Cognitively-Based Compassion Training (CBCT®) in Breast Cancer Survivors: A Randomized Clinical Trial Study

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Abstract

Context. Breast cancer (BC) requires a significant psychological adaptation once treatment is finished. There is growing evidence of how compassion training enhances psychological and physical well-being, however, there are very few studies analyzing the efficacy of compassion-based Interventions on BC survivors. Objective. To study the efficacy of the Cognitively-Based Compassion Training (CBCT) protocol in a BC survivor sample on quality of life, psychological well-being, fear of cancer recurrence, self-compassion, and compassion domains and mindfulness facets. Furthermore, enrollment, adherence, and satisfaction with the intervention were also analyzed. Methods. A randomized clinical trial was designed. Participants (n = 56) were randomly assigned to CBCT (n = 28) or a treatment-as-usual control group (TAU; n = 28). Pre-post intervention and 6-month follow-up measures took place to evaluate health-related quality of life, psychological wellbeing; psychological stress, coping strategies, and triggering cognitions; self-compassion and compassion; and mindfulness in both intervention and wait-list groups. Results. Accrual of eligible participants was high (77%), and the drop-out rate was 16%. Attendance to CBCT sessions was high and practice off sessions exceeded expectations). CBCT was effective in diminishing stress caused by FCR, fostering self-kindness and common humanity, and increasing overall self-compassion scores, mindful observation, and acting with awareness skillsets. Conclusion. CBCT could be considered a promising and potentially useful intervention to diminish stress caused by FCR and enhance self-kindness, common humanity, overall selfcompassion, mindful observation, and acting with awareness skillsets. Nevertheless, future randomized trials are needed and a process of deeper cultural adaptation required.

Keywords

breast cancer, survivorship, compassion training, well-being, self-compassion, fear of cancer recurrence, contemplative training

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Introduction

Breast cancer (BC) has been the second most common cancer in the world and the most frequent cancer among women, with an estimated 1.67 million new cancer cases diagnosed in 2012 (25% of all cancers). BC has been associated with a number of physical, social, and psychological impairments, such as problems of adaptation, difficulties in communication, or depressive and anxious symptoms. ²⁻⁴ It has been observed how psychological and emotional stress increased the experience of pain in patients and reduced overall social performance and is a fundamental factor of suicidal ideation and suicide attempts. ^{5,6}

In addition to confronting intrusive medical procedures (chemotherapy and/or radiotherapy) and side effects, ⁷ it has been reported how BC treatment requires a significant

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psychological adaptation.⁴ Furthermore, once treatment is finished, fear of cancer recurrence (FCR) occurred in around 70% of patients, which has been associated with long-term functional impairments.^{8,9} In nearly half of the survivors, intrusive thoughts about the disease and its treatment (unwanted thoughts, images and memories) occurred years after successful treatment.¹⁰ In such patients, it has been observed that even when the rates of depression decreased, overall well-being did not improve.¹¹ Fatigue and sleep problems were also clinically significant in 60% of patients, which diminished quality of life (QoL).^{12,13}

Nowadays, several psychological interventions have been shown to be beneficial for BC patients. ¹⁴ Recently, interest in mindfulness-based interventions (MBIs) for BC patients has increased significantly, ^{15,16} especially for those patients who have passed the initial malignancy and its treatment but had to deal with functional, behavioral, and persistent emotional difficulties, such as depression, fatigue, fear of illness recurrence, and cognitive impairments. ^{17,18} A systematic review has shown that a specific MBI for cancer patients can be considered an effective coping strategy that diminishes anxiety, stress, fatigue, general mood, and sleep disturbances and enhances QoL. ¹⁹

Compassion is a construct closely related to mindfulness²⁰ and can be defined as the desire to alleviate the suffering and its causes in one's self and those around us.²¹ When compassion is directed toward oneself, it is called self-compassion.²² This process involves kindness and understanding toward oneself in terms of pain or failure, instead of being self-judgmental; perceiving one's difficulties as part of the human experience rather than experiencing them with a sense of isolation; and observing the thoughts and painful feelings with mindfulness instead of overidentifying with them.²³

Like mindfulness, compassion can be trained using specific techniques and procedures (compassion-based interventions [CBIs]) designed to specifically generate cognitive and emotional compassionate habits. Some authors have argued that CBIs could provide useful skills to treat and prevent several psychological difficulties (resources for interpersonal relationships, reduction of depressive symptomatology, reduction of social anxiety, marital conflict, and anger management and deal with the difficulties of being a caregiver). In addition, evidence points out that CBI has been associated with decreased inflammatory responding to a psychosocial stressor.

