

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A Comparative Study on the Efficacy of Meaning-Centered Pain Coping Skills Training and Mindfulness-Based Stress Reduction on Pain Levels, Pain Self-efficacy, Death Anxiety, and Life Expectancy in Breast Cancer Patients

Protocol summary

Study aim

Comparing of the Effectiveness of Meaning-Centered pain Coping Skills Training and Mindfulness-Based Stress Reduction on Pain, Pain Self-Efficacy, Anxiety of Death and Life Expectancy in patients with Breast cancer

Design

The clinical trial has a control group and parallel groups. The sample size was calculated by G*POWER as 36. Considering the possibility of a drop in clients, 15 people were selected for each group and randomly put into the intervention and control groups.

Settings and conduct

The present study is a clinical trial with pre-test and post-test design with two experimental groups and a control group. Among breast cancer patients referred to Tehran Bazarganan Hospital, the samples that meet the inclusion criteria will be randomly assigned to two experimental (30) and one control group (15 patients).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Subjects must be under chemotherapy or radiotherapy. Exclusion Criteria: Having used psychedelic drugs in the past three months. Any major mental disorder (such as psychosis, bipolar disorder, and chronic depression) or physical illness other than cancer.

Intervention groups

Patients will be divided into three group (two intervention and one control groups). The first intervention group will receive 4 sessions of Meaning Centered Pain Coping Skills and second intervention group will receive 8 sessions of mindfulness-based stress reduction . The control group will not receive any psychological intervention.

Main outcome variables

Pain, Pain Self-Efficacy, Anxiety of Death and Life Expectancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230303057600N1**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Mina Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-10, 1402/01/21

Expected recruitment end date

2023-07-17, 1402/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Parallel
Scientific title A Comparative Study on the Efficacy of Meaning-Centered Pain Coping Skills Training and Mindfulness-Based Stress Reduction on Pain Levels, Pain Self-efficacy, Death Anxiety, and Life Expectancy in Breast Cancer Patients	Other design features Teaching and comparing meaning-based pain coping skills with mindfulness-based stress reduction on their effects on the pain scale, pain self-efficacy, death anxiety, and life expectancy of patients with breast cancer for the first time in Iran
Public title A Comparative Study on the Effectiveness of Meaning-Centered Pain Coping Skills Training and Mindfulness-Based Stress Reduction in Breast Cancer Patients	Secondary Ids empty
Purpose Supportive	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Age range between 30 to 60 years old Having at least a diploma Based on clinical findings and cytology studies and doctor's diagnosis, they are diagnosed with stage 3 breast cancer and more than 6 months have passed since the diagnosis of breast cancer. Subjects must be under chemotherapy or radiotherapy. Subjects should not participate in other psychotherapy courses simultaneously. They should obtain an adequate score in the Brief Pain Inventory as the baseline. Exclusion criteria: Having used psychedelic drugs in the past three months. Any major mental disorder (such as psychosis, bipolar disorder, and chronic depression) or physical illness other than cancer.	1 Ethics committee Name of ethics committee Ethics Committee of Islamic Azad University, Sari branch Street address Sari Islamic Azad University, On the 7th kilometer of Darya Road, Sari City, Mazandaran Province, Postal code 194-48164 City Sari Province Mazandaran Postal code 48161-19318 Approval date 2023-02-15, 1401/11/26 Ethics committee reference number IR.IAU.SARI.REC.1401.258
Age From 30 years old to 60 years old	Health conditions studied
Gender Female	1 Description of health condition studied Breast Cancer ICD-10 code C50 ICD-10 code description Malignant neoplasm of breast
Phase N/A	Primary outcomes
Groups that have been masked No information	1 Description Pain Timepoint Before intervention, immediately after intervention, and 45 days after intervention completion. Method of measurement Brief pain questionnaire (BPI)
Sample size Target sample size: 45	2 Description Pain self-efficacy
Randomization (investigator's opinion) Randomized	
Randomization description The randomization was performed by assigning a number from 1 to 45 to each participant, and the corresponding numbers were written on separate pieces of paper. The pieces of paper were then placed in one pouch. Additionally, 15 pieces of paper were labeled with the words "pain-focused coping skills," another 15 with "mindfulness-based stress reduction," and the remaining 15 with "control," which were also folded and placed in a separate pouch. A participant was asked to select one piece of paper from each pouch randomly, and based on the selected papers, the participant's group assignment and name were determined.	
Blinding (investigator's opinion) Not blinded	
Blinding description	
Placebo Not used	
Assignment	

Timepoint

Before intervention, immediately after intervention, and 45 days after intervention completion.

