

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of acceptance and commitment group psychotherapy on wellbeing and affective structure of breast cancer patients who participate in group therapy compared to matched control group who do not participate in group therapy

Protocol summary

Summary

This study is designed to improve wellbeing and affective structure of breast cancer patients. The patients will be randomly categorized in two groups: control and those who participate in group therapy sessions. 30 women will participate in this study: two groups of 15 patients. Inclusion criteria: age between 18-60; lack of disabling psychiatric disorder; they educated at least elementary level; under therapy now; maximum 3 years after diagnosis; at stage 2 or 3 of cancer. Exclusion criteria: not participating in group therapy; not consenting to participate in group therapy; patient does not participate in group therapy due to medical condition. Patients participate 8 session of group therapy during 1 month. It is expected that negative emotions decrease and quality of life and hope increase in patients who participating in group therapy.

General information

Acronym

ACT: acceptance and commitment therapy

IRCT registration information

IRCT registration number: **IRCT2016122131512N1**

Registration date: **2017-04-02, 1396/01/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Zahra Mehdipour

Name of organization / entity

Psychiatry department, Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 9319

Email address

mehdipourz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Science, central building of Shiraz University of Medical Science, zand Blvd., shiraz, fars

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acceptance and commitment group psychotherapy on wellbeing and affective structure of breast cancer patients who participate in group therapy compared to matched control group who do not participate in group therapy

Public title

Effect of acceptance and commitment group psychotherapy on wellbeing and affective structure of breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-60; lack of disabling psychiatric disorder; they educated at least elementary level; under therapy now; maximum 3 years after diagnosis; at stage 2 or 3 of cancer Exclusion criteria: no participation in group therapy; not consenting to participate in group therapy; patients do not participate in group therapy due to medical condition

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethics committee of Shiraz University of Medical Science

Street address

Shiraz University of Medical Science main building, Zand Blvd.

City

Shiraz

Postal code

Approval date

2015-08-05, 1394/05/14

Ethics committee reference number

IR.SUMS.med.REC.1394.39

Health conditions studied

1

Description of health condition studied

psychological status in breast cancer patients

ICD-10 code

F54

ICD-10 code description

Psychological and behavioural factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description

affective structure (negative and positive emotion)

Timepoint

before intervention, after end of intervention

Method of measurement

PANAS questionnaire

2

Description

wellbeing structure

Timepoint

before intervention, after end of intervention

Method of measurement

quality of life questionnaire

Secondary outcomes

1

Description

hope

Timepoint

before intervention, after ending intervention

Method of measurement

hope questionnaire

2

Description

improve mental health

Timepoint

before intervention, after ending intervention

Method of measurement

quality of life questionnaire

Intervention groups

1

Description

patients participate in acceptance and commitment group psychotherapy at 1 month for 8 sessions.

Category

Treatment - Other

2

Description

control group do not participate in group therapy and only receive booklets

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Motahari poly clinic

Full name of responsible person

Sara Hosseini

Street address

Matahari poly clinic, Namazi Square, Zand Blvd.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Science

Full name of responsible person

Ali Poostfroosh

Street address

Shiraz University of Medical Science building, Zand Blvd.

City

Shiraz

Grant name

Grant code / Reference number

9189-01-01-94

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali Poostforosh

Position

Research assistant of Shiraz University of Medical Science

Other areas of specialty/work

Street address

Shiraz University of Medical Science building, Zand Blvd.

City

Shiraz

Postal code

Phone

+98 71 3212 2389

Fax

Email

ali_po58@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Arash Mani

Position

Assistant professor of neuroscience

Other areas of specialty/work

Street address

Psychiatry department, Hafez hospital, Chamran Blvd.

City

Shiraz

Postal code

Phone

+98 71 3627 9319

Fax

Email

mania@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Zahra Mehdipour

Position

Psychiatry resident

Other areas of specialty/work

Street address

Building no. 91, 12 Alley, Besat Street

City

Shiraz

Postal code

Phone

+98 71 3647 6281

Fax

Email

mehdipourz@sums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty