

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Discovering the factors affecting the quality of life of married women with breast cancer and comparing the effectiveness of the therapy protocol with mindfulness therapy on the quality of marital relationships, alexithymia and their marital adjustment.

Protocol summary

Study aim

General purpose: 1- Discovery of factors affecting the quality of married life of married women with breast cancer. 2- Comparison of the effectiveness of a treatment package based on the components affecting the quality of married life with mindfulness therapy on the quality of marital relationships, emotional dyslexia, and marital adjustment of married women with breast cancer.

Design

A clinical trial with a control group with parallel and randomized groups. block randomization design was used for randomization.

Settings and conduct

The participants will be evaluated based on the entry criteria by attending the centers of Babol city, and then they will be randomly assigned to one of the groups, and the intervention sessions will be conducted.

Participants/Inclusion and exclusion criteria

Entry criteria: female gender, education of at least a diploma, suffering from breast cancer for at least one year, no history of neurological and psychological disease, living in Babol city, having the ability and interest to participate in the educational and treatment program, informed consent for Participating in research, not participating in training classes and similar methods with the intended intervention. Inclusion criteria: unwillingness to participate in the study, diagnosis of other severe mental or physical diseases, advanced stages of cancer.

Intervention groups

For the first group, training sessions on the components affecting marital quality, for the second group, cognitive therapy based on mindfulness will be conducted. The control group will not receive any intervention and will be considered as a waiting group.

Main outcome variables

Quality of marital relations; Alexithymia; Marital compatibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240615062137N1**

Registration date: **2024-07-08, 1403/04/18**

Registration timing: **prospective**

Last update: **2024-07-08, 1403/04/18**

Update count: **0**

Registration date

2024-07-08, 1403/04/18

Registrant information

Name

Zohreh Zadhasan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-19, 1403/07/28

Expected recruitment end date

2024-12-18, 1403/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Discovering the factors affecting the quality of life of married women with breast cancer and comparing the effectiveness of the therapy protocol with mindfulness therapy on the quality of marital relationships, alexithymia and their marital adjustment.

Public title

Comparing the effectiveness of the therapeutic package of the components affecting the quality of married life with mindfulness therapy on the quality of marital relationships, emotional dyslexia and their marital adjustment

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Female gender At least diploma education Suffering from breast cancer for at least one year Having no history of neurological and psychological diseases Living in Babol city Having the ability and interest to participate in educational and therapeutic program Informed consent to participate in Research Non-participation in educational classes and methods similar to the intended intervention

Exclusion criteria:

Diagnosis of other severe mental or physical illnesses Advanced stages of cancer Concomitant treatments with similar effects Severe marital problems Pregnancy or breastfeeding Drug use or alcohol abuse

Age

From **30 years** old to **60 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

Block randomization By using the block randomization method by the statistical consultant, randomization is done in 2 groups of training components affecting the quality of married life and mindfulness therapy as follows: First, a list of names of eligible people is provided and coded. In block randomization, the number of participants in all groups will be very close to each other. This is done by making blocks of sequences and intersections so that the same number of participants are assigned to the study groups within each group. First, we code the groups based on Latin letters as follows: A = Teaching the components affecting the

quality of married life, B = Mindfulness treatment In this study, with two groups A and B, we create the following two groups and assign numbers 1 to 2 to each of them: - AB-BA Then, using the table of random numbers, we contract that whenever the numbers 1 and 2 appear in order, one of these blocks will be selected, and if another number appears, we will assume it as null and proceed to the next selection. In fact, we have obtained a random sequence of numbers with the table of random numbers, where we consider the order of allocation for each number. In this way, the number of people in the groups will be almost equal.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad University, Ahvaz Branch

Street address

First floor office complex- Islamic Azad University Ahvaz Branch- Farhang Shahr- Golestan Highway

City

Ahvaz

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Postal code

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Approval date

2024-04-03, 1403/01/15

Ethics committee reference number

IR.IAU.AHVAZ.REC.1403.069

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

Quality of marital relations

Timepoint

Pre-test, post-test and follow-up (follow-up period three months later)

Method of measurement

Marital Relationship Quality Questionnaire (MMQ)

2

Description

Alexithymia

Timepoint

Pre-test, post-test and follow-up (follow-up period three months later)

Method of measurement

Alexithymia scale

3

Description

Marital Adjustment

Timepoint

Pre-test, post-test and follow-up (follow-up period three months later)

Method of measurement

Marital Adjustment Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: educational sessions on the factors affecting the quality of marriage will be compiled based on the factors affecting the quality of married life of women with breast cancer.

Category

Treatment - Other

2

Description

The second intervention group: cognitive therapy based on mindfulness was taught to the participants with the help of Kabat-Zin training package (2012) in 8 sessions and during one month.

Category

Treatment - Other

3

Description

Control group: will not receive any intervention and will be considered as a waiting group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baztab Center for Psychological Services and Counseling

Full name of responsible person

Mahmoudreza Hashemvarzi

Street address

Ferdous Garden, near Babylon Clinic, Farsh Nagin Mashhad, Unit 4

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad University

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Zohreh Zadhasan

Position

Ph.D student

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable