

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Feb 2026

### The effectiveness of Meta-cognitive therapy model on depression, cognitive emotion regulation and meta-cognitive beliefs in depressed patients with breast cancer

#### Protocol summary

##### Summary

The goal of this study is to determine the effectiveness of therapy on meta-cognitive model on the depression, cognitive emotion regulation and meta-cognitive beliefs for depressed women, with breast cancer, referred to medical centers in Shiraz in 1395. In this experimental study, the two groups, pre -test and post-test are performed, forty eight patients with breast cancer, according to Beck Depression questionnaire, are affected by mild to moderate depression, randomly, into two groups and control allocated. The samples are excluded in case of unwillingness to continue the treatment or failure to participate in more than two sessions . While patients in the control group are underwent routine management measures, 8 weekly sessions will be formed for the experimental group, based on meta-cognitive therapy. Before and after the sessions, patients in both groups are evaluated with Beck Depression questionnaire, cognitive emotional regulation and metacognitive beliefs. Re-evaluations will be repeated these tests a month later to assess the effect of treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201606288473N5**  
Registration date: **2016-09-05, 1395/06/15**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-09-05, 1395/06/15

##### Registrant information

##### Name

Masoud Bahreini

##### Name of organization / entity

Bushehr University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3345 3836

##### Email address

m.bahreini@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Bushehr University of Medical Sciences

##### Expected recruitment start date

2016-09-10, 1395/06/20

##### Expected recruitment end date

2016-10-06, 1395/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of Meta-cognitive therapy model on depression, cognitive emotion regulation and meta-cognitive beliefs in depressed patients with breast cancer

##### Public title

The effect of Metacognitive therapy on depression in women with breast cancer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age 20-55 years; with Breast Cancer;

ranging from mild to moderate depression score; the desire to participate in the study; lack of clear psychotic mental disorder; Exclusion criteria: lack of desire to continue to participate in the study; Failure to participate in more than two sessions

**Age**

From **20 years** old to **55 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Does not have

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Bushehr University of Medical Sciences

**Street address**

Salman Farsi street, Sabz Abad, Bushehr

**City**

Bushehr

**Postal code**

7518759577

**Approval date**

2016-06-20, 1395/03/31

**Ethics committee reference number**

IR.BPUMS.REC.1395.52

**Health conditions studied****1****Description of health condition studied**

Depression

**ICD-10 code**

F32

**ICD-10 code description**

Depressive episode

**Primary outcomes****1****Description**

Depression

**Timepoint**

Before the intervention; after the intervention; one months after the intervention

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes****1****Description**

Cognitive Emotion Regulation; Metacognitive Beliefs

**Timepoint**

Before the intervention; After the intervention; A month after intervention

**Method of measurement**

Cognitive Emotional Regulation Questioner; Meta Cognitive Questioner-30

**Intervention groups****1****Description**

In the case group, meta-cognitive group therapy method will be held for 8 sessions per week. Metacognitions placed in cognitive-behavioral third wave of the treatment field that instead of amending the content of cognition, the cognitive processing and correction mechanisms involved. In this approach, it is believed that in mental disorders, cognitive Self-Regulatory Executive Function (S-REF) is placed in a defective processing cycle, which is known as the cognitive attentional syndrome (CAS). This syndrome which is the result of positive and negative metacognitive beliefs, causes a diversion in attention, cognitive processing techniques, cognitive-emotional orientation, and thus, is the continuation of the disorder. The goal of the treatment is modification and decreasing cognitive attentional syndrome, with the help of the techniques of mindfulness, distraction, correction of negative and positive beliefs and pain and emotional suffering population.

**Category**

Treatment - Other

**2****Description**

There won't be any interfering for the control group and they will be treated routinely.

**Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Breast Research Center

**Full name of responsible person**

Fatemeh Hoseini

**Street address**

Fifth floor Motahhari clinic, Namazi Square

**City**

Shiraz

2

### Recruitment center

**Name of recruitment center**

Faghihi Hospital

**Full name of responsible person****Street address**

Faghihi Hospital, Zand Street, Shiraz, Iran

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice-chancellor for Research, Bushehr University of Medical Sciences

**Full name of responsible person**

Dr Afshin Ostovar

**Street address**

Bushehr University of Medical Sciences, Salman Farsi Street, Sabz Abad, Bushehr

**City**

Bushehr

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for Research, Bushehr University of Medical Sciences

**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**

Bushehr University of Medical Sciences

**Full name of responsible person**

Eelham Zahedian

**Position**

Masters Student of Nursing

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**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*