



Acceptance and Commitment Therapy for Demoralization Syndrome and Cancer-related Trauma: A Randomized Clinical Trial Study

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Abstract

Background: Many women with breast cancer in the process of diagnosing, treating, and surviving show psychological distress such as hopelessness and cancer-related stress. On the other hand, Acceptance and Commitment Therapy (ACT) as a psychological intervention provides a good model for coping with the disease.

Objectives: This study aimed at investigating the effectiveness of ACT on demoralization syndrome and cancer-related trauma in patients with breast cancer and survivors.

Methods: The present study was a clinical trial with pre-test and post-test. It was performed on 52 patients with breast cancer and survivors referred to the Golestan Cancer Patients Association in Gorgan in 2020. Initially, participants were selected by convenient sampling and randomly divided into two treatment groups (patients group and survivors group) and two control groups (patients group and survivors group). Then, the treatment groups underwent ACT for 8 consecutive weekly sessions, but the control groups did not receive any intervention. The data were obtained, using the Demoralization Scale (DS) and Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5) and analyzed by multivariate analysis of covariance (MANCOVA).

Results: The results of the study showed a significant difference in demoralization syndrome components and PCL-5 between the treatment groups of patients and survivors with control groups of patients and survivors ($P < 0.05$). Also, there was no significant difference between the treatment groups of patients and survivors in the components of demoralization and PCL-5 ($P > 0.05$) except for the feeling of failure component ($P = 0.048$).

Conclusions: According to the results, using ACT as a complementary treatment along with medical treatment to prevent and reduce demoralization syndrome and cancer-related trauma is recommended in patients with breast cancer and survivors.

Keywords: Breast, Demoralization, Post-traumatic, Cancer Survivors, Acceptance and Commitment Therapy

1. Background

As one of the most common types of cancer in women, breast cancer can lead to several physical and psychological consequences such as fear of death, fear of cancer recurrence, hopelessness, post-traumatic stress, sleep problems, and reduced quality of life. Even months and years after diagnosis or treatment, these patients may still experience psychological distress and emotional dysfunction (1, 2).

One of the most common clinical problems among patients with cancer and survivors is demoralization (3). Kissane et al. (4) defined the demoralization syndrome as "a psychiatric condition characterized by hopelessness, helplessness, lack of meaning, and existential distress". This syndrome is associated with the patient's persistent

perceived inability to cope with the situation. Also, studies show that demoralization syndrome is more closely related to patients' tendency to die and even predicts it better than depression. Therefore, demoralization syndrome is a significant mental health concern in patients with cancer and survivors that need scientific consideration and intervention (2, 3). On the other hand, despite the need for research on demoralization syndrome related to cancer, clinical factors affecting it and psychotherapy's role to modulate it are not well-established. Therefore, the study of the effect of psychological interventions on this syndrome's modulation seems necessary (5).

Today, with care advancements for patients with cancer, the survival rate of this group of patients is increas-

ing. Therefore, relief from physical and mental suffering is one of the essential goals of patient care. As a life-threatening disease, cancer can cause cancer-related post-traumatic stress in patients (6). In other words, another outcome of cancer diagnosis and treatment is the amount of stress experienced by patients, which in many cases is similar to the symptoms of post-traumatic stress disorder (PTSD). In this regard, studies show that about 50% to 60% of patients with breast cancer perceive cancer diagnosis and treatment as a severe threat to life and physical health. They show it with characteristics such as intense fear, panic, avoidance, and helplessness (7, 8). Also, lack of attention and treatment of post-traumatic stress symptoms in patients with cancer and their survivors can increase pain experience, wish to die, disability, poor self-care, and less healthy lifestyle (6, 9).

Recently, attention to acceptance and commitment therapy (ACT) for patients with cancer has increased. ACT was introduced by Steven C. Hayes in 1983, and compared to other psychological interventions, focuses less on the symptoms of psychological pathology. Instead, this treatment emphasizes acceptance and values because it affects the emotions of patients with cancer. Therefore, ACT addresses the specific and dynamic nature of cancer adaptability (10). ACT's goal is to create psychological flexibility (PF) in individuals via 6 core processes (i.e., acceptance, defusion, self-as-context, being present, values, and committed action). When facing life challenges, psychological flexibility can provide a significant potential for pattern change in the face of cancer-related problems and discomfort for patients with cancer and survivors. Therefore, unlike some psychological interventions that aim at changing disturbing thoughts and feelings, the ACT focuses on accepting those thoughts and feelings and living in the present based on one's life values despite internal discomforts such as challenging emotions, physical pain, and negative memories (11, 12).

