Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
Province
Khouzestan
Postal code
4741666454
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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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

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zohreh Zadhasan
Position
Ph.D student
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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