Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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Full name of responsible person
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Position
Masters Student of Nursing

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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