The Effectiveness of Group Meta-Cognitive Therapy on Depression, Cognitive Emotional Regulation, and Meta-cognitive Beliefs in Women With Breast Cancer: A Randomized Clinical Trial

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Research Article

Keywords: Breast cancer, depression, cognitive emotion regulation, meta-cognitive therapy, metacognitive beliefs

DOI: https://doi.org/10.21203/rs.3.rs-117625/v1

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Abstract

Background

Breast cancer is one of the most common cancers in Iranian women. They will experience a mental health problem such as depression before, during or after treatment. The aim of this study was to determine the effectiveness of group metacognitive therapy on depression, cognitive emotional regulation, and meta-cognitive beliefs in women with breast cancer.

Methods

In this randomized controlled clinical trial, a total of 24 depressed patients with breast cancer were randomly allocated to experimental and control groups. The experimental group received meta-cognitive therapy in 8 weekly sessions but control group received treatment as usual. Beck's Depression Inventory, cognitive emotion regulation questionnaire, and meta-cognitions questionnaire were completed before, after and one month after intervention. Data were analyzed using Wilcoxon and Chi-square tests.

Results

The mean score of depression in experimental group was reduced from 21.6 ± 4.83 in the pre-test to 13.83 ± 8.12 in one month follow-up (P = 0.16) but there was no significant difference in control group. The mean score of cognitive emotion regulation did not show a significant change in the two groups during the study and follow up period. The mean score of meta-cognitive beliefs was reached 68.75 ± 15.74 from 79.51 ± 10.72 in the experimental group during the follow-up period (P = 0.006), but there was no significant difference in control group in the score of metacognitive beliefs.

Conclusion

These findings support the efficacy of meta-cognitive therapy as a viable psychosocial intervention in depressed patients with breast cancer.

Trial registration

IRCT201606288473N5. Registered on: 05/09/2016

https://www.irct.ir/trial/8946.

Background

Breast cancer is the most common cancers among women [1] and is the second cause of cancer death after lung cancer [2]. More than 3.8 million US women with a history of breast cancer were alive on January 1, 2019 [3]. Some of these women were cancer-free, while others still had evidence of cancer and may have been undergoing treatment [4]. In Iran, Breast cancer is the most common type of cancer in women, which is ranked fifth in cancer mortality. The age of the onset of the disease in Iranian women is
a decade earlier than those in other developed countries [5]. Depression is one of the most common psychiatric disorders among women with breast cancer [6]. Results of some studies indicated that 58% of patients with cancer have mild depression and 38% have major depression [7]. Depression, reduced energy, increased stress from the disease which can ultimately lead to a reduction in the immune function, prolonged recovery time, or a decline in the quality of life of the patients with breast cancer [8]. These symptoms may also reduce individual and social performance [9]. Results of some studies have shown that increase in life expectancy in these patients is related to psychological interventions [10].

In the last few years, the Meta-Cognitive Therapy (MCT) has been considered as a novel approach to address a wide range of mental disorders. Findings indicated that metacognition appears to be related to anxiety, depression, and quality of life in patients with medical chronic conditions. Therefore, dysfunctional metacognitive beliefs might be a relevant factor associated with the process of adapting to illness [11]. Researchers believe that the pivot factor in depression disorder is negative thoughts so that negative attitudes are the main component of mood change [12]. Moreover, changes in each of the different sections of the cognitive system, such as memory, attention, and consciousness, make changes in the mood. In this approach, emotional disorders are attributed to the defect in controlling the negative emotions of negative thoughts and beliefs about the concern and the lack of using effective methods to counteract negative emotions. Consequently, the cognitive emotional regulation in the adaptation of individuals with stressful life events plays an important role that cannot be ignore [13].

