

# 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*