2. Objectives

Although there is evidence of the effectiveness of mindfulness-based interventions in improving the mental health of women with breast cancer, it seems that further research is needed to understand the clinical significance of these findings. Besides, ACT studies are low in patients with breast cancer. Therefore, this study aimed at considering the effectiveness of ACT on demoralization syndrome and cancer-related trauma in patients with breast cancer and survivors.

3. Methods

3.1. Research Design and Participants

The design of the current study was a randomized clinical trial (RCT) with pre-test and post-test with the control groups that were registered with the code IRCT20151228025732N60. Also, the present study with the code of ethics IR.SEMUMS.REC.1399.089 was approved by the Ethics Committee of Semnan University of Medical Sciences.

The statistical population of the present study included all patients and survivors of breast cancer referred to the Association for Support of Special and Cancer Patients of Golestan Province (Razieh Farzad Charity Institute) in Gorgan from October to November 2020. The required sample size for each group was determined, using G-Power software. Considering the significance level of 0.05, the effect size of 0.25, and the test power of 0.70, the software showed that the required sample for each group was 13. Therefore, using inclusion criteria and clinical interview, 52 participants including 26 patients and 26 survivors of breast cancer through convenient sampling were selected. Then, participants were divided into 2 treatment groups (patients group and survivors group) and 2 control groups (patients group and survivors group) through random assignment.

The inclusion criteria of patient groups included over 20 years of age, definitive diagnosis of cancer by an oncologist, at least 3 months following the diagnosis, and literacy to complete the research questionnaires. Also, the inclusion criteria of survivor groups included over 20 years of age, completion of common cancer treatments (e.g., surgery, chemotherapy, and radiation therapy) in a recent year, and literacy to complete the research questionnaires.

Exclusion criteria comprised absence from more than 2 treatment sessions, severe psychiatric disorders such as psychosis, mood disorders, and receiving simultaneously counseling or psychotherapy other than the present study. These criteria were investigated via interviews with participants.

3.2. Self-report Instruments

In the current study, data collection tools comprised Demoralization Scale (DS) and Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5).

3.2.1. Demoralization Scale (DS)

Kissane et al. (13) developed this questionnaire in 2004 to assess the demoralization of patients with cancer. This 24-items questionnaire includes 5 subscales of lack of means (5 items), boredom (5 items), disappointment (6 items), feeling of failure (4 items), and helplessness (4

items). It is scored, using the Likert scale in the form of 0 (never), 1 (seldom), 2 (sometimes), 3 (often), and 4 (All the time). Also, in this questionnaire, items 1, 6, 12, 17, and 19 are scored in reverse. Kissane et al. (13) obtained a Cronbach's alpha of this questionnaire of 0.94. In Iranian society, Sarizadeh et al. (14) Cronbach's alpha of this questionnaire in patients with cancer reported 0.82.

3.2.2. PTSD Checklist for DSM-5 (PCL-5)

This questionnaire is a 20-item self-report tool that meets PTSD's diagnostic criteria based on the DSM-5. Five items of this questionnaire are related to the symptoms of re-experiencing (Items 1 - 5). Two items are related to avoiding stimuli related to the traumatic event (Items 6 and 7). Seven items are related to negative alterations in cognitions and mood (Items 8 - 14) and 6 items are related to hyper-arousal (Items 15 - 20). This questionnaire includes a 5-point Likert scale and is scored as 0 (not at all) to 4 (extremely). Blevins et al. (15) reported Cronbach's alpha coefficient of this questionnaire as 0.94. Also, Varmaghani et al. (16) reported the Cronbach's alpha of this questionnaire as 0.92 in the Iranian people.