The MCT is based on Wells and Matthews Self-Regulatory Executive Function model [14]. The term metacognition was first defined as “Any kind of knowledge or cognitive process in which assessment, monitoring, or control exists [15] and refers to the ideas and opinions of the people in their recognition [16]. According to the fundamental bases of this therapy, psychological disorder occurs when a maladaptive thinking style called the Cognitive Attention Syndrome (CAS) is activated. This syndrome has an important effect on emotional regulation. Therefore, the purpose of the meta-cognitive model is to treat this syndrome and adjust the related meta-cognitive beliefs [17].

Meta-cognitive beliefs are also an important component in coping with depression. Meta-cognitive beliefs are, in fact, conscious assessments and interpretations from the concept of meta-cognitive thoughts and feelings in the individual and judgment about his/her cognitive status. Therefore, it can be said that meta-cognitive experiences can be correlated with emotional disorders [17]. Meta-cognitive beliefs include two categories of negative and positive beliefs. Negative beliefs are referred to as beliefs that are related to the uncontrollability of meaning, meta-cognitive experiences, and the importance and danger of thoughts and positive beliefs are associated with benefits of cognitive activities, such as thought rumination, concern, etc [18].

A growing body of research on MCT indicates an increase in the acceptance of this intervention. Bahrami et al. (2015) conducted a semi-experimental study to evaluate the effectiveness of meta-cognitive group therapy on meta-cognitive beliefs in women with cancer. The results showed that meta-cognitive therapy had a significant effect on the reduction of symptoms associated with meta-cognitive factors in women.
with breast cancer [19]. There is increasing evidence to support the clinical use of MCT for treatment of depression. Data from randomized trials of anxiety and depression have shown recovery rates in MCT of 72–80% [20]. In a randomized trial study, researchers compare MCT with the gold standard treatment, CBT, in patients with GAD. According to results of this study, researchers concluded that MCT seems to produce recovery rates that exceed those of CBT [21]. Normann and Morina in a systematic review, provide an updated meta-analytic review of the effect of MCT for psychological complaints. Their findings indicate that MCT is an effective treatment for a range of psychological complaints. They believed that to date, strongest evidence exists for anxiety and depression [22].

As mentioned, the chronic and prolonged nature of breast cancer disease makes it very difficult for patients to accept and cope with it. Depression is one of the most common psychiatric disorders associated with breast cancer diagnosis. On the other hand, studies suggest that depression affects cognitive and meta-cognitive styles as well as adaptive methods of regulating emotions in individuals. Therefore, the third-generation of cognitive-behavioral psychotherapies such as meta-cognitive therapy seeks to modify the mental processes of individuals.

**Aim of study:** The aim of the study was to determine the effectiveness of Group MCT on depression, cognitive emotional regulation, and meta-cognitive beliefs in women with breast cancer.

**Methods**

**Design and setting** This two-armed controlled clinical trial study was conducted in Shiraz in southern Iran. The study protocol was written in accordance with the CONSORT guidelines [23]. This study conducted in the Breast Disease Research Center that is one of the largest breast disease research and treatment center in southern Iran, which has annually over 25,000 visitors from around the country.

**Eligible criteria**

Participants were recruited from women with breast cancer who referred to the Breast Disease Research Center. The inclusion criteria admitted (a) adults 20-70 years of age, (b) being treated for a diagnosis of breast cancer, (c) mild to moderate depression score by beck’s depression inventory and (d) the ability to attend sessions according to the oncologist. The exclusion criteria were absence from treatment sessions, death, and severe psychological or physiological conditions coincides with the period of psychotherapy.

Estimation of sample size was set at 12 participants in each treatment arm, assuming a standard difference on 1.2 points on the primary outcome, and considering a bilateral significance level of 5% and a statistical power of 85%, adjusted by a 20% rate of dropouts. The estimation of sample size was based on a study by researchers who reported mean and standard deviation of depression in control and intervention groups respectively 21±1.4 and 19.50±1.5 [24].

