

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of compassion-based hypnotherapy and Acceptance and commitment therapy on pain intensity, depression symptoms and sleep quality in patients with breast cancer

Protocol summary

Study aim

This study aimed to compare two methods of compassion-based hypnotherapy and Acceptance & commitment therapy on pain intensity, depression symptoms, and sleep quality in patients with breast cancer in Yasuj.

Design

The present study is a randomized clinical trial in which a pre-test and post-test design with two experimental groups and two control groups will be used Independent variable (1X): compassion-based hypnotherapy Independent variable (2X): Acceptance & commitment therapy Pre-test (T1): Test for pain intensity, depression symptoms, and sleep quality Post-test (T2): Test for pain intensity, depression symptoms and sleep quality

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 Yasuj Cancer Clinic, the samples that meet the inclusion criteria will be randomly assigned to two experimental (30 patients) and one control group (30 patients).

Participants/Inclusion and exclusion criteria

The inclusion criteria are: Women diagnosed with breast cancer, according to oncologist and paraclinical findings, passing at least 6 months after diagnosis, lack of physical and mental disability that prevents patients from attending therapy sessions, and having symptoms of moderate or severe depression. Exclusion criteria: Absence from group therapy sessions for more than two sessions and unwillingness to continue the therapy, migration, or death of patients. .

Intervention groups

(1X): Compassion-based hypnotherapy (2X): Acceptance and commitment therapy

Main outcome variables

Independent variable : compassion-based Hypnotherapy

Independent variable : Acceptance & commitment therapy Pre-test : pain intensity, depression symptoms, and sleep quality Post-test : pain intensity, depression symptoms, and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220214054018N1**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Mohammadali Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 0790

Email address

mohamadaliavid1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of compassion-based hypnotherapy and Acceptance and commitment therapy on pain intensity, depression symptoms and sleep quality in patients with breast cancer

Public title
The effectiveness of hypnotherapy and acceptance and commitment therapy on pain intensity, depressive symptoms, and sleep quality.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women diagnosed with breast cancer, according to oncologist and paraclinical findings, passing at least 6 months after diagnosis, lack of physical and mental disability that prevents patients from attending therapy sessions, having symptoms of mild depression, and not attending mental courses at the same time.
Exclusion criteria:
Absence from group therapy sessions for more than two sessions and unwillingness to continue the therapy, migration, or death of patients.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a clinical trial with pre-test, post-test, and two experimental and one control group. The statistical population of the study will include all breast cancer patients referred to Yasuj Cancer Clinic in 2022. Then, 90 patients who meet the inclusion criteria will be selected and randomly assigned to study groups using a random number table. Then, 90 patients who meet the inclusion criteria will be selected and in order to ensure that an equal number of participants will enter the intervention and control groups, the research samples will be assigned to one of the three study groups using blocked random assignment (blocks of 3, 6 and 9 people).

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients receive therapeutic interventions, but they don't know what group they are in.

Placebo
Not used

Assignment
Other

Other design features
Psychological intervention and treatment techniques

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Islamic Azad University
- Yasouj Branch

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasouj

Province

Kohgilouyeh-va-Boyer-Ahmad

Postal code

7591784868

Approval date

2022-02-07, 1400/11/18

Ethics committee reference number

IR.IAU.YASOOJ.REC.1400.005

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Pain intensity, depression symptoms and sleep quality

Timepoint

Ninety days

Method of measurement

Questionnaire and interview

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Compassion-based hypnotherapy

Category

Behavior

2

Description

Intervention Group: Acceptance and Commitment Therapy

Category

Behavior

3

Description

Control group: without intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital in Yasuj (Cancer clinic)

Full name of responsible person

Mohammadali Javid

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591784868

Phone

+98 74 3323 0790

Email

mohamadali javid1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj Islamic Azad University

Full name of responsible person

Mohammadali Javid

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591784868

Phone

+98 74 3323 0790

Email

mohamadali javid1@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Yasuj Islamic Azad University and Yasuj University of
Medical Sciences

Proportion provided by this source

20

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

Mohammad ali javid

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591784868

Phone

+98 74 3323 0790

Email

mohamadali javid1@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammadali Javid

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591784868

Phone

+98 74 3323 0790

Email

mohamadaliavid1@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohamadali Javid

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

First Unit., Sina Building, , Pezeshk Alley, Motahhari St
Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591784868

Phone

+98 74 3323 0790

Fax**Email**

mohamadaliavid1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The research paper will be uploaded on the site.

When the data will become available and for how long

From March 2022 to September 2023

To whom data/document is available

Researchers and patients with breast cancer

Under which criteria data/document could be used

Psychotherapy, research, and education

From where data/document is obtainable

Researcher, Yasouj Islamic Azad University, and the journal in which the article will be published.

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

The process of intervention, data collection, and data analysis will take 6 months.

Comments