

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

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. The 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

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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

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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

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

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Person responsible for updating data

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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

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