A Double-Blind Randomized Controlled Trial on the Effectiveness of Acceptance and Commitment Therapy on Resiliency, Anxiety and Perceived Stress in Women with Breast Cancer

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Abstract

Introduction: Breast cancer is considered to be the most common cancer diagnosis in the world. Psychological distresses lead to increase in the mortality rate among patient with breast cancer. The present study was conducted to evaluate the effectiveness of acceptance and commitment therapy (ACT) on resiliency, anxiety and stress in women with breast cancer.

Methods: In a double-blind randomized controlled trial, during May to August 2017, 32 women with non-metastatic breast cancer who referred to oncology department of three public hospitals in Ahvaz were selected using a respondent-driven sampling (RDS) and were randomly assigned to experimental and control groups via block randomization method. ACT was provided to the experimental group for eight consecutive weekly ninety minutes and the control group was merely received the treatment as usual (TAU, Pharmacotherapy). Resiliency, anxiety and stress indices were evaluated at two intervals of pre-test and post-test. Data were analyzed by covariance analysis and Pearson correlation by SPSS software, version 22.

Results: The primary outcomes showed that eight weeks of acceptance and commitment therapy were effective on the three variables of resiliency, anxiety and stress (all P<0.001). Secondary outcomes also showed that there is a significant reverse relationship between resiliency variable and anxiety and based on the stress (P<0.05).

Conclusion: These results suggest that the therapeutic models of the third wave are effective and could be associated with clinical applications in the field of cancer prevention and treatment.

Declaration of Interest: None.

Key words: Acceptance and commitment therapy, Resiliency, Anxiety, Stress, Breast cancer.

Introduction

Despite significant advances in medical science, cancer still remains as one of the most important diseases of the present century and is the third leading cause of death after cardiovascular disease and accidents (1). Cancer, if not treated, is always fatal (2). It is characterized by abnormal cell deformation, loss of cell differentiation and irregular shapes (3). Today, the prognosis and survival rate of women with breast cancer has improved significantly throughout the world (4). Breast cancer is one of the most common invasive types of cancer among women, with negative consequences on both physical and psychological functioning (5). One of the side effects of cancer is the experience of anxiety, stress and depression in these patients. The constant concern of patients and their families
leads the patient to mental disorders and causes many social and psychological problems (5, 6). There is compelling evidence of an increased risk of anxiety, depression and suicide, and neurocognitive and sexual dysfunctions in breast cancer survivors compared with women with no prior cancer (7).

Resilience, as an ability to withstand and rebound from crisis and adversity, is becoming an increasingly popular concept in research on intervention and prevention of mental health. Resiliency is a psychological index that its promotion has been considered by researchers to help cancer patients. Resiliency refers to the ability to restore and survival of a painful life (8). Resiliency can be understood as the ability to live and grow in difficult circumstances with some risk factors, and it occurs when a person is in a difficult and unpleasant situation, in order to get rid of it or less damage, maximize the effort to discover and take advantage of personal and environmental protective factors. Resiliency makes the person to take advantage from challenge and tests as an opportunity to empower and excel (9). Studies have shown that resiliency is considered as an indicator of mental health in patients with cancer (10). Although the results of the study by Deshields et al. (11) suggest that the resiliency in the cancer patient is due to the development of disease and is partly the result of the cancer.

On the other hand, most of the survivors from cancer live well, but some of them are exposed to negative mood experiences such as fear of cancer, post-traumatic stress, anxiety and depression (12). Perceived stress is the feelings or thoughts that an individual has about how much stress they are under at a given point in time or over a given time period. Perceived stress incorporates feelings about the uncontrollability and unpredictability of one’s life, how often one has to deal with irritating hassles, how much change is occurring in one’s life, and confidence in one’s ability to deal with problems or difficulties. The results of the study by Kennedy et al. (10), show that stress plays an important role in the development of cancer in these patients. The American Psychological Association (APA) defines anxiety as “an emotion characterized by feelings of tension, worried thoughts and physical changes like increased blood pressure”. Anxiety is a common type of psychological distress in patients with cancer (13). Statistics show that the level of anxiety in patients with cancer is higher than the general population, and a significant proportion of cancer patients report moderate to severe anxiety rate (14). On the other hand, Acceptance and Commitment Therapy (ACT) is a cognitive-behavioral therapy that one of the main goals is psychosocial flexibility, which can be appropriate for improving mental health (15). ACT is a third-wave therapy of behavioral therapy that was introduced by Steven Hayes et al. from the beginning of the 1980s and is known as ACT, rooted in the profound philosophy of "functional conceptualism" and is theoretically based on the theory of the relational frame theory (RFT), which determines how to create suffering by the human mind and the useless ways of dealing with it, as well as the underlying alternatives for these domains. ACT take its name from its main message: take on something beyond personal control and commit to a practice that enriches your life. Studies have shown that acceptance and commitment therapy may be effective in improving the quality of life (16), relieving pain (17), stress and depression (18). The results of the systematic review by González-Fernández et al. (19) suggest that acceptance and commitment therapy is useful in oncologic patients and has improved the emotional state, quality of life and psychosocial flexibility in these patients. Considering the high prevalence of breast cancer in Iranian women and considering the prospect of third wave interventions, we intend to study the effectiveness of acceptance and commitment group therapy on resiliency, anxiety and stress among women with breast cancer.