Different studies have shown how loving-kindness and compassion practices (included in CBIs) have been associated with less physical pain, lower anger, reduced feeling of loneliness, and increased positive emotions. ^{26,27} Other authors have found an increase in positive emotions in everyday experiences after training in compassion, which, in turn, enhanced purpose in life, social connection, and decrease in disease symptoms. ²⁸

Today, there are several CBI protocols²⁹⁻³¹: Zaragoza University's Attachment-Based Compassion Therapy,³² Stanford University's Compassion Cultivation Training,³³ Compassion Focused Therapy,³⁴ Mindfulness and Self-compassion,²² Cultivating Emotional Balance Training,^{35,36} and Cognitively-Based Compassion Training (CBCT).³⁷ Although there are numerous studies on the efficacy of these interventions in healthy populations as well as in clinical settings,^{38,39} there is not much data of the benefits of CBIs in cancer patients.

CBCT is a secular protocol to teach compassion. ²¹ CBCT has been shown to be effective in reducing hormone levels related to psychoimmunological stress systems as well as regulation of inflammatory processes in the adolescent population with early-life adverse events. ^{25,40-44} Recently, Dodds et al¹⁷ found that CBCT, when compared with a wait-list control, resulted in improvements in depression features, functional impairments related to FCR, and avoidance related to traumatic stress and an increase in vitality in a sample of BC survivors (BCSs). Nevertheless, effects of CBCT on QoL have not been thoroughly explored to date in cancer survivors and require further study in other populations.

The main aim of this study was to analyze the efficacy of a CBCT protocol in a randomized clinical trial (RCT; NCT03305952 October 9 to November 2017) on a sample of BCSs. Our primary outcome measure for this study was health-related QoL (physical, social, emotional, and functional domains). Physical and psychological well-being (somatic, depressive, anxious symptomatology), psychological dimensions linked to FCR, mindfulness, self-compassion, and compassion were secondary outcome measures. Moreover, acceptance, adherence, and satisfaction with the intervention were also evaluated.

Methods

Study Design

This RCT compared the benefits of a CBCT intervention versus a treatment-as-usual control group (TAU). The study was approved by FIVO's Clinical Research Ethics Committee (December 2015) and was conducted in compliance with the study protocol, following the CONSORT statement (Consolidated Standards of Reporting Trials), the Declaration of Helsinki, and good clinical practice. The trial was registered at ClinicalTrials.gov (NCT 03305952) on October 9, 2017.

Samble Size

Sample size was calculated a priori using the G*Power software. At total of 42 participants were estimated to be needed in the study to detect a moderate effect size (Cohen's d = 0.50) on the primary and secondary outcomes, an α error of .05, and a statistical power of 0.80. A moderate effect size was expected taking into account the results of Dodds et al, 17

where a compassion-based training in BCSs (compared with a wait-list) showed moderate effect size in QoL-related outcomes (depression, functional impairment, vitality/fatigue) at postintervention. Nevertheless, because we anticipated dropouts, 14 more participants were randomized.

Participants, Recruitment, and Randomization

Eligible participants were recruited and randomized from January 2016 to May 2017. The eligibility criteria were as follows: (1) age between 18 and 75 years, (2) being able to read and write using the Spanish language, (3) history of treated BC within the past 15 years, (4) being free from oncological illness, (5) not receiving any kind of chemotherapy and/or radiotherapy treatment during study, and (6) being free from severe psychiatric disorders assessed with the Mini International Neuropsychiatric Interview (MINI)⁴⁶ Spanish version.⁴⁷ Eligible participants were contacted by their personal psychooncologist either by a telephone call or at a periodic psychooncology appointment visit where they were invited to an explanatory meeting of the study. Potential participants were excluded at the beginning of the study for active severe mental disorders (schizophrenia, bipolar disorder, eating disorders, and major depression), substance use disorders, cognitive impairment, or impaired medical condition. Past and current psychiatric and medical history was determined by clinician assessment with the MINI⁴⁶ Spanish version.⁴⁷

A total of 95 patients were invited to participate in the study, 72 showed interest and 56 met all the inclusion criteria. After signing the informed consent, participants were randomly assigned (by a list of random numbers generated by Research Randomizer software [http://www.randomizer.org]) to either 8 weeks of CBCT or TAU. TAU participants were offered the CBCT protocol at the end of research. Study participants were blinded to group assignment until completion of all baseline assessments. Moreover, outcome assessors, data analysts, and staff were blinded to the allocation at all times during study. Participants were evaluated before and after intervention and at the 6-month follow-up (see Figure 1).

Measures

Measures were obtained on all study participants (CBCT and TAU) at 3 time points: recruitment into the study pre-test), two months after baseline evaluation (posttest) and at 6 months (follow-up). Data were collected on satisfaction, acceptance, and adherence to the CBCT Program, demographic factors, and medical history.

