

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

Other areas of specialty/work

Street address

Bushehr University of Medical Sciences, Bushehr, Iran

City

Bushehr

Postal code

Phone

+98 77 3345 0187

Fax

Email

elhamzahed8766@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Masoud Bahreini

Position

PhD in nursing

Other areas of specialty/work

Street address

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

City

Bushehr

Postal code

7518759577

Phone

+98 77 3345 0187

Fax

Email

msdbahreini@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Masoud Bhareini

Position

PhD of Nursing

Other areas of specialty/work

Street address

Bushehr Univeristy of Medical Sciences, Salman Farsi Street, Sabz Abad ,Bushehr,Iran

City

Bushehr

Postal code

7518759577

Phone

+98 77 3345 0187

Fax

Email

msdbahreini@yahoo.com

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