3.3. Procedure

After referring to the Association for Support of Special and Cancer patients of Golestan Province (Razieh Farzad Charity Institute) and coordinating with the director and social worker's association, using inclusion criteria, participants were selected and completed the study questionnaires (pre-test phase). Then, the treatment group patients on Tuesdays and the treatment group survivors on Sundays received ACT for 8 consecutive weeks. However, the control group did not receive any treatment, but they were placed on a waiting list to receive treatment. Therefore, 4 sessions of treatments were given for those who wished after completing the study.

Also, we tailored treatment sessions based on the specific circumstances of patients and survivors of breast cancer. For example, the participant may be skeptical about therapies or avoid related thoughts (experiential avoidance). Therefore, using experiential exercises and metaphors tried to create willingness toward them (acceptance). Also, thoughts such as "complete recovery may not be possible" or "there is not much time left in life" are considered only as thought and not an absolute reality (cognitive defusion). A summary of treatment sessions is provided in Table 1 (17, 18). At the end of the treatment sessions, all participants completed the study questionnaires again (post-test phase). Moreover, the necessary ethical principles such as informed consent, health and safety priorities of the participants, and confidentiality and protection of participants' information were observed during the study.

Also, treatment of sessions was held outdoor (association yard) due to the prevalence of Covid-19 with distributing sanitary packages (e.g., masks, hand sanitizer, and gloves) and social distance.

3.4. Statistical Analysis

To analyze the data obtained, descriptive indices (the mean and the standard deviation) and after examining statistical assumptions, multivariate analysis of covariance (MANCOVA) and analysis of covariance (ANCOVA) were used with SPSS software version 25. Also, the significance level of the tests was considered 0.05.

4. Results

4.1. Demographic Characteristics

The present study was performed on 52 patients with breast cancer and survivors. The mean and standard deviation of participants' age was in the patient groups (treatment group 43.30 ± 6.43 and control group 46.92 ± 7.74) and survivors groups (treatment group 53.15 ± 6.28 and control group 49.15 ± 8.71) years ($P > 0.05$). Other demographic characteristics of the participants, such as education, marital status, job, duration of illness, and family history of cancer are presented in Table 2. As shown, there is no significant difference between demographic characteristics in the studied groups ($P > 0.05$).

4.2. Descriptive Indicators of Variables

Table 3 shows the descriptive indicators of demoralization syndrome and PCL-5 separately for patients and survivors in the pre-test and post-test stages. As shown, in the post-test phase, the mean scores of the components of demoralization syndrome and PCL-5 decreased in the treatment groups. However, in the control groups, this decrease was absent or insignificant.

4.3. Results of MANCOVA and ANCOVA

After examining the statistical presuppositions, MANCOVA was used to compare the treatment and control groups in the demoralization syndrome and PCL-5. The results showed the assumption of homogeneity of covariance matrices for the patient groups (Box's $M = 32.15$, $F = 1.11$, $P = 0.329$) and survivors groups (Box's $M = 31.70$, $F = 1.09$, $P = 0.346$) is approved. Also, by examining Levene's test in the patients' group, it was found that the assumption of homogeneity of variances for all variables except the feeling of failure and PCL-5 is established ($P > 0.05$). Also, in the survivors' group, the assumption of homogeneity of variances for all variables except lack of means is established ($P > 0.05$).

Table 1. Summary of the ACT Sessions (17, 18)

| Sessions | Content Sessions |
|----------|--|
| 1 | Familiarize participants with the therapist and each other, implement pre-test and familiarize participants with the ACT and therapeutic relationship and contract (e.g., the two mountains metaphor). |
| 2 | Introduce experiential avoidance, and that "control is the problem, not the solution" (e.g., the polygraph metaphor), create creative hopelessness (e.g., the man in the hole metaphor), and homework presentation include a control strategies worksheet. |
| 3 | Assess the task, introduce willingness and acceptance as an alternative to avoidance in participants (e.g., the two scales metaphor), and homework presentation include filling in the head worksheet. |
| 4 | Assess the task, introduce cognitive fusion, introduce defusion exercises for participants (e.g., milk, milk, milk, and labeling thoughts exercises), and homework presentation include moving from fusion to defusion worksheet. |
| 5 | Assess the task, introduce self-as-context: "a transcendent sense of self" for participants (e.g., the chessboard metaphor), and homework presentation include the observer worksheet. |
| 6 | Assess the task, introduce mindfulness exercises for participants (e.g., observing thoughts and body scan exercise), and homework presentation include a notice 5-things worksheet. |
| 7 | Assess the task, introduce and clarify values of the participants (e.g., using a table of values and the funeral metaphor), and homework presentation include a personal values worksheet. |
| 8 | Assess the task, introduce action plans and commitment to them, introduce barriers of commitment action (e.g., the Bubble metaphor), a summary of treatment sessions, encourage participants to follow their exercises, and implement post-test. |