Psychological variables were assessed using standardized and validated self-administered questionnaires. Primary outcome measures included health-related QoL in BC as measured by the Functional Assessment of Cancer Therapy—Breast Cancer (FACT-B+4⁴⁸; Spanish validation⁴⁹) using the

physical QoL, social/family, and social QoL; emotional QoL; functional QoL; and other concern measures. Secondary measurements included the following: somatic, emotional, and general well-being as measured by the Brief Symptom Inventory (BSI-18),⁵⁰ Spanish version⁵¹; Cancer Recurrence Fear assessed with the Fear of Cancer Recurrence Inventory (FCRI)⁵²; self-compassion evaluated with the Self-Compassion Scale–Short Form,⁵³ Spanish version⁵⁴; compassion as measured by the The Compassion Scale⁵⁵; mindfulness facets measured with the Five Facets of Mindfulness Questionnaire–Short Form (FFMQ-SF),⁵⁶ Spanish validation.⁵⁷ Acceptance satisfaction and adherence was measured with the CBCT Evaluation Survey.⁵⁸

Intervention

CBCT was delivered over 8 continuous weeks, in a 2-hour session format through didactics, class discussion, and guided meditation practice. CBCT is a CBI designed by study contemplative investigator Lobsang Tenzin Negi, Ph.D. Although secular in presentation, CBCT is derived from Tibetan Buddhist mind-training (Tibetan lojong) practices. These practices differ in important ways from the MBI practices; whereas MBI practices emphasize the development and maintenance of a nonjudgmental stance toward thought processes and emotional reactions, CBCT practices apply a cognitive, analytic approach. CBCT introduces participants to attentional and mindfulness-based techniques (modules 1-2) to improve attention and awareness before beginning specific compassion practices in training modules 3 to 6. The training protocol modules are sequential and iterative, such that once the 6 modules are completed, each student's daily meditation practice (guided by audio recordings) begins with a brief period of shamatha to calm and focus the mind, followed by analytical practices designed to challenge unexamined assumptions regarding feelings and actions toward others with a focus on generating spontaneous empathy and compassion for themselves and others. A sequence of 8 sessions included didactic teaching combined with meditations designed to build a suite of skills. The CBCT instructor was a clinically trained psychologist, researcher, and experienced 18-year meditator fulfilling requirements for CBCT teacher certification of Emory University Center for Contemplative Science and Compassion-Based Ethics (CCSCBE). To ensure fidelity, 80% of classes taught were video recorded and reviewed by the CBCT training supervisor at CCSCBE. The supervisor reviewed CBCT class plans weekly. The CBCT teacher manual²¹ guided class content. CBCT components of each module were as described below.

Module I: Developing attentional stability and mental clarity. This component was delivered in week 1. The foundation for the practice of compassion is the

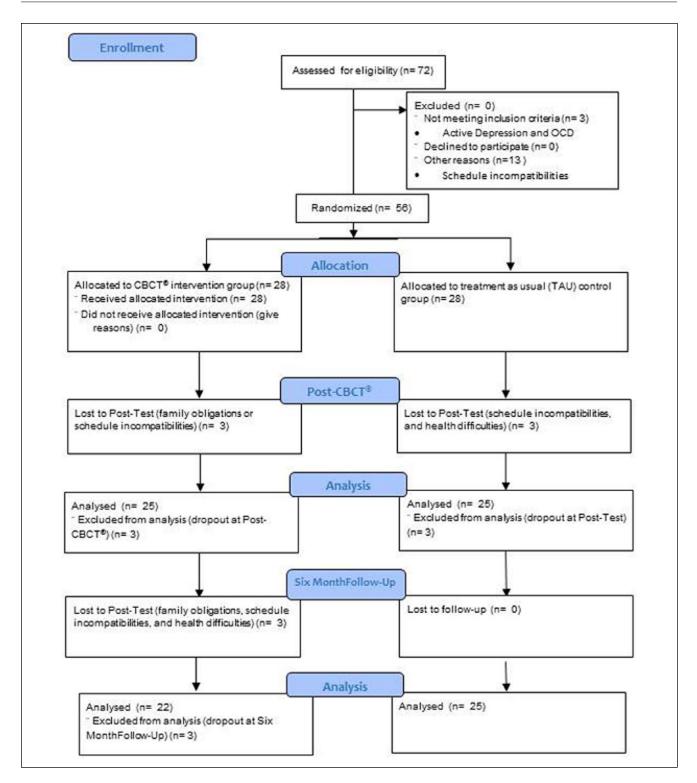


Figure 1. CONSORT 2010 flow diagram for randomized controlled trial of CBCT versus TAU condition. Abbreviations: CBCT, Cognitively-Based Compassion Training; OCD, obsessive compulsive disorder.

cultivation of a basic degree of refined attention and mental stability. One of the basic skills trained in this module is the deliberate intention for cultivating a state of awareness, relaxation, stillness, and alertness. Module II: Cultivating insight into the nature of mental experience. This module is trained through week 2. The stabilized mind is then used to gain insight into the nature of the inner world of thoughts, feelings, emotions,

and reactions through nonjudgmental awareness and resulting in a mental state of nonreactivity and equanimity.

