

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+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

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Province

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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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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address**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

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Person responsible for updating data

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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