# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The Effect of Mindfulness-Based Compassion Therapy on Self-Criticism and Body Image in Women with Breast Cancer

## Protocol summary

**Study aim**
The impact of mindfulness-based compassion therapy on self-criticism and body image in married women

**Design**
This is a clinical trial . 30 samples were selected through convenience sampling and randomly assigned to intervention and control groups using online randomization software

**Settings and conduct**
Permission for sampling is granted through visits to Seyed al-Shohada Hospital. After obtaining consent, they are divided into two groups of 15 each. All participants complete questionnaires assessing levels of self-criticism and body image perceptions.

**Participants/Inclusion and exclusion criteria**
Aged 18-60 with breast cancer, at least three months post-diagnosis, receiving treatment, physically and mentally capable of participating, digitally literate, willing to join, free from psychiatric illnesses or relevant medications.

**Intervention groups**
The intervention group: eight sessions of Gilbert Mindfulness-Based Compassion Therapy The control group: no intervention.

**Main outcome variables**
Mindfulness-based compassion therapy can positively affect self-criticism and body image in women facing the challenges of breast cancer.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20251021067705N1**
Registration date: **2025-10-30, 1404/08/08**
Registration timing: **prospective**
Last update: **2025-10-30, 1404/08/08**
Update count: **0**

**Registration date**
2025-10-30, 1404/08/08

**Registrant information**

**Name**
Maryam Moghimian

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 913 114 3254

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-11-06, 1404/08/15

**Expected recruitment end date**
2025-11-27, 1404/09/06

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The Effect of Mindfulness-Based Compassion Therapy on Self-Criticism and Body Image in Women with Breast Cancer

**Public title**
The Effect of Mindfulness-Based Compassion Therapy on Self-Criticism and Body Image in Women with Breast Cancer

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Married women aged 18-60 years, with a definitive diagnosis of breast cancer, that has been free of symptoms for at least three months since their diagnosis, and the diagnosis crisis has passed Receiving treatments such as chemotherapy, radiotherapy, drug therapy, and surgery Physically and mentally able to participate in the study according to the patient's self-declaration Digital literacy and access to public virtual meeting rooms Willingness to participate in the study Permission from the patient's physician/psychologist to participate in the research

**Exclusion criteria:**

Suffering from specific psychiatric illnesses Taking specific psychiatric medications according to their self-declaration.

**Age**

From **18 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

30 women with breast cancer who met the inclusion criteria for the study were selected using a convenience method and were assigned equally to two intervention and control groups using online random software. First, each patient was given a number, then the software was asked to randomly assign numbers 1-30 to two groups (Group 1: Intervention and Group 2: Control). Accordingly, patients assigned to the aforementioned numbers will be assigned to the two intervention and control groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Islamic Azad University, Najafabad Branch

**Street address**

نجف اباد، دانشگاه ازاد اسلامی واحد نجف اباد، گروه پرستاری

**City**

Isfahan

**Province**

Isfehan

**Postal code**

۸۵۱۴۱۴۳۱۳۱

**Approval date**

2025-06-26, 1404/04/05

**Ethics committee reference number**

IR.IAU.NAJAFABAD.REC.1404.086

## Health conditions studied

**1**

**Description of health condition studied**

Breast cancer

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**

Self-criticism and body image

**Timepoint**

Before and immediately after the study

**Method of measurement**

Questionnaires for levels of self-criticism and multidimensional relationships with one's own body

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

The intervention group will receive mindfulness-based compassion therapy intervention based on Gilbert’s compassion therapy protocol in 8 weekly one-hour online group sessions. Each session will include training in mindfulness concepts and practical exercises to reduce self-criticism and improve body image. Interactive lectures, group discussions, and questions and answers will be used to deliver the training. At the end of each session, home exercises will be provided, and at the beginning of the next session, the exercises will be reviewed, and questions will be answered.

**Category**

Rehabilitation

**2**

**Description**

The control group receives routine hospital procedures.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Seyed Al-Shohada Hospital, Isfahan
**Full name of responsible person**
Yeganeh Mokhtari
**Street address**
Isfahan, Motahhari Street
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
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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**
Thesis

**Proportion provided by this source**
100

**Public or private sector**
Private

**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**
maryam Moghimian
**Position**
Faculty member
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not 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**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
All data is potentially shareable after de-identifying individuals.
**When the data will become available and for how long**
Immediately after printing the results
**To whom data/document is available**
Researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
Reference to the results of this study
**From where data/document is obtainable**
By email to the scientific correspondent of the study, Maryam Moghimian, maryam.moghimian@iau.ac.ir
**What processes are involved for a request to access data/document**
Submit a request via email, introduce yourself, introduce your study, explain the reason for the request and how the data will be used, and commit to referencing the current study.
**Comments**