Table 2. Demographic Characteristics of Participants ^a

| Variable | Patients Group | | | Survivors Group | | |
|----------------------------|----------------|-----------|---------|-----------------|-----------|---------|
| | Treatment | Control | P-Value | Treatment | Control | P-Value |
| Education | | | 0.522 | | | 0.443 |
| Elementary school | 9 (69.2) | 7 (53.8) | | 8 (61.5) | 6 (46.2) | |
| Diploma | 2 (15.4) | 4 (30.8) | | 4 (30.8) | 6 (46.2) | |
| Associate degree | - | - | | 1 (7.7) | - | |
| Bachelor's degree | 2 (15.4) | 1 (7.7) | | - | 1 (7.7) | |
| Master's degree | - | 1 (7.7) | | - | - | |
| Marital status | | | 0.141 | | | 1.00 |
| Single | - | 2 (15.4) | | - | - | |
| Married | 13 (100) | 11 (84.6) | | 13 (100) | 13 (100) | |
| Job | | | 0.218 | | | 1.00 |
| Housewife | 12 (92.3) | 11 (84.6) | | 12 (92.3) | 12 (92.3) | |
| Employee | - | 2 (15.4) | | 1 (7.7) | 1 (7.7) | |
| Self Employed | 1 (7.7) | - | | - | - | |
| Duration of illness | | | 0.352 | | | 0.395 |
| Under 1 year | 2 (15.4) | 4 (30.8) | | - | - | |
| 1 to 2 years | 11 (84.6) | 9 (69.2) | | - | - | |
| 2 to 3 years | - | - | | 8 (61.5) | 10 (76.9) | |
| Over 3 years | - | - | | 5 (38.5) | 3 (23.1) | |
| Family history | | | 0.216 | | | 0.116 |
| Positive | 6 (46.2) | 3 (23.1) | | 9 (69.2) | 5 (38.5) | |
| Negative | 7 (53.8) | 10 (76.9) | | 4 (30.8) | 8 (61.5) | |

^aValues are expressed as No. (%).

Table 3. Descriptive Indicators of Demoralization Syndrome and PCL-5 for Pre-test and Post-test in Patients with Breast Cancer and Survivors ^a

| Variable | Treatment Group | | Control Group | |
|---------------------------|-----------------|---------------|---------------|--------------|
| | Pre-test | Post-test | Pre-test | Post-test |
| Lack of means | | | | |
| Patients | 9.21 ± 5.73 | 5.02 ± 4.51 | 6.65 ± 2.67 | 6.46 ± 2.81 |
| Survivors | 7.36 ± 5.86 | 1.46 ± 1.50 | 7.46 ± 1.91 | 6.69 ± 1.79 |
| Disappointment | | | | |
| Patients | 12.50 ± 3.63 | 8.38 ± 5.55 | 12.15 ± 4.43 | 12.46 ± 2.56 |
| Survivors | 13.22 ± 5.64 | 5.75 ± 3.47 | 12.84 ± 1.77 | 12.76 ± 2.74 |
| Boredom | | | | |
| Patients | 12.24 ± 3.43 | 6.62 ± 3.66 | 11.87 ± 2.28 | 11.38 ± 2.25 |
| Survivors | 11.04 ± 4.19 | 5.61 ± 2.56 | 13.30 ± 1.49 | 13.15 ± 2.60 |
| Helplessness | | | | |
| Patients | 9.00 ± 3.93 | 4.76 ± 2.68 | 7.52 ± 2.43 | 7.92 ± 2.39 |
| Survivors | 7.38 ± 3.66 | 3.21 ± 2.23 | 7.53 ± 0.96 | 7.23 ± 1.64 |
| Feeling of failure | | | | |
| Patients | 7.61 ± 1.55 | 4.28 ± 3.01 | 6.69 ± 2.09 | 6.26 ± 1.87 |
| Survivors | 5.57 ± 2.91 | 2.22 ± 1.68 | 7.77 ± 1.01 | 7.23 ± 1.42 |
| PCL-5 | | | | |
| Patients | 41.91 ± 13.41 | 24.94 ± 13.17 | 38.46 ± 10.00 | 38.57 ± 9.51 |
| Survivors | 43.31 ± 11.48 | 24.30 ± 11.99 | 37.13 ± 5.23 | 34.53 ± 6.67 |

^aValues are expressed as mean ± SD.