**Measurements**
At baseline, the demographic data of the patients (age, marital status, occupational status, educational status, place of residence, history of depression, history of hospitalization, duration of cancer, type of cancer therapy, history of psychotherapy and frequency of fertility) was evaluated using a demographic questionnaire.

**Primary outcome**

The primary outcome measure was changes in depression score, measured at baseline (T0), immediately after (T1), and one month after the intervention (T2) using the Beck Depressive Inventory (BDI). The BDI is a 21-item; self-report rating inventory that measures characteristic attitudes and symptoms of depression. The questionnaire is designed for adults and adolescents over 13 years old in the form of self-assessment. The person is asked to consider his or her feelings in the last two weeks and answer the questions. The scores for each question are from zero to three. 2, 11, 2, 5, and 1 articles are dedicated to affection, cognition, overt behaviors, physical signs, and interpersonal semantics. This scale determines the degree of depression from mild to very severe. The score ranges from at least zero to at most 63. The 4-point Likert scale is from 0 to 3 for each substance. Internal consistency for the BDI ranges from .73 to .92 with a mean of .86. The BDI demonstrates high internal consistency, with alpha coefficients of .86 and .81 for psychiatric and non-psychiatric populations respectively [25]. The BDI-Persian had high internal consistency (Cronbach's alpha=0.87) and acceptable test-retest reliability (r=0.74) [26]. The BDI takes approximately 10 minutes to complete.

**Secondary outcomes**

**Cognitive Emotion Regulation Questionnaire (CERQ)**

This 36-item questionnaire evaluates the cognitive strategies that each person uses after experiencing threatening events or life stresses. This scale consists of the following 9 sub-scales, each consisting of four items and each referring to what someone thinks after the experience of threatening or stressful life events: self-blame, other-blame, rumination, catastrophizing, putting into perspective, positive refocusing, positive reappraisal, acceptance, and planning. Cognitive emotion regulation strategies were measured on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always). Individual subscale scores were obtained by summing the scores belonging to the particular subscale (ranging from 4 to 20). The total score is placed in the range of 36 to 180. The psychometric properties of the CERQ were studied in an adult general population sample. The results showed that the CERQ had good factorial validity and high reliabilities, with Cronbach's alphas ranging between .75 and .87 [27]. This questionnaire is a valid, reliable, and appropriate instrument for detecting and assessing cognitive strategies in Iranian patients [28].

**Meta Cognitions Questionnaire (MCQ)**

The MCQ-30 is a short version of the original MCQ and measures individual differences in a selection of meta-cognitive beliefs, judgments and monitoring tendencies considered important in the meta-cognitive
model of psychological disorders. The questionnaire is a 30 items, 4-point Likert, self-report scale. The questionnaire has five subscales. The five subscales of the MCQ-30 are: cognitive confidence, positive beliefs about worry, cognitive self-consciousness, negative beliefs about uncontrollability of thoughts and danger, and beliefs about the need to control thoughts. Subscale scores range from 6 to 24, and total scores range from 30 to 120, with higher scores indicating higher levels of unhelpful metacognitions. Subscales are calculated by summing the following item: lack of cognitive confidence: 8, 14, 17, 24, 26 and 29; positive beliefs about worry: 1, 7, 10, 19, 23 and 28; cognitive self-consciousness: 3, 5, 12, 16, 18 and 30; negative beliefs about uncontrollability and danger: 2, 4, 9, 11, 15 and 21; need to control thoughts: 6, 13, 20, 22, 25 and 27. The MCQ-30 showed good internal consistency, convergent validity, and acceptable to good test-retest reliability [29]. The Cronbach's alpha coefficient of the subscales varied from 0.72 to 0.93. The Cronbach's alpha coefficient of total scale in the Iranian sample has been reported as much as 0.91 [30].

Blindness and randomization

Due to the nature of the meta-cognitive therapy neither the therapist nor the participants can be blinded for the delivered treatment. Data collectors and data analyzer were blind regarding group membership.

