

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating the effect of Acceptance and Commitment Therapy (ACT) with two methods of internet-based and bibliotherapy on anxiety and depression in patients with breast cancer

#### Protocol summary

##### Study aim

Comparison of the effect of bibliotherapy and internet-based therapy on anxiety and depression in breast cancer patients

##### Design

A clinical trial with intervention and control groups, without blinding, randomized using R statistical software on 99 patients

##### Settings and conduct

After obtaining a written consent form and performing T0, if all the entry conditions are met, the participants will be divided into three bibliotherapy, internet-based and control group with the help of a random number table. Then, by making a phone call, the selected people for each group will be informed about the implementation method. Then, the interventions were carried out for 6 weeks and immediately after the intervention and 4 weeks after the end of the intervention, they were measured using the tools of Beck anxiety and Beck depression short inventory

##### Participants/Inclusion and exclusion criteria

non-metastatic breast cancer women, having the condition of age, reading and writing Farsi, appropriate physical and mental conditions to participate in the study and the ability to use the online space; Failure to participate in educational workshops with similar content to this study or other interventional research at the same time; Absence in more than one session

##### Intervention groups

bibliotherapy: providing the book Flying over thunderstorms for study and practice; Internet intervention: provision of weekly online training and practice sessions by psychiatric nurses; Control group: receiving usual care provided by health centers. After completing the interventions of the other two groups and performing the post-test, this group can receive any of the interventions of the other groups as they wish

#### Main outcome variables

Independent variable: internet-based intervention, bibliotherapy; Dependent variable: depression, anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231209060301N1**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **prospective**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

##### Registration date

2023-12-23, 1402/10/02

##### Registrant information

##### Name

Niloufar Baghelani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3333 8852

##### Email address

baghlani.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-31, 1402/10/10

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of Acceptance and Commitment Therapy (ACT) with two methods of internet-based and bibliotherapy on anxiety and depression in patients with breast cancer

**Public title**

The effect of acceptance and commitment therapy with two methods of internet-based and bibliotherapy on anxiety and depression

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 18 and over Reading and writing literacy in Persian language Interested in participating in a research project Being able to make phone calls and receive SMS Signed written informed consent The use of conventional psychotropic drugs is accepted only if the dosage has been stable for the past 3 months The possibility of using a computer and / or smartphone and the Internet Daily access to the Internet by computer and / or smartphone The ability to participate in research in terms of physical and cognitive Having clinically significant symptoms of mild to moderate anxiety (BAI scores 8 to 25) and/or mild to moderate depression (BDI-S scores 5 to 15)

**Exclusion criteria:**

Significant cognitive impairment or communication problem that affects the ability to provide consent or participate in the study Suffering from other medical diseases and other types of cancer and mental disorders Participating in other interventional research projects at the same time History of participation or intention to participate in an educational workshop that covers the content of the intervention of this research (ACT) Unstable or severe physical or mental conditions Inability to cooperate and give informed consent Having metastatic breast cancer Severe mental illness or disorder or ongoing psychological treatment Inability to use a computer and / or smartphone and the Internet Inability or unwillingness to comply with study requirements Participants who underwent removal of a breast cyst, limited arm and/or shoulder motion, treatment for another type of cancer or diagnosis of another type of cancer, or breast reconstruction Absence of more than one session in intervention group meetings

**Age**

From **18 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **99**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Before sampling, a statistician creates a random allocation algorithm using R statistical software, with random block sizes of 7, 14, 21 and 28 and an equal allocation ratio (33 people in each arm). 99 patients using Permutation block randomization method and equal allocation ratio are randomly assigned to one of the 3 study groups

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

A statistician creates a random allocation algorithm before sampling using R statistical software and then analyzes the data and will be blinded in both steps. The participants in each group are aware of the implementation method and the researcher, who is responsible for communicating with the people in the groups, knows about the people in each group, so these two are not blind

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan Ave

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733331

**Approval date**

2023-12-02, 1402/09/11

**Ethics committee reference number**

IR.AJUMS.REC.1402.468

**Health conditions studied****1****Description of health condition studied**

Depression

**ICD-10 code**

F32.0

**ICD-10 code description**

Major depressive disorder, single episode, mild

## 2

### **Description of health condition studied**

Depression

### **ICD-10 code**

F32.1

### **ICD-10 code description**

Major depressive disorder, single episode, moderate

## 3

### **Description of health condition studied**

Anxiety

### **ICD-10 code**

F41.9

### **ICD-10 code description**

Anxiety disorder, unspecified

## 4

### **Description of health condition studied**

Breast cancer

### **ICD-10 code**

D05

### **ICD-10 code description**

Carcinoma in situ of breast

## **Primary outcomes**

### 1

#### **Description**

Depression score in short form Beck depression inventory

#### **Timepoint**

Before the intervention, after the intervention, 4 weeks after the intervention

#### **Method of measurement**

Beck depression short inventory

### 2

#### **Description**

Anxiety score in Beck anxiety inventory

#### **Timepoint**

Before the intervention, after the intervention, 4 weeks after the intervention

#### **Method of measurement**

Beck anxiety inventory

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: bibliotherapy; In this group, a printed or electronic version of the book Flying over thunderstorms is presented, the cost of which has been paid. The intervention (study and practice) does not

require an in-person visit, and patients can do it at any place and time they want. They are requested to use the book for a period of one and a half months in such a way that they study and practice a specific part of the book, which has about 40 pages, every week. They can do this at their own pace, time and place, and can review as many times as they want

#### **Category**

Behavior

### 2

#### **Description**

Intervention group: Internet-based intervention; All participants in this group must have access to a smart phone or computer. Weekly meetings are held in the virtual space of the university. The link is sent to the patients along with the guide to participate in the meetings. An internet package is prepared for the connection of each patient. The content of the sessions is actually the same as the bibliotherapy group that is taught online by a psychiatric nurse. Then the participants ask their questions and the guide answers them. Patients' exercises are provided to them in the form of pdf and printed files, which they should do and review as much as they can until the next session

#### **Category**

Behavior

### 3

#### **Description**

Control group: Participants in the control group receive routine hospital care provided by health care centers. After completing the interventions of the other two groups and performing the post-test, this group can receive any of the interventions of the other groups as they wish

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Baghaei 2 hospital

##### **Full name of responsible person**

Niloufar Baghelani

##### **Street address**

Shahid Baghaei 2 hospital, Baghaei Sq

##### **City**

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##### **Province**

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##### **Phone**

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**Email**  
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**Web page address**  
<https://h-baghaei2.ajums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Mehrnosh Zakerkish  
**Street address**  
Golestan Ave  
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**Province**  
Khuzestan  
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**Fax**  
**Email**  
zakerkish-m@ajums.ac.ir  
**Web page address**  
<https://vchresearch.ajums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz University of Medical Sciences

#### 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**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Kourosh Zarea  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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zarea\_k@ajums.ac.ir

**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 data file will be shared with the SPSS software format

**When the data will become available and for how long**

The access period begins after the publication of the findings in the form of a printed article

**To whom data/document is available**

The data will be available to researchers working in academic institutions

**Under which criteria data/document could be used**

Data will only be available for use in review studies and meta-analyses

**From where data/document is obtainable**

Through Kouros Zarea's academic email: zarea\_k@ajums.ac.ir

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

Send an email to the author and mention the purpose of receiving the information. If there are no problems, you will receive the information one to three weeks later

**Comments**