According to the linear composition of the studied variables, the results of Wilks' Lambda test showed a significant difference in the post-test phase between the treatment and control groups of patients ($P = 0.001$, $df = 6$, $F = 8.72$) and the treatment and control groups of survivors ($P = 0.001$, $df = 6$, $F = 7.81$). Then, ANCOVA was used to decide which of the studied variables was significantly different in the treatment and control groups.

As shown in Table 4, there was a significant difference in the components of disappointment ($P = 0.013$), boredom ($P = 0.001$), helplessness ($P = 0.005$), feeling of failure ($P = 0.046$), and PCL-5 ($P = 0.001$) between the treatment and control groups of patients. However, there was no significant difference in the lack of mean component between the treatment and control groups of patients ($P = 0.150$). Also, there was a significant difference in the components of lack of means ($P = 0.001$), disappointment ($P = 0.001$), boredom ($P = 0.001$), helplessness ($P = 0.012$), feeling of failure ($P = 0.001$), and PCL-5 ($P = 0.001$) between the treatment and control groups of survivors. Finally, there was no significant difference in the components of lack of means ($P = 0.075$), disappointment ($P = 0.129$), boredom ($P = 0.700$), helplessness ($P = 0.344$), and PCL-5 ($P = 0.265$) be-

tween treatment groups of patients and survivors except for the feeling of failure component ($P = 0.048$).

5. Discussion

This study aimed at evaluating the effectiveness of ACT on demoralization syndrome and cancer-related trauma in patients with breast cancer and survivors. The results of this study indicate the effectiveness of ACT in reducing the demoralization syndrome and cancer-related trauma symptoms in patients with breast cancer and survivors. The findings of the present study are consistent with the studies of Rostami et al. (19), which showed that ACT is effective on the demoralization syndrome in the elderly. Also, Sharifiyan Ghazijahani et al. (20) showed that ACT is effective on demoralization syndrome in women with AIDS. However, one of the differences between the current study and the above studies was to consider the effectiveness of ACT on the subscales of demoralization syndrome in the current study. Besides, the results of this study showed that ACT is effective in reducing PTSD symptoms in patients with breast cancer and survivors. This result was in line with previous studies (21-23), which showed that

Table 4. Results of ANCOVA for Demoralization Syndrome and PCL-5 in Patients with Breast Cancer and Survivors

| Variable | P-Value | Effect Size | Power |
|--|---------|-------------|-------|
| Comparison of the treatment group of patients with the control group | | | |
| Lack of means | 0.150 | 0.11 | 0.29 |
| Disappointment | 0.013 | 0.29 | 0.73 |
| Boredom | 0.001 | 0.68 | 1.00 |
| Helplessness | 0.005 | 0.36 | 0.85 |
| Feeling of failure | 0.046 | 0.20 | 0.52 |
| PCL-5 | 0.001 | 0.55 | 0.99 |
| Comparison of the treatment group of survivors with the control group | | | |
| Lack of means | 0.001 | 0.56 | 0.99 |
| Disappointment | 0.001 | 0.47 | 0.96 |
| Boredom | 0.001 | 0.53 | 0.99 |
| Helplessness | 0.012 | 0.30 | 0.74 |
| Feeling of failure | 0.001 | 0.64 | 1.00 |
| PCL-5 | 0.001 | 0.45 | 0.95 |
| Comparison of treatment groups of patients and survivors. | | | |
| Lack of means | 0.075 | 0.16 | 0.43 |
| Disappointment | 0.129 | 0.12 | 0.32 |
| Boredom | 0.700 | 0.00 | 0.06 |
| Helplessness | 0.344 | 0.05 | 0.15 |
| Feeling of failure | 0.048 | 0.19 | 0.51 |
| PCL-5 | 0.265 | 0.06 | 0.19 |

ACT effectively reduces the PTSD symptoms in veterans and women who have experienced infidelity.

