Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

a randomized clinical trial assessment between in-person and online group therapy based on acceptance and commitment therapy on anxiety, experiential avoidance and psychological flexibility using acceptance and commitment therapy in women recovered from breast cancer

Protocol summary

Study aim
Determining the effectiveness of face-to-face group therapy compared to online group therapy on anxiety, experiential avoidance and psychological flexibility using acceptance and commitment-based therapy in women recovered from breast cancer.

Design
randomized not blinded factorial group trial

Settings and conduct
The group therapy method based on acceptance and commitment is implemented during 6 group sessions, one session for the groups every week, and before the start of the sessions, at the end of the third session and at the end of the last session, questionnaires are taken from the two groups online. To implement this process treatment from the participants in the treatment; The treatment sessions are organized by a doctor of psychology at Seyed Al-Shahda Hospital in Isfahan. The experimental group performs homework such as mindfulness between sessions and the homework is discussed in the sessions. The obtained data are analyzed by t-test in SPSS software.

Participants/Inclusion and exclusion criteria
All women who have been cured of breast cancer for more than 6 months and willing to cooperate.

Intervention groups
face-to-face acceptance and commitment therapy vs online acceptance and commitment therapy

Main outcome variables
Anxiety, experiential avoidance and psychological flexibility

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221227056942N1**
Registration date: **2023-04-08, 1402/01/19**
Registration timing: **prospective**

Last update: **2023-04-08, 1402/01/19**
Update count: **0**

Registration date
2023-04-08, 1402/01/19

Registrant information

Name
Mahdi Mirpourian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3331 6138

Email address
mhdmirpourian@res.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-09, 1402/01/20

Expected recruitment end date
2024-04-08, 1403/01/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
a randomized clinical trial assessment between in-person

and online group therapy based on acceptance and commitment therapy on anxiety, experiential avoidance and psychological flexibility using acceptance and commitment therapy in women recovered from breast cancer

Public title

assessment of the effectiveness of face-to-face group therapy compared to online group therapy on anxiety, experiential avoidance and psychological flexibility using acceptance and commitment therapy in women recovered from breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients with grade 1 to 3 breast cancer of Seyed al-Shohad Hospital. The chemotherapy and radiation therapy of these patients has ended. These patients do not participate in other psychotherapy sessions

Exclusion criteria:

Reluctance to cooperate Patients receiving chemotherapy and radiation therapy The presence of psychiatric disorders in patients

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, the study population will be randomly assigned to two intervention groups, face-to-face and online, using the double consent zelen preference method. In order to randomly assign patients to each group, the block balance method will be used, in this way, we use a block of 4 letters to make random allocation sequences and choose the number of letters in each block as 4 and choose the total number of blocks. Finally, we will have a list where the letter in front of each number indicates which group the person belongs to. The said process was done with the help of sealedenvelope website.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of isfehan university of medicine

Street address

Isfehan university of medicine, Hezar jerib street, Isfehan

City

Isfehan

Province

Isfehan

Postal code

81746-73461

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.ARI.MUI.REC.1401.304

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

The score of Spielberger Trait State Anxiety Questionnaire

Timepoint

before the intervention,the third and the sixth week of the intervention

Method of measurement

Spielberger Trait State Anxiety Questionnaire

2

Description

The score of Multidimensional Experiential Avoidance Questionnaire

Timepoint

before the intervention,the third and the sixth week of the intervention

Method of measurement

Multidimensional Experiential Avoidance Questionnaire

3

Description

The score of the comprehensive evaluation questionnaire of the ACT process

Timepoint

before the intervention,the third and the sixth week of the intervention

Method of measurement

the comprehensive evaluation questionnaire of the ACT process

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 weekly one-hour face-to-face group intervention therapy based on acceptance and commitment. Content of sessions: first session: productions of the mind and familiarity with anxiety, second session: creative despair and acceptance, third session: failure, fourth session: present tense, fifth session: experiential avoidance, sixth session: spiritual health and values.

Category

Treatment - Other

2

Description

Intervention group: 6 weekly one-hour sessions of online group therapy intervention based on acceptance and commitment. The content of the sessions includes the following: first session: mind productions and familiarity with anxiety, second session: creative frustration and acceptance, third session: failure, fourth session: present tense, fifth session: experiential avoidance, sixth session: spiritual health and values.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed al-Shohada Hospital

Full name of responsible person

Narges Rahmanian

Street address

Seyed al-Shohada Hospital, Motahari street, Isfehan

City

isfehan

Province

Isfehan

Postal code

8184917354

Phone

+98 31 3235 0210

Email

nrg-rahmanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Neda Yavari

Street address

Esfahan university of medicine, Hezar herib street, Esfahan

City

isfehan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

edo@med.mui.ac.ir

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

Narges Rahmanian

Position

Research assistance

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Hezar Jarib st, Medical University of isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone
009832371103
Email
nrg_rahmanian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Kolahdoozan
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Esfahan university of medical science, Hezar jarib street
City
isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 8134
Email
akolahdouzan@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mahdi Mirpourian
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Esfahan university of medical science, Hezar Jarib Street
City
isfehan
Province
Isfehan
Postal code
81874673461
Phone
+98 31 3792 8134
Email
mhdmirpourian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
All information will be defined in the article and will not be shared separately.
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available