Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 toTehran 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

+98 21 2288 3845

Email address

minaansari995@gmail.com

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

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

Public title
A Comparative Study on the Effectiveness of Meaning-Centered Pain Coping Skills Training and Mindfulness-Based Stress Reduction in Breast Cancer Patients
Purpose
Supportive
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.
Age
From **30 years** old to **60 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
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
Parallel
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

Secondary Ids

empty

Ethics committees

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

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, immediately after intervention, and 45 days after intervention completion.
Method of measurement
Brief pain questionnaire (BPI)

2

Description
Pain self-efficacy

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
Street address
Bazarganan Hospital (Shahid Andarzgoo), next to Rey Bridge, Ahang Highway
City
Tehran
Province
Tehran
Postal code
1173814411
Phone
+98 21 3352 2001

Email
info@bazargananhospital.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Ali Abbaszadeh
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
Phone
+98 11 3303 2891
Email
ravabet-omomi@iau-tnb.ac.ir
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
Street address
No. 3,The 8th Dashtestan Pasdaran Avenue
City
Tehran
Province
Tehran
Postal code
1947854911
Phone
+98 21 2288 3845
Email
minaansari995@gmail.com

Person responsible for scientific 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
Street address
No. 3,The 8th Dashtestan Pasdaran Avenue
City
Tehran
Province
Tehran
Postal code
1947854911
Phone
+98 21 2288 3845
Email
minaansari995@gmail.com

Person responsible for updating data

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
Street address
No. 3, Pasdaran St., Dashtestan 8th
City
Tehran
Province
Tehran
Postal code
1947854911
Phone
+98 21 2288 3845
Email
minaansari995@gmail.com

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