Module III: Cultivating self-compassion. Participants tune in their innate aspirations for happiness and well-being as well as those for freedom from unhappiness and dissatisfactions. This is progressively realizing which mental states contribute to well-being and which ones bring about anxiety, disappointment, and dissatisfaction. Afterward, participants learn to bring to mind the determination and skills to transcend the mental patterns and emotional states that promote distress. These mindsets and skillsets are covered in weeks 3 and 4.

Module IV: Developing equanimity and impartiality. This module focuses on creating balanced relationships with others promoting the initial mental and emotional conditions for constructive social connections through week 5. This is relevant because of the social disconnection that human beings experience when going through traumatic and stressful life events.

Module V: Developing appreciation, affection, and empathy for others. Social connection and gratitude is fostered through the emotional insight of interdependence. This prevents the feeling of isolation. Social connection and gratitude weakens self-centeredness and strengthens endearment and affection toward others, which serves as the catalyst for compassion. Endearment and affection foster a perception of the world based on kindness and not on threat. These emotional states were trained and fostered through week 6.

Module VI: Realizing engaged compassion. During weeks 7 and 8, patients were taught and invited to rest in a compassionate state of mind. The primary focus of this session was to cultivate the essential skillsets and mindsets for interacting in a proactive way with personal and social difficulties, preventing burnout and fostering a motivational readiness to act altruistically.

Each session included lecture, discussion, experiential exercises, and guided meditations. Over the intervention, participants were led through the entire series of integrated, cumulative meditations and provided with guided recordings for each module to support the systematic development of compassion. In between class sessions, participants were encouraged to meditate daily using the recorded meditations and to gradually increase both the length of time for an individual meditation session as well as the cumulative amount of practice time.

The TAU control group continued with their normal rehabilitation program, attendance at briefings given at FIVO, pharmacological treatment, and psychological counseling. TAU participants were offered the CBCT course at the end of research.

Data Analyses

Group differences at baseline on demographic characteristics and clinical variables were analyzed using independent-samples t-tests for continuous data and χ^2 tests for categorical variables. Intent-to-treat mixed-models analyses without any ad hoc imputation were used to handle missing data.⁵⁹ This approach is appropriate for RCTs with multiple time points and pre-to-post-only designs and does not assume that the last measurement is stable (the last observation carried forward assumption). This method is conducted using all available observations.^{60,61} For each outcome measure, a linear mixed model was implemented with Time (pre, post, and 6-month follow-up) as withingroup factor and Group (CBCT and TAU) as betweengroup factor using the MIXED procedure with 1 random intercept per subject. An identity covariance structure was specified to model the covariance structure of the random intercept. Significant effects were followed up with pairwise comparisons. Effect sizes (Cohen's d; 95% CI) were calculated for within- and between-group comparisons. 62-65 All statistical analyses were performed using IBM SPSS version 23 for Windows.

Results

Participant Flow

The final sample was composed of 56 women between 39 and 70 years old (mean age = 52.13 years [SD = 6.96]; 100% female; see Figure 1). During the study, 3 of the 28 participants from the CBCT condition dropped out because of family obligations or schedule incompatibilities at posttest, and 3 more participants could not continue with the study at follow-up because of family obligations, schedule incompatibilities, and health difficulties. Regarding TAU condition, 3 of the 28 participants dropped out because of schedule incompatibilities and health difficulties at posttest. There were no dropouts at follow-up in the TAU group (for more details, please see Figure 1).

Baseline Data

Table 1 shows sociodemographic characteristics and Table 2 clinical features for the CBCT and TAU groups. There were no significant differences between groups in all demographic characteristics or outcome measures at baseline, except for clinical severity (oncological stage when first diagnosed) and Insight factor from the FCRI: F(1, 97.17) = 4.176; P < .05. As for clinical severity when first diagnosed, the CBCT group had a larger number of participants with oncological stage III when compared with the TAU group. The CBCT group also had larger scores for the Insight factor when compared with the TAU group.

Table 1. Sociodemographic and Clinical Data in CBCT and WL Groups.

Sociodemographic and Clinical Data	CBCT (n = 28)	WL (n = 28)	Student t/χ^2	P
Age (in years)	51.64 (6.87)	52.63 (7.16)	0.52	.60
Time since first diagnosis (years)	11.32 (1.44)	10.46 (2.90)	-1.40	.17
Oncological stage at first diagnosis			18.49	.047
I	I (3.6)	3 (10.7)		
II	13 (46.4)	18 (64.3)		
III	14 (50)	7 (25)		
IV	_	_		
Breast cancer treatments			41.48	.21
Partial mastectomy (removal of tumor along with some of the breast tissue around it)	5 (17.9)	7 (25)		
Total mastectomy (removal of entire breast)	17 (60.7)	12 (42.9)		
Radiotherapy	19 (67.9)	18 (64.3)		
Chemotherapy	25 (89.3)	23 (82.1)		
Other	14 (50)	18 (64.3)		
Educational level			2.12	.55
Elementary school or less	7 (25)	6 (21.40)		
Middle school	I (3.6)	I (3.60)		
High school	7 (25)	12 (42.9)		
University studies or more	13 (46.4)	9 (32.1)		
Employment status			1.12	.77
Employed	17 (60.7)	18 (64.3)		
Unemployed	l (3.6)	0 (0)		
Retired	4 (14.3)	5 (17.9)		
Off work	6 (21.4)	5 (17.9)		

