Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Spiritual Therapy and Mindfulness Education on Quality of Life, Life expectancy and resilience in breast cancerous patients

Protocol summary

Study aim
Comparing the effectiveness of spiritual therapy with mindfulness on quality of life, life expectancy and resilience in breast cancer patients

Design
Clinical trial, parallel groups, block randomized, 30 patients.

Settings and conduct
At Dr. Ghaliani's consulting office in Park Wei, after explaining the purpose of the intervention and obtaining informed consent, patients answered the questionnaires. Then, by block random method, they were divided into two groups of 15 samples (No. 1 and 2). Spiritual therapy was performed for group 1 and mindfulness training for group 2. The intervention was performed in 8 individual and face-to-face sessions of 30-45 minutes. After the intervention in the first stage, the questionnaires were completed by both groups. A one-week break was given. Questionnaires were completed again by both groups. At this stage, mindfulness training was performed for group 1 and spiritual therapy was performed for group 2. At the end of the second eight sessions, the questionnaires were completed again by both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with breast cancer. Exclusion criteria: History of mental illness in the past or present; history of taking psychiatric drugs.

Intervention groups
Spiritual therapy based on the sound heart model and mindfulness education

Main outcome variables
Quality of life, life expectancy and resilience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190715044212N1**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **retrospective**

Last update: **2020-11-12, 1399/08/22**
Update count: **0**

Registration date
2020-11-12, 1399/08/22

Registrant information

Name
Bahare ghalyani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2276 4267

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
2019-11-06, 1398/08/15

Actual recruitment end date
2019-12-06, 1398/09/15

Trial completion date
2020-02-29, 1398/12/10

Scientific title
Comparison of the Effectiveness of Spiritual Therapy and Mindfulness Education on Quality of Life, Life expectancy

and resilience in breast cancerous patients

Public title
Comparison of the Effectiveness of Spiritual Therapy and Mindfulness Education on Quality of Life, Life expectancy and resilience in breast cancerous patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Breast Cancer Disease Diploma and higher education Degree of disease between level 1 to 3 Being able to communicate and understand the lessons Familiarity with Persian language

Exclusion criteria:
History of mental illness in the past or present history of taking psychiatric drugs Taking psychotropic drugs or a history of drug addiction Having another illness, or complications that may result in hospitalization in ICU Unwilling to continue research during the study Simultaneous participation in other research The occurrence of a major life crisis in addition to the illness crisis during the study

Age
From **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The name of the people with consent form were written on the similar papers and folded, mixed and put into a container, then we asked one person outside the study group to pull each paper out of the container in a row with closed eyes and assign them in two groups A or B.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
model-based

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics in Research of Islamic Azad University Science and Research Branch

Street address
University of Science and Research , End of Sattari Highway

City
Tehran

Province
Tehran

Postal code
32224574145

Approval date
2019-10-16, 1398/07/24

Ethics committee reference number
IR.IAU.SRB.REC.1398.149

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of Life: The World Health Organization (2000) defines the concept of quality of life in terms of people's understanding of their life situation in terms of their culture, the value system they live in, their goals, expectations, standards and priorities (Karimloo et al., 2010).

Timepoint
Pre-test and Post-test

Method of measurement
Quality of Life Questionnaire

2

Description
Life expectancy: Life expectancy is a mental set that is based on a mutual sense of will and planning to achieve a goal (Schneider et al., 2006).

Timepoint
Pre-test and Post-test

Method of measurement
Hope Questionnaire

3

Description
Resilience: In the Merriam-Webster culture, resilience is called the ability to recover after difficult conditions or to adapt to those conditions. In other words, resiliency is one of the behavioral traits of individuals who are exposed to certain risk factors and can overcome the risks and avoid negative consequences such as delinquency and behavioral problems (Massen, 1999).

Timepoint
Pre-test and Post-test
Method of measurement
Conner and Davidson's Resiliency Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The first Intervention group: The interventions were made in both groups. A quasi-experimental crossover design method was used. To this end, a pre-test design, including the quality of life, life expectancy, and resilience questionnaires, was initially implemented for all the subjects. The subjects were then matched based on age, education level, and the degree of disease who were randomly assigned to two groups of A and B. The spiritual therapy interventions' plan was implemented for group A, while group B received the mindfulness training. A post-test of the three mentioned scales (quality of life, life expectancy, and resilience) was implemented for both groups three days after the end of all interventions for both test groups.
Category
Behavior

2

Description
The second Intervention group: The interventions were changed for the groups after one week; i.e., group B received the spiritual therapy training and mindfulness training was implemented for group A. The post-test design was conducted for both groups three days after the end of the training course. Finally, the results of the mean values of each group, and each individual were evaluated and compared with themselves. The findings were also analyzed using SPSS software, Ver. 23.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Minoo Asadzandi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
فردی
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Abdul Majid Bahraini
Position
Faculty
Latest degree

Ph.D.

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
privacy policy

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
No - There is not 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
article publication

When the data will become available and for how long
2020

To whom data/document is available
open access

Under which criteria data/document could be used
scientific article

From where data/document is obtainable
journal site

What processes are involved for a request to access data/document
article title searching

Comments