Methods

The present study was conducted as a double blind randomized controlled trial during May to August 2012. In this regard, among the population of cancer patients in Ahvaz referring to three oncology department of the city, 32 cancer patients were selected in two and three stages by Cloninger formula and based on the alpha (0.05), beta and $\beta \rightarrow \gamma$ (20) using respondent-driven sampling (RDS) method, and randomly assigned to two experimental and control groups through block randomization method. Preliminary evaluation was carried out 28 days prior to the registration of the baseline included an electrocardiogram examination, blood and urine tests by a team consisting of a psychiatrist, two clinical psychologists, and a nurse. Inclusion criteria were diagnosis of breast cancer (stages 2 and 3) defined by The American Joint Committee on Cancer (AJCC), completion of chemotherapy or radiotherapy, age ranges between 18-40 years, ability to read and write in completing questionnaires, resident of Ahvaz or the suburbs.
with a deviation of 30 square kilometers from the center. Exclusion criteria included common psychiatric disorders such as schizophrenia or personality disorders, consumption of psychiatric medication or receiving psychological interventions within the three months prior to the study as well as having experienced any trauma. ACT was provided to the experimental group for ninety minutes session in eight consecutive weeks, and the control group was merely received the TAU. The patients underwent chemotherapy and doxorubicin (Adriamycin), cyclophosphamide (Cytoxan), Tamoxifen (TMX) TAU.

Stage II as invasive breast cancer, the tumor in this stage measures between 2 cm to 5 cm, or the cancer has spread to the lymph nodes under the arm on the same side as the breast cancer. Stage II breast cancer indicates a slightly more advanced form of the disease. At this stage, the cancer cells have spread beyond the original location and into the surrounding breast tissue, and the tumor is larger than in stage I disease. However, stage II means the cancer has not spread to a distant part of the body. At stage II, a tumor may be detected during a breast self-exam as a hard lump within the breast. Breast self-exams and routine screening are always important and can often lead to early diagnosis, when the cancer is most treatable. Stage III as locally advanced breast cancer, the tumor in this stage of breast cancer is more than 2 inches in diameter across and the cancer is extensive in the underarm lymph nodes or has spread to other lymph nodes or tissues near the breast. Stage III breast cancer is a more advanced form of invasive breast cancer. At this stage, the cancer cells have usually not spread to more distant sites in the body, but they are present in several axillary (underarm) lymph nodes. The tumor may also be quite large at this stage, possibly extending to the chest wall or the skin of the breast.

At the beginning of each session, a review of the past assignment was made and then new techniques of ACT were taught, followed by the discussion and teaching of the subject matter in each session was carried out. During the session, special exercises were devoted to the sessions, and at the end of the meeting, some assignments were provided for the subjects. Also, therapeutic sessions ended with the shared experiences of the group members. Resiliency, anxiety and stress indices were evaluated at two intervals of pre-test and post-test. In this study, demographic checklist, structured clinical interview, Connor-Davidson Resilience Scale (CD-RISC), Spielberger’s State-Trait Anxiety Inventory (STAI) and Perceived Stress Scale of Cohen et al were used. The data were analyzed by parametric analysis of covariance and Pearson correlation in SPSS software, version 22 and the significance criterion was 0.05. All the data of this study were collected after agreement with the patient, and informed consent was received before the intervention and publication, and all stages of the study were conducted based on the latest version of the Helsinki Declaration.

