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

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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

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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