Health-Related QoL in BC Survival

Even though, no Time \times Group effect was observed in any of the health-related QoL subscales that compose FACT-B+4 (all P > .05), a Time \times Group tendency was observed for social/family QoL [F(2, 94.758) = 2.710; P = .072], where participants allocated to the CBCT group scored somewhat higher than the TAU control group. Results from within-group comparisons revealed a significant pre-to-post change for emotional and general QoL in the CBCT group with moderate effect sizes (-0.56 and -0.46, respectively). No significant changes were found in TAU (Table 3).

Somatic, Emotional, and General Well-being

In relation to our secondary outcomes, no significant Time \times Group effect was observed for any of the BSI-18 factors. However, within-group comparisons revealed significant pre-to-post and pre-to-follow-up improvements for depressive and general distress symptomatology in the CBCT group, with moderate effect sizes (Cohen's d ranging from 0.44 to 0.55, respectively); no significant changes were observed in the TAU group (Table 3).

Cancer Recurrence Fear

Psychological Stress factor from the FCRI showed significant Time × Group interaction: F(2, 96.863) = 3.521; P < .05. No significant interaction effects were found for any other of the FCRI factors (all P > .05). Within-group comparisons showed significant pre-post and pre-to-follow-up changes for psychological stress in the CBCT group, with effects sizes of 0.68 and 0.49, respectively. No significant changes were found in the TAU group (Table 3).

Self-compassion

A significant Time × Group interaction was seen for self-kindness [F(2, 97.453) = 5.769; P < .01], common humanity [F(2, 98.323) = 6.161; P < .01], and Self-compassion Scale overall score [F(2, 96.277) = 5.423; P < .01]. Overall, participants scored higher on those measures at post- and follow-up time compared with TAU, although no significant differences were found except for self-kindness, indicating that CBCT scored significantly higher compared with TAU at the 6-month follow-up (P < .05; Cohen's d = 0.94; 95% CI = [0.34, 1.55]). Within-group analyses showed significant pre-to-post changes for self-kindness, self-judgment, common humanity, over identification, and self-compassion

Table 2. Participants' Enrollment, Satisfaction, Adherence to Program, and Contemplative Practice Experience Data in the CBCT and TAU Groups.^a

Data Description	
Number of sessions attended	
0	0 (0.00)
I	I (3.55)
2	0 (0.00)
3	0 (0.00)
4	0 (0.00)
5	3 (10.70)
6	5 (17.90)
7	9 (32.15)
8	10 (35.70)
Mean time of practice after session (minutes)	
0	2 (7.15)
9	I (3.55)
12	3 (10.70)
15	6 (21.40)
18	4 (14.30)
More than 24	12 (42.90)
Percentage of home practice with meditation recordings	,
0%	2 (7.15)
10%	l (3.55)
20%	0 (0.00)
30%	0 (0.00)
40%	0 (0.00)
50%	0 (0.00)
60%	3 (10.70)
70%	0 (0.00)
80%	4 (14.30)
90%	2 (7.15)
100%	16 (57.15)
Frequency of practice (days)	()
0	2 (7.15)
Ī	2 (7.15)
2	5 (17.90)
3	6 (21.40)
4	4 (14.30)
5	5 (17.90)
6	2 (7.15)
7	2 (7.15)
Intention to attend to future CBCT groups	2 (7.13)
Yes	25 (89.30)
No	3 (10.70)
Intention to continue CBCT personal practice	3 (10.70)
Yes	25 (89.30)
No	3 (10.70)
CBCT recommendation to others	3 (10.70)
Yes	24 (02.0)
nes No	26 (92.9)
Satisfaction with instructor	2 (7.10)
	37 (03.0)
Yes	26 (92.9)
No	2 (7.10)

 ${\bf Abbreviations: CBCT, Cognitively-Based \ Compassion \ Training; TAU, treatment-as-usual.}$

^aPercentage shown in parentheses.