To explain the study findings, it can be said that patients with cancer usually use experiential avoidance as a coping strategy that increases psychological problems among them. ACT does not directly focus on reducing symptoms, but reducing the symptoms as a byproduct of re-interacting with valuable life and accepting painful inner experiences (24). In other words, compared to other psychological interventions, the ACT is less problem-oriented and, therefore, can better show the personal and dynamic nature of cancer adaptation (25). Trying to accept unpleasant feelings, thoughts, emotions, and memories instead of changing and eliminating them help people move toward the essential values of their lives instead of being psychologically confronted with these problems. In other words, ACT focuses on promoting value-related behaviors (commitment action) because the goal is for people to act effectively through acceptance, being present, self-as-context, cognitive fusion, and clarifying values despite facing psychological problems (1).

ACT reduces avoidance strategies by psychological flex-

ibility in patients with breast cancer and survivors, allowing them to adopt more adaptive strategies to cope with the challenges associated with cancer and its consequences (11). It seems the ACT is a proper intervention for patients with cancer and survivors because cancer causes a specific type of stress. In other words, patients and survivors of cancer experience adverse and stressful events, which are mostly related to feelings of loss of control and uncertainty. In return, ACT seeks to reduce these concerns by teaching 6 core skills. The premise of ACT for patients with cancer is to improve acceptance, focus on life in the present, improve their psychological flexibility, and not fight or avoid painful emotions. Therefore, once these painful feelings become normal, patients can holistically look at their own lives, recognize the present's values, and take action to improve their condition and quality of life (10).

In summary, the current research supports the use of ACT in the oncology setting. This may be due to the emphasis of treatment on accepting problematic anxieties and feelings such as pain, finding new meaning, purpose, and direction in life through a challenging situation. ACT has

been shown to effectively resolve various problems of patients with cancer such as pain, promoting health-related behaviors, reducing mental distress, and improving physical function. However, it is necessary for more empirical evidence of its effectiveness and cost-effectiveness to widespread use of this treatment in the oncology setting (26).

Despite its strengths, the present study has its limitations. Firstly, the present study was performed on patients with breast cancer and survivors in Gorgan. Therefore, it is necessary to generalize the results of this study with caution to other groups and cities. Secondly, referral to the Association of Cancer Patients of Golestan Province was non-randomly due to the inadequacy of the study site in other associations. Therefore, it is suggested that to increase the generalizability of the study results, patients and survivors referred to other supportive associations should be studied. The third limitation was the impossibility of evaluating follow-up after treatment due to the lack of access to a significant part of the participants. Therefore, it is recommended to be careful about the stability of the therapeutic outcomes after the intervention. Eventually, the lack of use of standard clinical interview structures and qualitative methods was another limitation that needed attention in future studies.

5.1. Conclusions

According to the results, it seems ACT positively affects reducing demoralization syndrome and cancer-related trauma symptoms. Therefore, it is suggested that in addition to conventional medical therapies, ACT should be used as a complementary therapy to prevent demoralization syndrome and cancer-related trauma in patients with breast cancer and survivors. Also, it is suggested that future studies look at the effectiveness of this treatment in other types of cancer.

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Footnotes

Authors' Contribution: Study concept and design: IRB, MSS. Acquisition of data: MSS. Data curation: IRB. Statistical analysis, Analysis, and interpretation of data: ST. Drafting

of the manuscript: MSS. Critical revision of the manuscript for important intellectual content: IRB, ST, FGH. Administrative, technical, and material support: IRB, ST, FGH. Study supervision: IRB

Clinical Trial Registration Code: The design of the current study was a Randomized Clinical Trial (RCT) with pre-test and post-test with the control groups that were registered with the code IRCT20151228025732N60.

Conflict of Interests: The authors have no conflict of interest.

Ethical Approval: The present study with the code of ethics IR.SEMUMS.REC.1399.089 was approved by the Ethics Committee of Semnan University of Medical Sciences.

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Informed Consent: Informed consent was taken from all the participants.

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