Participants randomized on a 1:1 basis into the intervention group (meta-cognitive therapy) or the control group (Treatment As Usual; TAU). In order to randomly allocate the participants to one of the two conditions (intervention and control), a computer generated random number sequence (https://www.randomizer.org/) used by means of a simple allocation strategy. Randomization performed by a statistician otherwise not involved in the study.

Interventions

This study conducted in the fall and winter of 2017. Participants recruited from patients with breast cancer that referred to Breast Cancer Disease Research center. Patients with breast cancer who had the mild to moderate depression, enrolled as participants based on Beck's Depression Inventory. After obtaining informed consent, samples gave their phone numbers and addresses in order to participate and announcing the time, date and place of the therapy sessions by phone (education place was at Breast Disease Research Center). The samples were randomly allocated into two experimental and control groups. Initially, the pretest (MCQ-30 and CERQ) was conducted to obtain the basic data. Then, eight 90-minute sessions were performed for intervention group in addition to TAU (table 1). Each week, a session were held in groups with assignments during and between sessions for this group of samples. The control group received treatment as usual. TAU consist in giving the usual treatment to patients according to accepted standards for depression (except psychotherapy which will not be allowed 6 months before the study nor during it). Post-test was carried out after completing the sessions and one month later from both groups. The method of teaching was a lecture, group discussion, role play, and homework according to Welles’ educational program [31].

Table 1. Content of MCT
| Session | Content                                                                                                                                                                                                                                                                                                                                 | Time |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 1       | Welcome, provide summaries of the treatment model and goals of the sessions, case formulation, conduct a pre-test, practice of ATT, completion of ATT summary sheet. Homework: Practice mindfulness training technique (twice a day), record daily practice of mindfulness training technique.                                                                                       | 90 min |
| 2       | Review of homework, socialize the patient to the maintaining processes, including the impact of worry and rumination and the ineffectiveness of current coping strategies, review of negative beliefs and ruminations as ineffective coping strategies, introduce and practice of Detached Mindfulness (DM), introduce Thinking procrastination, as an experiment to change beliefs related to thinking uncontrollability, Practice ATT. Homework: Practice ATT, Apply DM, Thinking Delay. | 90 min |
| 3       | Review of Homework and MDD-S Scale, review of CAS, metacognitive beliefs are verbally challenged in Socratic dialogues, and behavioral experiments are used to test and generate change in the person's metacognitive predictions or beliefs about CAS strategies, instruct to postpone worry and rumination processes, Identifying Thinking Motivators, and applying DM, practice ATT. Homework: Recording thoughts, Practice ATT, Using DM, activity scheduling. Postpone of thinking, increase the level of activity. | 90 min |
| 4       | Review of homework and MDD-S scale, negative beliefs related to thinking uncontrollability, levels of activity and maladaptive coping, checking the use of thought postpone, Challenging with Positive Metacognitive Beliefs Related to Thinking, Practicing ATT. Homework: recording thoughts, Practice ATT, Expanding the Application of DM, Procrastination, activity scheduling. | 90 min |
| 5       | Review of homework and completion of MDD-S scale, positive metacognitive beliefs, levels of activity and dysfunctional coping, checking the continuous and widespread use of DM, continuing to challenge positive metacognitive beliefs related to thinking, review Levels of activity and suggestions for improving it (identifying and stopping other ineffective coping techniques such as sleeping too much, or possibly drinking alcohol), practicing ATT. Homework: Practice ATT, postpone Thinking, Increasing Activity Level. | 90 min |
| 6       | Homework review and MDD-s scale, positive metacognitive beliefs, activity levels, examining and challenging negative beliefs about emotion and depression, practice ATT (increasing difficulty level). Homework: practice ATT, postpone thinking, continuing activities.                                                                                                                                                     | 90 min |
| 7       | Review the homework and the MDD-S scale, metacognitive beliefs and dysfunctional coping, work on developing a new processing plan (completing the program summary sheet and providing a copy to the patient), reviewing and overcoming fears the patient recovers from depressive symptoms. Practice ATT. Homework: Practice ATT, apply and reinforce.                                                                                     | 90 min |
| 8       | New processing plan, starting work on initial treatment plan, reviewing homework                                                                                                                                                                                                                                                          | 90 min |
and MDD-S scale, preventing recurrence (completing treatment plan), working on remaining metacognitive beliefs, predicting possible motivators and discussing how using a new processing program, scheduling reinforcement sessions.

