Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of logo-therapy with and without yoga education on anxiety, depression, happiness in breast cancer survivors: a randomized controlled trial

Protocol summary

Study aim
Determining the effect of logo therapy with and without yoga on anxiety and depression in patients with breast cancer after treatment

Design
Clinical trial work of two arm parallel, with blinded, randomized intervention groups on 90 patients with breast cancer is used to block randomization .

Settings and conduct
This study is performed in Jihad University breast cancer clinic. Samples are selected from patients with depression (depression score above 14). By random block method, 15 blocks of 6, are extracted and allocated by simple random method in two intervention groups; logo therapy alone and the logo therapy and yoga groups.

Participants/Inclusion and exclusion criteria
Age between 18-65 years; Stage 1-3;Completion of breast cancer conventional treatments;Had a minimum score of 10 based on a beck Inventory; Have a minimum of literacy Possibility to attend meetings; Willingness to cooperate The criteria for not entering the study are as follows: Mental or physical disability;Treating psychiatric illness Taking antidepressants; Performing yoga activities or attending yoga classes and receiving psychological treatments from the time of diagnosis ;Physical / medical limitations in performing yoga activities

Intervention groups
Group 1: Psychological training of logo therapy with yoga: Based on the approach of logo therapy and then yoga , 8 sessions are performed as a treatment group on 45 patients, patients. Group 2: Psychological training of logo therapy without yoga: Based on the approach of logo therapy,performed for 8 sessions as a treatment group on 45 patients.

Main outcome variables
Anxiety and depression

General information

Reason for update
Added happiness

Acronym

IRCT registration information
IRCT registration number: **IRCT20200422047170N2**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **prospective**

Last update: **2021-08-04, 1400/05/13**
Update count: **1**

Registration date
2020-07-25, 1399/05/04

Registrant information

Name
Akram Sajadian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8879 7246

Email address
assajadi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-10, 1399/05/20

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of logo-therapy with and without yoga education on anxiety, depression, happiness in breast cancer survivors: a randomized controlled trial

Public title
Yoga and logo therapy in breast cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
18-65y Stage1-3 End of breast cancer treatment Have a minimum depression score of 10 from the Beck Depression Inventory Have a minimum of literacy Ability to participate in intervention sessions Would Like to attend intervention sessions
Exclusion criteria:
Mental or physical disability ،and; Treatment of psychiatric illness Use of antidepressants Doing or attending yoga classes Receiving psychological treatment from the time the disease is diagnosed Physical / medical limitations in performing yoga activities
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
First, the Beck Depression Inventory is used for screening, then scores above 14 (meaning depression) are selected. By Permuted Block Randomization method; depending on the sample size of 90 people, 15 blocks of six are selected. In 6 blocks, a simple random method is used to assign to the intervention groups. This means that 45 people in each group are replaced by a simple random method.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, it is not possible to blind in the group of patients and interventions. It is only possible to blind the result evaluator and the analyzer
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in the research of Motamed Jihad University Research Institute
Street address
No.146 Gandi Ave. Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1517964311
Approval date
2018-02-04, 1396/11/15
Ethics committee reference number
1396.16.RE.IR.ACECR.IBCRC.REC

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Reduction of depression based on Beck questionnaire
Timepoint
Before and after the intervention
Method of measurement
Beck Depression Inventory

2

Description
Increasing happiness
Timepoint
Before and after the intervention
Method of measurement
Oxford Happiness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Based on the logo therapy approach, interventions are performed on patients of intervention groups for 8 sessions. In these 8 sessions, using the main concepts of logo therapy such as freedom, responsibility and finding meaning in suffering and using contradictory techniques, Correction of attitudes and reflexes helped to help clients cope with their anxiety, as well as help reduce depression and anxiety. And yoga training for eight weeks and sixty minutes will be performed in the form of physical, aerobic and relaxation movements for this group. It is necessary to explain that these two interventions are performed consecutively.

Category
Behavior

2

Description
Intervention group2: Intervention group: Based on the logo therapy approach, interventions are performed on patients of intervention groups for 8 sessions. In these 8 sessions, using the main concepts of logo therapy such as freedom, responsibility and finding meaning in suffering and using contradictory techniques, Correction of attitudes and reflexes helped to help clients cope with their anxiety, as well as help reduce depression and anxiety.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Breast Diseases Clinic, Cancer Motamed Research Institute

Full name of responsible person
Akram Sajadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
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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
Iranian academic center for education culture and research

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Akram Sajadian

Position
Associated professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Master

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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

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable