code
7513759577
Phone
+98 77 3345 0178
Fax
+98 77 3345 2228
Email
Pkarshenasan@yahoo.com
Web page address
http://rs.bpums.ac.ir/fa/index.aspx

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
Street address
Moalem Avn, Bushehr Province University Of Medical Science-manager area-layer 2
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
00987733329198-00987733323121
Fax
+98 77 3332 3123
Email
hossaini@outlook.com
Web page address
http://bpums.ac.ir/fa/default.aspx

Person responsible for scientific inquiries

Contact

Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Zinab
Position
employee of manager area
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Moalem Avn, Bushehr Province University Of Medical Science-manager area-layer 2
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3332 9198
Fax
+98 77 3332 3123
Email
hossaini@outlook.com

Person responsible for updating data

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
Street address
Moalem Avn, Bushehr Province University Of Medical Science-manager area-layer 2
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3332 9198
Fax
+98 77 3332 3123
Email
hossaini@outlook.com
Web page address
http://bpums.ac.ir/fa/default.aspx

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 afert 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