Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

The effect of virtual training of mindfulness based cognitive therapy on pain severity and quality of life in women treated with breast cancer

Protocol summary

Study aim
Determining the effect of virtual training of cognitive therapy based on mindfulness on pain intensity and quality of life of women undergoing breast cancer treatment

Design
A clinical trial with a control group, randomized, on 54 patients, was used for randomization using four permutation blocks

Settings and conduct
Eligible participants will be randomly divided into two test and control groups and entered into the study. Research questionnaires are designed virtually. Before the educational intervention, the Arnson Quality of Life Questionnaire, the brief Cleveland Pain Severity Questionnaire, and the demographic information form will be completed virtually by all subjects in both groups. In the control group, no action is taken, and the test group is subjected to the intervention of cognitive therapy training based on mindfulness in virtual form during 8 sessions of 90 minutes (once a week) in the form of lectures and questions and answers. One week after the intervention, both the test group and the control group completed the quality of life and pain intensity questionnaire again and were compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Diagnosis of breast cancer (phase I and II) 2- Age range between 18 and 60 years 3-Consent to participate in the study 4- Ability to read and write 5- Absence of speech, hearing and vision problems 6- Access to social networks 7- Absence of active mental disorder Exit criteria: 1-Diagnosis of metastatic breast cancer 2- Patient withdrawal from the study 3- Absence of more than two sessions in training sessions

Intervention groups
All women undergoing breast cancer treatment referred to Seyed al-Shohda Hospital in Isfahan city

Main outcome variables
People's scores in Arnson's Quality of Life Questionnaire and Cleveland Brief Pain Intensity Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230620058544N1**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date
2023-06-27, 1402/04/06

Registrant information

Name
Arefeh Ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5722 5027

Email address
arefehebrahimi4@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-22, 1402/04/31

Expected recruitment end date
2023-08-05, 1402/05/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of virtual training of mindfulness based cognitive therapy on pain severity and quality of life in women treated with breast cancer

Public title
The effect of virtual training of mindfulness based cognitive therapy on pain severity and quality of life in women treated with breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1-Diagnosis of breast cancer (phase I and II) 2- Age range between 18 and 60 years 3-Consent to participate in the study 4- Ability to read and write 5- Absence of speech, hearing and vision problems 6-Access to social networks 7- Absence of active mental disorder

Exclusion criteria:
1-Diagnosis of metastatic breast cancer based on the opinion of an oncologist 2-Patient withdrawal from the study 3-Absence of more than two sessions in educational sessions

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done in an easy and purpose-based way according to the criteria for entering and exiting the research community. People will be selected from among the women undergoing primary breast cancer treatment in Isfahan treatment centers who meet the entry criteria, and then they will be randomly assigned to the intervention and control groups using four permutation blocks. Six possible states (BABA, ABBA, BAAB, AABB ABAB, BBAA) are listed and by throwing a dice, the number of blocks will be randomly selected until a sufficient number of samples, and people will be placed in two intervention (A) and control (B) groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Type of study: randomized clinical trial with a pre-test-post-test design with a control group. First, people will be randomly divided into two test and control groups and will enter the study. Both groups complete the quality of life and pain intensity questionnaire before the intervention. No action is taken in the control group and the experimental group is subjected to the intervention of cognitive therapy training based on mindfulness. One week after the intervention, both the test group and the control group completed the quality of life and pain intensity questionnaire again and were compared.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Side of the Asian road,Gonabad

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2023-05-03, 1402/02/13

Ethics committee reference number
IR.GMU.REC.1402.045

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
People's scores in Arnson's quality of life questionnaire

Timepoint
Checking the quality of life of the participants before the intervention and one week after the end of the intervention

Method of measurement
Arnson quality of life questionnaire

2

Description
People's scores in the Brief Cleveland Pain Intensity

Questionnaire

Timepoint

Examining the pain intensity of the participants before the start of the intervention and one week after the end of the intervention

Method of measurement

Brief Cleveland Pain Intensity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before the start of the intervention, the virtual questionnaire of quality of life and brief pain intensity questionnaire will be completed by the test and control group. The test group is subjected to the intervention of cognitive therapy training based on mindfulness in virtual form during 8 sessions of 90 minutes (once a week) in the form of lectures and questions and answers. The first and last meeting will be held online on the Zinomite platform, and other meetings will be held offline through the formation of a group on the Yes social network in the form of sending a video. Also, in order to provide guidance and answer the questions of the participants, audio and video calls will be made during the week.he training program consists of two parts: a training course provided by the researcher (after training under the supervision of an experienced psychologist in mindfulness interventions), the other is a 45-minute home exercise (after each virtual session for 6 days a week). One week after the intervention, both the test group and the control group completed the quality of life and pain intensity questionnaire again and were compared.

Category

Other

2

Description

Control group: Before the start of the intervention, the virtual questionnaire of quality of life and brief pain intensity questionnaire will be completed by the test and control group. There is no intervention on the control group. One week after the intervention, both the test group and the control group completed the quality of life and pain intensity questionnaire again and were compared. Finally, in order to comply with the ethical principles, the people in the control group who want individual counseling will receive the training program.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohda Hospital

Full name of responsible person

Arefeh Ebrahimi

Street address

Nehar Farshadi Alley, Khayyam St, Esfahan

City

Esfahan

Province

Isfehan

Postal code

8431967181

Phone

+98 31 3235 0210

Email

arefehebrahimi4@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Leila Sadegh Moghadam

Street address

Gonabad University of Medical Sciences, Side of the Asian road, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3401

Email

hms@gmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad University of Medical Sciences

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
Gonabad University of Medical Sciences
Full name of responsible person
Arefeh Ebrahimi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Side of the Asian road
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 5027
Fax
+98 51 5723 6160
Email
arefehebrahimi4@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Arefeh Ebrahimi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Side of the Asian road
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 5027
Fax
+98 51 5723 6160
Email
arefehebrahimi4@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Arefeh Ebrahimi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Side of the Asian road
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 5027
Fax
+98 51 5723 6160
Email
arefehebrahimi4@gmail.com

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