

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of a designed pain management program and Mindfulness-Based Interoceptive Exposure Task [MIET] on experienced pain and life expectancy of breast cancer patients

Protocol summary

Study aim

Comparison of the effectiveness of a designed pain management program and Mindfulness-Based Interoceptive Exposure Task [MIET] on experienced pain and life expectancy of breast cancer patients

Design

Clinical trial, with control group, with parallel groups, without blinding, in which 45 breast cancer patients with neuropathic pain will be randomly assigned to three groups.

Settings and conduct

The study population will be breast cancer patients aged 18 to 70 years who suffer from pain referred to the Namazi Medical Center. They will be assigned to three groups randomly (through lottery). The intervention of pain management and MIET intervention is a group therapy during 6 weekly sessions of 120 minutes in the conference hall of Namazi Hospital-Motahari Clinic located on the ground floor, which is designed for group interventions. The control group received no psychological intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 70 years, Having breast cancer type 1 to 3, Receiving chemotherapy, Suffering from pain experienced during chemotherapy, Minimum diploma education. Exclusion criteria: Unwillingness to participate in meetings, Receiving individual psychological interventions, Receiving strong painkillers.

Intervention groups

Intervention group 1: They will receive group training on the pain management program during 6 sessions of 120 minutes which is compiled based on the background and theories of pain. Intervention group 2: They will receive group training on mindfulness-based internal exposure therapy (MIT), during 6 sessions of 120 minutes, which is teaching mindfulness, a different way of facing pain.

Control group: This group goes through the usual process of cancer treatment and does not receive a psychological intervention.

Main outcome variables

Pain experienced, hope for life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055860N1**

Registration date: **2022-09-29, 1401/07/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-29, 1401/07/07**

Update count: **0**

Registration date

2022-09-29, 1401/07/07

Registrant information

Name

Mohsen Arefian

Name of organization / entity

The University of Isfahan

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2022-10-23, 1401/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Comparison of the effectiveness of a designed pain management program and Mindfulness-Based Interoceptive Exposure Task [MIET] on experienced pain and life expectancy of breast cancer patients
Public title
Comparison of designed pain management program and internal exposure on pain experienced in breast cancer patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Breast cancer diagnosis Receive chemotherapy experience pain Agreeing to participate in the research
Exclusion criteria:
Age
From **18 years** old to **70 years** old
Gender
Female
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to 3 groups of 15 using simple randomization (by lottery method).
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

Research Ethics Committees of University of Isfahan

Street address

Azadi Square, University Street, Isfahan University,

Department of Education and Graduate Studies
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81174673441
Approval date
2022-08-06, 1401/05/15
Ethics committee reference number
IR.UI.REC.1401.059

Health conditions studied

1

Description of health condition studied

Patients with breast cancer who suffer from pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain experienced

Timepoint

Before intervention, immediately after intervention, 1 month after intervention

Method of measurement

Brief pain intensity questionnaire (Klind, 1991)

Secondary outcomes

1

Description

life expectancy

Timepoint

Before intervention, immediately after intervention, 1 month after intervention

Method of measurement

Life expectancy questionnaire of Snyder, Harris and Anderson (1991)

Intervention groups

1

Description

Intervention group1: They will receive group training on the designed pain management program through 6 120-minute sessions. This intervention includes the introduction of the group and cancer and treatment stages, inviting two people who have recovered from breast cancer to express their experiences, introducing harmful thoughts and behaviors during chemotherapy, teaching the concept of acceptance and avoidance, and finally training Techniques that help increase self-acceptance and reduce avoidance of cancer.

Category

Lifestyle

2**Description**

Intervention group 2: They will receive group training on the Mindfulness-Based Interoceptive Exposure Task [MIET] through 6 120-minute sessions. The content of the intervention is: explaining the logic of the treatment, teaching concentration techniques, breathing meditation, sensory meditation and finally teaching the MIET technique in which the person pays attention to the pain in different parts of the body for 30 seconds and tries to accept these pains and does not react to them and does not judge them.

Category

Behavior

3**Description**

Control group: does not receive interference

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Special and Subspecialty Clinic

Full name of responsible person

Fatemeh ghodosi

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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

The University of Isfahan

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**

The University of Isfahan

Full name of responsible person

Mohsen Arefian

Position

PhD student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available