Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Khouzestan
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
Khouzestan
Postal code
6138933333
Phone
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Fax
+98 61 3375 0416

Email
baghlani.n@ajums.ac.ir
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
Mehrnoosh Zakerkish
Street address
Golestan Ave
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 1544
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
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Person responsible for scientific inquiries

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Position
Associate professor
Latest degree
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Phone
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Email
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Person responsible for updating data

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
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Postal code
6135715794
Phone
+98 61 3373 8333

Email
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 Kourosh 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