Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of effectiveness of group internet-delivered Mindfulness Based Cognitive Therapy in anxiety , depression and level of mindfulness in breast cancer patients receiving chemotherapy with the control group: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effectiveness of group Internet delivered Mindfulness Based Cognitive Therapy on Anxiety, Depression and Mindfulness level in breast cancer patients receiving chemotherapy

Design

A clinical trial with two experimental and control groups was conducted on 60 patients with randomization on www.random.org and allocation concealment with sealed opaque envelopes.

Settings and conduct

60 breast cancer patients receiving chemotherapy referred to the outpatient oncology department of Panj Azar Hospital in Gorgan in 2024 are divided into two experimental and control groups. The Experimental group recieve Group Internet delivered Mindfulness Based Cognitive Therapy.In both groups pretest and post test are taken for measurement of anxiety, depression and mindfulness level and the results are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria were having breast cancer, age 20 to 55 years, having basic skills of working with the internet and access to the internet at a suitable speed. Exclusion criteria were the presence of another concurrent cancer, having full criteria for other psychological disorders, being under drug or nondrug treatment for psychiatric diseases, drug or alcohol abuse, having suicidal or homicidal thoughts, Low Performance level related to cancer(Equation ECOG 3 and 4).

Intervention groups

The experimental group recieve eight sessions of ninety minute weekly Group Internet delivered Mindfulness Based Cognitive Therapy by the researcher under the supervision of a clinical psychologist, and the control group does not receive any intervention.

Main outcome variables

Severity of Anxiety; Severity of Depression; Level of mindfulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240311061251N1**
Registration date: **2024-07-16, 1403/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-16, 1403/04/26**
Update count: **0**

Registration date

2024-07-16, 1403/04/26

Registrant information

Name

Nazli sharbaf

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3234 9206

Email address

shaarbaf@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of effectiveness of group internet-delivered Mindfulness Based Cognitive Therapy in anxiety , depression and level of mindfulness in breast cancer patients receiving chemotherapy with the control group: a randomized controlled clinical trial

Public title

Effect of Group Internet-Delivered Mindfulness Based Cognitive Therapy (MBCT) in Breast Cancer Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer diagnosed by oncologist and based on pathology report The person must have basic internet and computer skills Access to the Internet at a suitable speed Age 20 to 55 years

Exclusion criteria:

The presence of another concurrent cancer Having full criteria for other psychological disorders based on the researcher's clinical interview in accordance with DSM5 criteria Being under drug or non-drug treatment for psychiatric diseases Substance or alcohol abuse Having Active Suicidal or Homicidal ideas Low Performance Level related to cancer (equation ECOG 3 and 4) , which is determined by the Oncologist based on the ECOG Scale (the Eastern Cooperative Oncology Group Scale)

Age

From **20 years** old to **55 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

randomization technique is simple randomization. unit of randomization is individual participants. randomization tool is table of random numbers. Before starting of the study, Random numbers are generated using www.random.org by a member of the team who does not participate in the study. allocation concealment is done by sealed opaque envelopes. generated random numbers will be kept in sealed opaque envelopes until the start of the study. Allocation concealment will be maintained until the participant completes the demographic checklist. At this stage, the interviewer opened the sealed envelope to reveal the study group.

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 Golestan University of Medical Sciences

Street address

No.14, 3rd Amini Alley, 14 janbaz Ave.,Janbazan Blvd.,Gorgan Town

City

Gorgan

Province

Golestan

Postal code

4916657661

Approval date

2024-03-06, 1402/12/16

Ethics committee reference number

IR.GOUMS.REC.1402.509

Health conditions studied

1

Description of health condition studied

اختلال خلقی ناشی از وضعیت فیزیولوژیک شناخته شده با خصوصیات افسردگی

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

2

Description of health condition studied

اختلال اضطرابی ناشی از وضعیت فیزیولوژیک شناخته شده

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety score in Beck Anxiety Inventory

Timepoint

The beginning of the study (before the intervention) and

the end of the study (after the intervention)

Method of measurement

Beck Anxiety Inventory

2

Description

Depression score in Beck depression Inventory - second edition

Timepoint

The beginning of the study (before the intervention) and the end of the study (after the intervention)

Method of measurement

Beck depression Inventory - second edition

3

Description

Mindfulness level in Five Facet Mindfulness Questionnaire

Timepoint

The beginning of the study (before the intervention) and the end of the study (after the intervention)

Method of measurement

Five Facet Mindfulness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : Pre-test with Beck Depression Inventory - Second Edition (BDI-II), Beck Anxiety Inventory (BAI) and Five Facet Mindfulness Questionnaire (FFMQ) will be implemented in both intervention and control groups. The intervention group are subjected to eight sessions of ninety minute weekly group internet-delivered Mindfulness Based Cognitive Therapy (iMBCT) in two groups of 15 participants. The iMBCT program is taken from the original version of Mindfulness-Based Cognitive Therapy from Segal et al.,2013 Handbook. then the post-tests will be administered in both groups.

Category

Treatment - Other

2

Description

Control group: Pre-test with Beck Depression Inventory - Second Edition (BDI-II), Beck Anxiety Inventory (BAI) and Five Facet Mindfulness Questionnaire (FFMQ) will be implemented. During period of time that intervention group is recieving therapy, the control group is under usual care and does not receive any intervention. then the post-tests will be administered in both intervention and control groups.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan 5azar hospital

Full name of responsible person

Nazli shaarbaf

Street address

5Azar hospital, 5azar Ave., Gorgan Town

City

Gorgan

Province

Golestan

Postal code

4917761551

Phone

+98 17 3232 7910

Fax

+98 17 3223 8363

Email

modir-5azar@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Narges beygom Mirbehbahani

Street address

Golestan university of medical sciences, shastkola Ave. entrance , Gorgan Town

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Email

mirbeh@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Nazli Shaarbaf
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 19,3rd Amini Alley, Janbaz14 Ave., Janbazan Blvd., Gorgan
City
Gorgan
Province
Golestan
Postal code
4916657661
Phone
00981749206
Email
shaarbaf@goums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Nazli Shaarbaf
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No.19 , 3rd amini alley , Janbaz14 Ave. , Janbazan Blvd.,Gorgan Town
City
Gorgan
Province
Golestan
Postal code
4916657661
Phone
+98 17 3234 9206
Email
shaarbaf@goums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Nazli Shaarbaf
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No.19 , 3rd amini alley , Janbaz14 Ave. , Janbazan Blvd.,Gorgan Town
City
Gorgan
Province
Golestan
Postal code
4916657661
Phone
+98 17 3234 9206
Email
shaarbaf@goums.ac.ir

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