

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)

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnosh Zakerkish
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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
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Other areas of specialty/work
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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

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