Ethical considerations

This research has been approved and registered by the ethics committee of the Research deputy of Bushehr University of Medical Sciences with the ethics code [IR.BPUMS.REC.1395.52]. Patients entered this study emphasizing the principle of confidentiality with complete discretion and with informed consent.

Data analysis

Data were analyzed using descriptive statistics (frequency, mean and standard deviation) and inferential statistics via SPSS23 (SPSS, Inc., Chicago, IL, USA) software at a significance level of less than 0.05. The distribution of variables was analyzed by the Kolmogorov-Smirnov test at a significant level of 0.05. Since the distribution of the studied variables was not normal, non-parametric statistical tests such as Chi-square for comparison of demographic variable, Mann Whitney for between group comparison, and Wilcoxon and Friedman tests for within group comparisons were used to analyze the data.

Results

For each group, the number of participants who were randomly assigned, received intended intervention, and were analyzed for the primary outcome, is displayed in the study flowchart (figure 1) according to CONSORT diagram. The trial was completed on schedule.

The participants were in the range of 27-67 years old with average of $50.75(11.34)$ and $47.33(12.34)$ for control and experimental group respectively. The results showed that the variables including marital status, occupational status, educational status, place of residence, history of hospitalization, history of mastectomy and chemotherapy, history of psychotherapy in both experimental and control groups were not statistically significant according to Chi-square test ($p = 0.05$) (Table 2).

In experimental group and in a within-group comparison, results showed that there was a significant difference between the T0 and T1 of depression scores ($P = 0.025$). Moreover, the within-group comparisons showed that the depression score of the patients in the experimental group in T2 was significantly lower than the depression score in the T1 ($P = 0.019$). These changes did not show a significant difference in the control group ($P = 0.393$). In addition, the within-group analysis indicates the difference between the level of depression in the T0 with T2 ($P = 0.016$) (table 2). The results indicated no difference in the mean depression scores between the two groups in T0 ($P = 0.416$). The results also indicated that there was no difference in mean score of depression between two groups in T1 ($P = 0.073$), but the depression score in the two groups in T2 showed a significant difference ($P = 0.006$), so that the mean score of depression in the experimental group was lower than the control group (table 3).
Regarding secondary outcomes, there was no significant difference between the mean score of cognitive emotional regulation in T1 and T2 between the experimental and control groups \((P = 0.908)\) (table 3). The within-group comparison indicated that there was no difference in the total score of cognitive emotional regulation in T1 and T2 in the experimental group \((P = 0.758)\) and in the control group \((P = 0.627)\). The comparison revealed no difference in the total score of meta-cognitive beliefs in T0 \((P = 0.506)\), T1 \((P = 0.488)\), and T2 \((P = 0.088)\) in patients participating in two groups. There was no significant difference between the scores before and immediately after intervention in the experimental group \((P = 0.051)\). However, there was a significant difference between the pre-test and the follow up period score \((P = 0.006)\), so that the follow up score was less than the pre-test score. There was no significant difference between the scores of meta-cognitive beliefs before, immediately after intervention and during follow-up period in the control group \((P = 0.062)\) (table 3).

