Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of internet-based Acceptance And Commitment Therapy on Acceptance of Illness, Emotional Regulation and Reduction of Symptom Interference with Function in Patients with Breast Cancer

Protocol summary

Study aim
Determining the Effectiveness of internet-based Acceptance And Commitment Therapy on Acceptance of Illness, Emotional Regulation and Reduction of Symptom Interference with Function in Patients with Breast Cancer

Design
Randomized clinical trial, control group and random assignment by a person who is not aware of the research and treatment process, on 36 patients with breast cancer

Settings and conduct
At first, the eligible patients referred to Isfahan Macsa Center will be provided with informed consent and checklists and related questionnaires (basic evaluation), then patients are randomly assigned to one of the two control or experimental groups and The experimental group will receive acceptance and commitment therapy in the form of group video call during 10 sessions of 45 minutes, the control group will receive the education and support program in the form of group video call. Finally, after the sessions, using the tool The desired post-test and follow-up are performed 12 weeks later in both groups. The lead researcher and outcome assessors are unaware of the allocation of study groups. Google Meet space will be used to form group meetings and WhatsApp will be used to follow and coordinate meetings and evaluations.

Participants/Inclusion and exclusion criteria
Inclusion:first and second stages of breast cancer،Age group under 55،At least 2 months and at most 6 months have passed from their active treatment
Exclusion:Unwillingness to continue the treatment process،The occurrence of major and severe physical problems ،Failure to complete the questionnaires

Intervention groups
The experimental group includes patients with breast cancer who receive Acceptance and commitment therapy. The control group includes patients with breast cancer who receive Education and Support programs.

Main outcome variables
Emotional Regulation، Acceptance of Illness and Symptom Interference with Function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211107052984N1**
Registration date: **2022-02-02, 1400/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**
Update count: **0**

Registration date
2022-02-02, 1400/11/13

Registrant information

Name
Sara Mirzaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3668 9313

Email address
bagherian@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of internet-based Acceptance And Commitment Therapy on Acceptance of Illness, Emotional Regulation and Reduction of Symptom Interference with Function in Patients with Breast Cancer

Public title

Effect of internet-based Act in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of the first and second stages of breast cancer Age group under 55 years At least 2 months and at most 6 months have passed from their active treatment Lack of major psychiatric disorders such as schizophrenia and bipolar Lack of other severe and chronic physical illnesses Not receiving hospital care at the time of registration Lack of severe inability to perform activities Having motivation and desire to participate in psychotherapy sessions Internet access

Exclusion criteria:

Unwillingness to continue the treatment process Absence for more than 2 consecutive sessions and 3 sessions in general The occurrence of major and severe physical problems Hospitalization Failure to complete the questionnaires

Age

To **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size consists of 36 women. There are currently three models of random allocation, and since this study is in two groups, the first generation prototyping model is used, each sample is placed in a treatment group and is done through the site https : // www. .randomize.net / which means that the assignment of samples to each of the two groups does not occur in the order of A and B, respectively, in the order in which the software output is placed. Groups A and B enter the treatment groups section through the blocks on the site, The samples are then entered in the number of people in the treatment blocks, where the software randomly assigns each of the samples to one of the two groups A and B.

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

Research Ethics Committees of School of Medicine-Isfahan University of Medical Sciences

Street address

Department of Health Psychology, Isfahan University of Medical Sciences

City

Esfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.MUI.MED.REC.1400.550

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Emotional Regulation

Timepoint

Before the intervention (Pre-test),After the intervention (Post-test),12 weeks after the intervention

Method of measurement

Difficulties in Emotion Regulation Scale

2

Description

Acceptance of Illness

Timepoint

Before the intervention (Pre-test) ,After the intervention (Post-test),12 weeks after the intervention

Method of measurement

acceptance of illness scale questionnaire

3

Description

Symptom Interference with Function

Timepoint

Before the intervention (Pre-test),After the intervention (Post-test),12 weeks after the intervention

Method of measurement

The MD Anderson Symptom Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Internet-based Acceptance And Commitment Therapy *Session 1: Housekeeping, Group Culture, Conceptualization, Creative Hopelessness *Session 2: Control as the Problem/Willingness *Session 3: Willingness/Defusion *Session 4: Deliteralization /Defusion *Session 5: Contacting the Present *Session 6: Self-as-Context *Session 7: Values Clarification *Session 8: Committed Action *Session 9: Pulling it all together *Session 10:Conclusion and Ask about useful aspects of therapy ,Ask about areas that client will struggle with going forward and Say goodbye.

Category

Treatment - Other

2

Description

Control group(Education/Support): *Session 1: *Session 2: Overview of quality of life issues *Session 3:Discussion of physical quality of life *Session 4:Discussion of social quality of life and referral to resources *Session 5:Discussion of emotional quality of life and referral to resources *Session 6:Discussion of Cognitive and spiritual quality of life quality of life and referral to resources *Session 7: Discussion of quality of financial life and referral to resources *Session 8 :Tips for evaluating health information in books,magazines, and websites *Session 9 : Review of prior sessions and referral to websites with cancer-related information *Session 10 :Conclusion and Ask about useful aspects of therapy ,Ask about areas that client will struggle with going forward and Say goodbye.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ala Cancer Prevention and Control Center (Macsa))

Full name of responsible person

Mohamadreza Sharbafchi

Street address

No. 29, Amin al-Dawle Dead End, 35th Alley, after Shiri Bridge,Motahhari St.

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Email

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Web page address

https://macsa.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh haghjooye javanmard

Street address

Isfahan University of Medical Sciences,,Isfahan,Iran

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saramirzaeiii997@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Sara mirzaei

Position
student

Latest degree
Master

Other areas of specialty/work
Psychology

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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
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 are potentially shareable after patients are unidentifiable.

When the data will become available and for how long
After completing the process and publishing the article.

To whom data/document is available
It will be accessible to researchers, students, medical staff and patients.

Under which criteria data/document could be used
If it is for the purpose of scientific advancement and therapeutic progress of patients as well as the expansion of the present research, sending the request is unrestricted.

From where data/document is obtainable
Phone number: 00989133826394 email: saramirzaeiii997@gmail.com

What processes are involved for a request to access data/document
After sending the necessary and relevant requests and reviews by the professors and the Masca Center, the applicant will receive the documents.

Comments