Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity
The University of Isfahan

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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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Province

Isfehan

Postal code

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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 accepts 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
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Sponsors / Funding sources

1

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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
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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