Table 3. Within-Group Comparisons and Effect Sizes at Preintervention, Postintervention, and 6-Month Follow-up.^a

				CBCT					TAU	
	Preintervention (n = 28)	Preintervention Postintervention Follow-up (n = 28) (n = 26) (n = 22)	n Follow-up (n = 22)	Preintervention vs Postintervention, Mean Difference d [95% CI]	Preintervention vs FW, Mean Difference d [95% CI]	Preintervention (n =28)	Preintervention Postintervention Follow-up (n = 28) (n = 25) (n = 25)	Follow-up (n = 25)	Preintervention vs Postintervention, Mean Difference d [95% CI]	Preintervention vs FW, Mean Difference d [95% CI]
FACTGP	18.93 (5.70)	21.50 (3.93)	21.27 (4.09)	-2.24, -0.44 [-0.87, -0.01]	-2.20, -0.40 [-0.89, 0.09]	17.57 (5.96)	17.68 (6.16)	17.52 (5.34)	-0.08, -0.02 [-0.24, 0.20]	0.07, 0.01 [-0.35, 0.36]
FACTGS	17.11 (6.05)	19.23 (5.51)	18.82 (5.79)	-1.81, -0.34 [-0.65, -0.03]	-1.12, -0.27 [-0.59, 0.04]	17.56 (5.46)	16.60 (5.39)	16.40 (5.07)	0.86, 0.17 [-0.07, 0.41]	1.06, 0.21 [-0.14, 0.55]
FACTGE	13.07 (5.26)	16.12 (4.09)	14.00 (4.69)	-2.84,** -0.56 [-0.92, -0.20]	-0.68, -0.17 [-0.56, 0.22]	13.39 (4.94)	14.72 (4.63)	13.32 (5.32)	-1.33, -0.26 [-0.46, -0.07]	0.07, 0.01 [-0.40, 0.43]
FACTGF	15.75 (6.10)	17.54 (3.20)	17.64 (4.61)	-1.55, -0.29 [-0.72, 0.15]	-1.68, -0.30 [-0.76, 0.16]	13.82 (5.68)	15.40 (4.39)	15.56 (4.81)	-1.41, -0.27 [-0.55, 0.01]	-1.57, -0.30 [-0.75, 0.16]
FACTGEN	64.86 (20.04)	74.38 (11.48)	71.73 (15.45)	-8.45,* -0.46 [-0.82, -0.10]	-5.73, -0.33 [-0.73, 0.06]	62.85 (15.86)	64.40 (14.73)	62.80 (17.63)	-1.60, -0.09 [-0.33, 0.14]	0.00, 0.00 [-0.40, 0.41]
BSI SOM	7.39 (5.87)	4.88 (4.04)	5.64 (4.18)	2.00, 0.42 [0.11, 0.72]	1.53, 0.29 [-0.16, 0.74]	8.93 (5.47)	8.64 (5.70)	8.32 (5.03)	0.31, 0.05 [-0.17, 0.27]	0.63, 0.11 [-0.24, 0.46]
BSI DEP	9.18 (7.13)	5.65 (5.27)	5.14 (5.19)	2.91,* 0.49 [0.11, 0.87]	3.55,* 0.55 [0.13, 0.97]	9.36 (6.24)	7.76 (6.54)	8.56 (5.87)	1.68, 0.25 [0.00, 0.50]	0.88, 0.12 [-0.16, 0.41]
BSI ANX	8.21 (5.93)	6.15 (5.01)	6.09 (5.38)	1.69, 0.34 [-0.05, 0.73]	1.96, 0.35 [-0.12, 0.81]	9.00 (6.51)	7.88 (5.94)	7.56 (5.49)	1.27, 0.17 [-0.02, 0.35]	1.59, 0.21 [-0.10, 0.53]
esi	24.79 (17.55)	16.69 (13.12)	16.86 (13.12)	6.51,* 0.45 [0.10, 0.79]	6.98,* 0.44 [0.00, 0.88]	27.29 (16.84)	24.28 (16.74)	24.44 (15.26)	3.28, 0.17 [-0.03, 0.37]	3.12, 0.16 [-0.14, 0.47]
FCRTRIG	13.11 (9.30)	13.04 (8.12)	13.59 (9.28)	0.00, 0.01 [-0.32, 0.33]	-0.49, 0.14 [-0.32]	11.43 (8.81)	12.32 (8.98)	13.44 (7.42)	-1.08, -0.10 [-0.27, 0.08]	-2.20, -0.22 [-0.47, 0.03]
FCRPSTR	8.39 (5.12)	4.81 (3.43)	5.95 (4.50)	3.41,*** 0.68 [0.36, 1.00]	2.34,* 0.46 [0.06, 0.86]	7.93 (4.45)	7.40 (3.96)	8.16 (4.05)	0.57, 0.12 [-0.14, 0.37]	-0.20, -0.05 [-0.41, 0.31]