Tools

1- **Demographic Checklist**: This questionnaire was developed by the researcher to collect personal information such as parental age, children, and parent education.

2- **Structured Clinical Interview (SCID)**: It is a Clinical Interview that is used to diagnose dysfunctions of axis 1 based on DSM-IV. The reliability coefficient between evaluators for SCID is reported to be 0.60 (21). The diagnostic agreement of this tool was favorable for Persian language for most of the specific and general diagnosis with reliability greater than 0.60. The kappa coefficient for all of the current diagnoses and life expectancy diagnosis was 0.52 and 0.55, respectively (22).

3- **The Connor-Davidson Resilience Scale (CD-RISC)**: The Connor-Davidson Resilience Scale is a 25-item instrument that measures the resiliency in a 5 Likert scale from zero to four. The minimum score of the resiliency in this scale is zero and the maximum score is 100. Results of the study by Ye et al. (23) reported the psychometric properties of this instrument as optimal in the population of cancer patients. The results study of Jowkar et al. (24) indicate that the CD-RISC may be a valid and reliable scale for the assessment of resilience protective resources in an Iranian population.

4- **Spielberger's State-Trait Anxiety Inventory (STAI)**: This questionnaire was designed by Spielberger et al. to assess the level of anxiety. The subjects report the severity of their anxiety feeling in a 4 degree scale (at all, to a degree, moderate, and very high) at a specific time (right now or at this moment). Conclusion the results study of Gholami Booreng et al. (25) showed that research anxiety scale has acceptable reliability and validity and can be used for a variety of applications in an Iranian population. In this study, the reliability coefficient of this questionnaire was estimated to be 0.97.

5- **Cohen et al's Perceived Stress Scale (PSS-14)**: This questionnaire was developed by Cohen et al. and has 3 editions of 4-10 and 14 items that are designed to assess the general stresses perceived in the past month. The finding study of Maroufizadeh et al. (26) the Persian version of PSS demonstrated
satisfactory reliability and validity for assessing perceived stress. In this study, the reliability coefficient of this questionnaire was estimated to be 0.96 using Cronbach's alpha for the whole scale.

Results
To analyze the data, the covariance analysis test with delineation of the effect of pre-test was used. Before applying the parametric test of covariance analysis, its assumptions were examined. The assumption of normal distribution of the data were evaluated by Shapiro–Wilk test (p<0.05). The assumption of the homogeneity of the coefficients was also established. Also, the results of the Leven test indicated the equalization of variances (p > 0.05).

In terms of age index, the average age of participants was 42.4 with a deviation of 5.31. The highest frequency is in the bachelor's degree education. Distribution of the scores of indices of resiliency, anxiety and perceived stress is presented in Table 1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experiment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-test</td>
<td>Post-test</td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Resiliency</td>
<td>28.31 ± 5.41</td>
<td>72.50 ± 6.21</td>
</tr>
<tr>
<td>Anxiety</td>
<td>65.50 ± 5.65</td>
<td>35.44 ± 5.37</td>
</tr>
<tr>
<td>Perceived stress</td>
<td>39.19 ± 4.33</td>
<td>17.44 ± 4.01</td>
</tr>
</tbody>
</table>

In order to evaluate the difference between the scores in the pre-test and post-test phases, the covariance analysis test was used. The results are presented in Table 2.