Method of measurement

Pain self-efficacy questionnaire (PSEQ)

3

Description

death anxiety

Timepoint

Before intervention, immediately after intervention, and 45 days after intervention completion.

Method of measurement

Templer death anxiety questionnaire (DAS)

4

Description

life expectancy

Timepoint

Before intervention, immediately after intervention, and 45 days after intervention completion.

Method of measurement

Schneider life expectancy questionnaire (AHS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: They receive instruction for meaning-oriented pain coping skills for four weeks, receiving a 45- to 60-minute group session every week based on Winger and colleagues' protocol (2021). First session plan: conducting the pretest, communicating, reviewing the intervention, meaning and pain, guided imagery to relax, reliving meaningful moments, at-home practice: guided imagery, questioning meaningful moments. Second session plan: sources of meaning, scheduling meaningful activities, activity cycle- rest to speed up the meaningful activities, at-home practice: guided imagery, meaningful activities, activity cycles-rest. The third session, plan: response to suffering (physical, emotional, and spiritual), coping phrases, brief relaxation, at-home practice: the previous skills, coping phrases, and brief relaxation. Fourth session plan: life legacy (the past, present, and future), goal setting based on value, problem-solving, and planning for practicing the current skills.

Category

Behavior

2

Description

Intervention Group 2: They received instruction for mindfulness-based stress reduction for eight weeks, a 90-minute session per week based on Kabat-Zinn

Protocol (2013). The first session plan: Communicating and familiarizing the treatment goals, introducing the intervention plan, intervention schedule, mindfulness as the way of living, mindful eating practices, body monitoring, discussion and feedback about practices. The second session plan: yoga, discussing the interaction between mindful activities, familiarizing at-home practices and body monitoring, discussing mindfulness (no conflict and contrast), introducing seated meditation, seated mediation guide (10 minutes), discussion and feedback about seated meditation. The third session plan: yoga, seated meditation (15 minutes), practices based on mindfulness (watching and listening mindfully) for five minutes, discussing mindful attitudes (not being judgmental and being graceful), dividing mindfully, introducing mindful dialogue as a practice, Muraqabah (meditation) guide, walking and breathing based on mindfulness (a 1-minute breathing space). The fifth session plan: Yoga; seated Muraqabah (mediation); mindful breathing, body, voices, and thoughts; discussing mindful attitudes (actively accepting and releasing); attending to problematic feelings and emotions. The sixths session plan: mindfulness of thoughts, breathing practices to manage anger, mindfulness and relationships, and meditation in nature. The seventh session plan: awareness and kindness, meditation. The eighth session plan: summarizing the intervention and discussing how patients use mindfulness practices practically to transform their lifestyle.

Category

Behavior

3

Description

Control Group: No intervention (they only participate in the pretest-posttest stage of the course and do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology Department of Bazarganan Hospital

Full name of responsible person

Dr.Sayyed Hadi Molana

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Bazarganan Hospital (Shahid Andarzgoo), next to Rey Bridge, Ahang Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Ali Abbaszadeh

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Sari Islamic Azad University, On the 7th kilometer of Darya Road, Sari City, Mazandaran Province, Postal code 194-48164

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mina Ansari

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of educational protocols by citing the source and author of the article and the main author will be unimpeded

From where data/document is obtainable

Mina Ansari minaansari995@gmail.com

What processes are involved for a request to access data/document

6 months after the results of the study protocols will be published and the applicant can send her request using the registered email

Comments