FCRCOP	22.11 (5.41)	23.96 (3.84)	21.36 (4.75)	-1.61, -0.33 [-0.89, 0.22]	1.07, 0.13 [-0.27, 0.54]	23.39 (5.69)	23.72 (6.26)	22.76 (4.56)	-0.08, -0.06 [-0.26, 0.15]	0.88, 0.11 [-0.22, 0.44]
FCRINS	7.18 (5.29)	6.65 (4.91)	6.95 (5.20)	0.43, 0.10 [-0.11, 0.31]	0.12, 0.04 [-0.14, 0.22]	6.96 (5.05)	7.00 (4.75)	6.88 (3.52)	-0.04, -0.01 [-0.23, 0.22]	0.08, -0.02 [-0.27, 0.30]
SCS_SK	2.59 (1.11)	3.27 (0.86)	3.34 (0.78)	-0.63,* -0.60 [-1.08, -0.11]	-0.70,** -0.66 [-1.2, -0.11]	2.79 (1.19)	2.72 (1.19)	2.42 (1.09)	0.04, 0.06 [-0.20, 0.31]	0.34, 0.30 [-0.10, 0.70]
SCS_SJ	3.43 (1.26)	2.79 (1.03)	2.70 (1.01)	0.57,* 0.49 [0.07, 0.92]	0.72,** 0.56 [0.19, 0.93]	3.34 (1.27)	2.94 (1.42)	3.28 (1.01)	0.40, 0.31 [0.01, 0.60]	0.06, 0.05 [-0.24, 0.33]
SCS_CH	2.70 (1.02)	3.27 (1.03)	3.45 (0.82)	-0.54,* -0.54 [-1.01, -0.07]	-0.75,** -0.71 [-1.18, -0.25]	3.16 (1.20)	2.82 (1.00)	2.84 (0.98)	0.32, 0.28 [-0.20, 0.75]	0.30, 0.26 [-0.18, 0.70]
SCS_I	2.98 (1.21)	2.62 (1.18)	2.64 (1.13)	0.29, 0.29 [-0.06, 0.64]	0.31, 0.27 [-0.13, 0.67]	3.02 (1.26)	2.66 (1.26)	3.06 (0.93)	0.35, 0.28 [0.03, 0.52]	-0.49, -0.03 [-0.40, 0.34]
SCS_M	2.82 (1.02)	3.23 (0.82)	3.20 (0.87)	-0.36, -0.39 [-0.87, 0.08]	-0.35, -0.36 [-0.81, 0.08]	3.16 (1.11)	3.10 (1.11)	3.00 (0.90)	0.07, 0.05 [-0.30, 0.41]	0.17, 0.14 [-0.18, 0.46]
SCS_OI	3.39 (1.17)	2.75 (0.96)	2.84 (0.99)	0.60,* 0.53 [0.16, 0.90]	0.52, 0.46 [0.14, 0.78]	3.42 (1.17)	3.18 (1.33)	3.32 (1.07)	0.27, 0.20 [-0.10, 0.50]	0.13, 0.08 [-0.33, 0.50]
SCS_TOTAL	2.71 (0.90)	3.27 (0.76)	3.30 (0.73)	-0.49,** -0.60 [-0.98, -0.23]	-0.55,** -0.64 [-1.00, -0.28]	2.89 (0.91)	2.98 (0.93)	2.77 (0.69)	-0.10, -0.10 [-0.33, 0.14]	0.11, 0.13 [-0.20, 0.45]
COMP_TOTAL	20.41 (2.89)	22.01 (2.36)	21.76 (2.75)	-1.53,* -0.54 [-0.95, -0.13]	-1.49, -0.45 [-0.90, -0.01]	19.95 (2.68)	20.87 (2.80)	20.70 (3.15)	-0.88, -0.33 [-0.64, -0.03]	-0.71, -0.27 [-0.68, 0.14]
FFMQ_OB	12.03 (2.85)	14.54 (2.93)	13.50 (2.81)	-2.41,*** -0.86 [-1.26, -0.45]	-1.25, -0.50 [-0.93, -0.07]	12.89 (2.71)	13.28 (3.82)	12.20 (3.14)	-0.41, -0.14 [-0.34, 0.06]	0.67, 0.25 [-0.07, 0.56]
FFMQ_D	13.07 (4.45)	13.62 (3.32)	13.09 (4.02)	-0.37, -0.12 [-0.36, 0.12]	-0.13, 0.00 [-0.25, 0.24]	13.25 (3.28)	12.84 (3.39)	13.20 (2.93)	0.37, 0.12 [-0.18, 0.42]	0.01, 0.01 [-0.39, 0.42]
FFMQ_AW	11.68 (3.62)	11.92 (3.31)	11.82 (3.59)	-0.29, -0.06 [-0.40, 0.27]	-0.54, -0.04 [-0.45, 0.37]	12.14 (3.57)	11.88 (4.10)	10.32 (2.87)	0.14, 0.07 [-0.18, 0.32]	1.70,* 0.50 [0.14, 0.85]
FFMQ_NJ	11.93 (3.83)	12.38 (3.68)	13.00 (4.07)	-0.42, -0.11 [-0.47, 0.24]	-0.93, -0.27 [-0.62, 0.07]	10.96 (4.26)	12.20 (4.62)	11.04 (4.17)	-1.12, -0.28 [-0.52, -0.05]	0.05, -0.02 [-0.36, 0.32]
FFMQ_NR	11.54 (2.50)	12.12 (2.49)	12.27 (2.96)	-0.51, -0.23 [-0.68, 0.23]	-0.59, -0.28 [-0.67, 0.10]	11.54 (2.47)	11.76 (2.37)	10.92 (2.84)	-0.15, -0.09 [-0.50, 0.32]	0.69, 0.24 [-0.12, 0.60]