Table 2: Descriptive characteristics

| P value | Experimental (n=12) | Control (n=12) | Category | Variable                      |
|---------|--------------------|----------------|----------|-------------------------------|
| 0.34    | 1(8.3)             | 2(16.7)        | single   | Marital status (%)            |
|         | 11(91.7)           | 10(83.3)       | married  |                               |
| 0.13    | 11(91.7)           | 12(100)        | Non academic | Educational status (%)      |
|         | 1(8.3)             | 0(0)           | academic |                               |
| 0.16    | 7(58.3)            | 5(41.7)        | Housewife | Occupation (%)                |
|         | 4(33.34)           | 5(41.7)        | Retired  |                               |
|         | 1(8.3)             | 2(16.6)        | Employee |                               |
| 0.11    | 7(58.3)            | 6(50)          | city     | Place of residence (%)        |
|         | 5 (41.7)           | 6 (50)         | village  |                               |
|         | 12(100)            | 12(100)        | yes      | History of hospitalization (%)|
|         | 0(0)               | 0(0)           | no       |                               |
|         | 12(100)            | 12(100)        | yes      | Mastectomy and chemotherapy   |
|         | 0(0)               | 0(0)           | no       |                               |
|         | 0(0)               | 0(0)           | yes      | History of psychotherapy (%)  |
|         | 12(100)            | 12(100)        | no       |                               |

Table 3. Mean difference on primary and secondary outcome at T0 (baseline), T1 (after intervention) and T2 (follow-up) in the experimental/control groups
| variable      | group        | T0 M(SD) | T1 M(SD) | P value | T2 M(SD) | P value* |
|---------------|--------------|----------|----------|---------|----------|---------|
| Depression    | experimental | 21.16(4.83) | 15.58(8.50) | 0.025 | 12.83(88.21) | 0.016 |
|               | Control      | 22.66(5.34) | 23.16(8.89) | 0.969 | 25.75(8.22) | 0.285 |
|               | P value      | 0.416 | 0.073 | 0.006 |
| CE Regulation | experimental | 105(14.72) | 108.41(15.80) | 0.442 | 111.08(23.30) | 0.480 |
|               | control      | 108(13.08) | 111.58(11.56) | 0.102 | 110.16(7.76) | 0.656 |
|               | P value      | 0.644 | 0.644 | 0.908 |
| M C Beliefs   | experimental | 79.51(10.72) | 72.66(11.42) | 0.050 | 68.72(15.74) | 0.006 |
|               | control      | 76.33(12.08) | 76.01(11.62) | 0.769 | 77/91(12.94) | 0.906 |
|               | P value      | 0.506 | 0.488 | 0.088 |

*compare T0 to T2

**Discussion**

The purpose of this research was to determine the effectiveness of MCT on depression, cognitive emotions regulation, and meta-cognitive beliefs in depressed women with breast cancer. The results of post test response indicated that the average of depression in the experimental group decreased significantly from baseline response. These results did not show a significant difference between posttest and one month follow-up measurements. This can support the long term effects of MCT as well as the sustainability of the effects on depression of these patients. The results of a clinical trial study were consistent with the results of present study and showed a reduction in depression in 70% of patients in the post-test and in 90% of patients in the follow-up period [31]. Also, in Iran, Ashoury conducted two methods of CBT and MCT in his study and concluded that MCT and CBT were more effective than pharmacotherapy alone in treatment of major depressive disorder [32]. Furthermore, the results of some studies were consistent with results of this study and reveal the decrease in depression after the intervention of MCT [33-36]. It should be noted that since patients are taught in MCT to challenge beliefs through the use of attention teaching techniques to reduce them, to cut them off by practice or to change their beliefs. In this way, the self-regulatory executive function is disrupted in these individuals and the likelihood of relapse of depression disorder is reduced. In the present study, the rate of depression in the follow-up period was reduced further in comparison with the post-test period. It seems that, since meta-cognitive therapy focuses on mental processes and its controlling factors, changes in these structures require time lapse. In other words, because the thought content is interfered in this therapeutic approach,
more time will be required for the emergence of therapeutic effects than therapies that target behavioral modification.