<table>
<thead>
<tr>
<th>Test name</th>
<th>Magnitude</th>
<th>Assumption df</th>
<th>Error df</th>
<th>F</th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pillai's trace</td>
<td>0.961</td>
<td>3</td>
<td>25</td>
<td>206.14</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Based on the results of Table 2, there is a significant difference between the experimental and control groups at least in one of the dependent variables (resiliency, anxiety and perceived stress) (p <0.0001 and F = 206.14). In order to evaluate more precisely and in the form of post-test, one-way covariance analysis test was used, which is presented in Table 3.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Source of changes</th>
<th>Sum of squares</th>
<th>df</th>
<th>Mean of squares</th>
<th>F</th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resiliency</td>
<td>Pre-test</td>
<td>22.15</td>
<td>1</td>
<td>22.15</td>
<td>0.755</td>
<td>0.393</td>
</tr>
<tr>
<td></td>
<td>Group</td>
<td>14768.67</td>
<td>1</td>
<td>14768.67</td>
<td>503.02</td>
<td>0.0001</td>
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<tr>
<td></td>
<td>Error</td>
<td>792.71</td>
<td>27</td>
<td>29.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>Pre-test</td>
<td>1.41</td>
<td>1</td>
<td>1.41</td>
<td>0.041</td>
<td>0.841</td>
</tr>
<tr>
<td></td>
<td>Group</td>
<td>7176.85</td>
<td>1</td>
<td>7176.85</td>
<td>207.53</td>
<td>0.0001</td>
</tr>
<tr>
<td></td>
<td>Error</td>
<td>933.70</td>
<td>27</td>
<td>34.58</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived stress</td>
<td>Pre-test</td>
<td>1.90</td>
<td>1</td>
<td>1.90</td>
<td>1.90</td>
<td>0.102</td>
</tr>
<tr>
<td></td>
<td>Group</td>
<td>4080.13</td>
<td>1</td>
<td>4080.13</td>
<td>217.29</td>
<td>0.0001</td>
</tr>
<tr>
<td></td>
<td>Error</td>
<td>506.97</td>
<td>27</td>
<td>18.77</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As the results of Table 3 shows, the intervention based on acceptance and commitment has a significant effect on resiliency, anxiety and perceived stress variables (p <0.0001). Pearson correlation test was used to assess the relationship between the variables of resiliency,
anxiety and perceived stress. The results showed that there is a significant inverse relationship between resiliency and anxiety and perceived stress (P< 0.05).

Discussion

The present study was conducted aimed to evaluate the effectiveness of ACT on the indices of resiliency, anxiety and stress in women with breast cancer. The primary outcomes showed that ACT was effective on the three variables of resiliency, anxiety and stress. The secondary outcomes also showed that there is a significant negative relationship between the variables of resiliency, anxiety and stress. In line with our results, the results of the systematic review study by Gonzalez-Franandez and Fernández-Rodriguez (27) show that ACT affects mood and psychosocial flexibility in a significant way. In this regard, the results of the study by Gonzalez-Fernandez et al. (28) showed that acceptance and commitment therapy was effective in improving emotional problems in cancer patients. Also in line with the results of the present study, the results of the study by Fashler et al. (29) show that acceptance and commitment therapy reduces the symptoms of anxiety and improves psychological indices such as psychological flexibility. The results of Datta et al. (30) show that acceptance and commitment therapy, due to increased acceptance, improves the meaning of life and reduces anxiety in cancer patients. Contrary to our results, the results of the study by Low et al. (31) showed that the use of acceptance and commitment therapy compared to routine treatments of cancer had not a significant effect on overall functions of the patients.

A part of the results of this study showed that there is a significant inverse relationship between psychological flexibility and anxiety and perceived stress. In line with our results, the study by Li and Wang (32) show that psychological flexibility has a negative relationship with anxiety and depression.

In explaining these results, it can be acknowledged that the main purpose of acceptance and commitment therapy is to create and increase flexibility that means, to create and increase the ability to choose an option more appropriate among the various options, which would increase the resiliency, psychological well-being and a relaxed feeling. Also, ACT helps to identify people's tensions, thereby reducing mental and emotional exacerbations and coping with stressful resources, and by presenting an acceptance technique or a willingness to experience difficulty coping, or other disturbing events without trying to curb them, makes a greater sense of the concept of standing against the challenges of life. Therefore, avoidance, distress and fear of the challenges are reduced in them. As a result, ACT can reduce the perceived stress of the patients. Also, acceptance and commitment therapy encourages referents to deal with their self-assess as simple thoughts and the individuals are trained to correct negative assessments. It also seeks to undermine empirical avoidance and encourages authorities to fully accept their thoughts, feelings, emotions and impulses, and to set goals for which they will reduce patient anxiety. This treatment can be used as an independent method or along with other therapies such as drug therapy and improve the psychological and behavioral problems of cancer in individuals.

This study was subject to some limitations in the implementation process. The use of self-reporting tool can be associated with the respondent bias. Due to the limited sample of women with breast cancer, the generalization of the results to other groups is not possible, and the lack of follow-up of therapeutic changes due to time constraints can be cited as some of the limitations of this study. It is suggested that future studies along with the paper and pen tools should use biological evaluations to evaluate the efficacy of the treatment. Also, a clinical trial in men with cancer can be a good route for future studies.

Conflict of interest

The authors did not report any conflicts of interest.

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