

# 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  
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#### Postal code

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#### Phone

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#### Email

mohamadaliavid1@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Yasuj Islamic Azad University

#### Full name of responsible person

Mohammadali Javid

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

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## 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

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Phone**

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**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**