Other findings of the present study showed that MCT had no significant effect on cognitive emotional regulation. The results of a study which express the direct relationship between the effect of MCT on the cognitive emotional regulation of depressed people [37], contrasts with the results of this study, which indicate further studies in this regard. However, it's important to note that cancer has different pressures and effects on the lives of affected patients. These patients also struggle with the stress and complications of cancer treatments and disease-related crises in addition to depression [38]. It seems that the severity of stress and its accompanying with depression can reduce the effect of the intervention, which as demonstrated in the form of the lack of cooperation of these patients in doing their assignment, reduction their motivation, and the lack of cooperates with their therapist. On the other hand, scientists explain the effect of aging on the reduction of meta-cognitive perceptual function. The average age of the participants in this study was relatively high and it seems that the high mean age of the participants affected the reduction of the treatment effect [39].

The data indicate the reduction of metacognitive beliefs score in the experimental group. There was a significant reduction in metacognitive beliefs score compared with the pre-test and one-month follow-up scores. Wells et al. (2012) stated that the metacognitive beliefs score in depressed patients decreased after metacognitive therapy [40]. Finding of some trial studies also showed a reduction in meta-cognitive beliefs score during MCT [41-43].

Non-homogeneity of the group therapy, lack of controlling the severity of the disease in the group, selection of sample from only one clinic in Shiraz, and short-term follow-up period the limitations of this research. Therefore, the generalizations of the trial finding should be done with caution. It is recommended to conduct future studies with higher standards for sampling as well as inclusion and exclusion criteria to enhance the generalizability. It is also recommended to carry out studies with long-term follow-up.

**Conclusion**

The results of this study indicated that the MCT was effective on depressed patients with breast cancer and reduced the level of depression and meta-cognitive beliefs in these patients. These results lead us to use new methods of psychotherapy such as metacognitive therapy. Women are the mainstay of the family and their mental health ensure the health of the family and society. On the other hand, due to the increasing rate of breast cancer and its psychological consequences, effective treatment of these consequences will prevent challenges in the lives of these people.

**Abbreviations**

MDD: Major Depressive Disorder
MCT: Meta Cognitive Therapy

MCB: Meta Cognitive Beliefs

MCQ: Meta Cognitive Questionnaire

CERQ: Cognitive Emotional Regulation Questionnaire.

TAU: Treatment As Usual.

**Declarations**

**Ethics approval and consent to participate**

This research has been approved and registered by the Ethics Committee of the Research Deputy of Bushehr University of Medical Sciences with the ethics code [IR.BPUMS.REC.1395.52]. Patients entered this study emphasizing the principle of confidentiality with complete discretion and with informed consent.

**Consent for publication**

Not applicable.

**Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests**

The authors declare that they have no competing interests.

**Funding**

This study was funded by Research Deputy of Bushehr University of Medical sciences [grant numbers 1401/71/20/DP]. The funder will have no role in the study implementation, data collection, data analyses or interpretation of study results.

**Authors' contributions**

As the project supervisor, MB was the Chief Investigator; EZ was the Principal Student Investigator, KM and NG were the co-supervisors. MB had over-sight of the project design which was developed jointly with EZ with advice from KM and NG. NG and EZ involve in intervention and data collection. KM provided statistical advice for the design of the data collection, analysis and randomization. All authors read, amended and approved the manuscript.
Acknowledgments

This study is part of a thesis submitted in the partial fulfillment of the requirement for a Master’s degree in Psychiatric Nursing (EZ). We would like to express our appreciation to the Breast Disease Research Center in Shiraz and Clinical Research Development Center of the Shohadaye Khalij Fars Hospital in Bushehr city. Trial registration: IRCT201606288473N5. Registered on: 2016-09-05

https://www.irct.ir/trial/8946.

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