Abbreviations: CBCT = Cognitively-Based Compassion Training TAU, treatment as usual control group; FW. 6-month follow-up; FACTGF, Physical quality of life; FACTGEN, General quality of life; BSI Som, Brief Symptom inventory somatic symptoms; BSI Dep, BSI depressive symptoms; BSI anxiety symptoms; GSI, General Symptom ludex; FCRTRIG, Fear of Cancer Recurrence triggers; FCRPSTR, FCR psychological stress; FCRCOP, FCR coping strategies; FCRINS, FCR insight; SCS_SK, Self-Compassion Scale self-kindness; SCS_SI, SCS indiffulness; SCS_OI, SCS overidentification; SCS_Total, SCS total; COMP_TOTAL, Total Compassion Score; FFMQ_OB, five Facets of Mindfulness Questionnaire observe; FFMQ_D, FFMQ describe; FFMQ_AW, FFMQ awareness; FFMQ_II, FFMQ nonjudgmental; FFMQ_NR, FFMQ NONREACTIVITY.

overall scores in the CBCT group (Table 3). These changes were maintained at follow-up for all those outcomes, except for the overidentification subscale. In the TAU group, non-significant changes were found.

Compassion

Results showed no significant Time × Group effect. Withingroup comparisons revealed a significant pre-to-post change in the CBCT group with moderate effect size (d = 0.75) and nonsignificant change in the TAU group (Table 3).

Mindfulness Facets

Results showed a significant interaction of Time × Group for observing (F[2, 96.052] = 4.709; P < .05) and awareness facets (F[2, 98.598] = 3.444; P < .05) from FFMQ. Participants in the CBCT scored significantly higher than those in the TAU group for observing at postintervention (P < .05; d = 0.37; 95% CI [-0.19, 0.92]) and follow-up (P < .05; d = 0.43; 95% CI [-0.15, 1.01]) as well as for awareness at follow-up (P < .05; d = 0.45; 95% CI [-0.12, 1.04]). Within-group comparisons revealed a significant pre-post change for observing in CBCT, with large effect size (-0.86), and a significant pre-intervention to follow-up change for awareness in TAU, with moderate effect size (0.50; Table 3).

Acceptance Satisfaction and Adherence

In the CBCT group, 27 participants (96.4%) attended 5 or more of the 8 sessions of the program. In all, 25 (89.30%) participants practiced at home from 12 to 24 or more minutes in total, across all 8 weeks; 25 (89.30%) participants practiced on their own with the meditation recordings, and 9 (32.15%) of the 28 participants used the prerecorded meditation between 60% and 90% of the time (for more details see Table 2); and 13 (46.50%) participants practiced from 4 to 7 days a week. A total of 25 participants (89.30%) indicated that they would participate in future CBCT courses if offered and that they would continue to practice after the course program ended; 26 (92.90%) said that they were satisfied with the program and that they would recommend CBCT to other participants, and confirmed that they felt satisfied with the instructor's ability to facilitate the course sessions.

Discussion

The present article aimed to analyze the efficacy of a CBCT program to improve variables associated with health-related QoL (physical, social, emotional, and functional dimensions); somatic, depressive, and anxious symptomatology; psychological dimensions linked to FCR; and

self-compassion, compassion, and mindfulness trait in a BCS clinical sample compared with a TAU control group after the intervention and a 6-month follow-up. Feasibility, acceptance, and satisfaction of this program was also evaluated.

Our findings suggest that an 8-week CBCT protocol is efficacious in reducing psychological stress related to FCR and increasing self-kindness, common humanity, general self-compassion, observation, and acting with awareness mindfulness skills. Regarding QoL, CBCT was not shown to be efficacious compared with TAU; however, in the pre-post analysis, it shows effects on emotional and general factors. Regarding symptoms, participants allocated to the CBCT intervention did show reductions in depressive and general distress symptomatology compared with those in the TAU group; however, improvements in pre-post analysis in the CBCT group were observed in depressive and general symptomatology after intervention and at 6-month-follow-up. Growing literature has validated interventions with active mindfulness components to be effective for diminishing depression and increasing general psychological well-being in oncological survivorship.66 More specifically, previous studies with CBCT have also been validated as a promising intervention for depressive symptomatology in the healthy population⁶⁷ and specific clinical oncological settings.¹⁷

It is widely known how once the physical threat of cancer is surpassed, FCR is one of the most significant sources of distress in BCSs. 68-71 Previous studies showed how implementing a contemplative practice in daily life resulted in significant reductions in FCR which, in turn, mediated significant reductions in perceived stress and anxiety. CBCT has shown hints of significant improvements in functional impairment associated with fear of recurrence. In the present study, CBCT has proved to be efficacious in facilitating motivational, attentional, cognitive, and emotional resources and enables BCSs to cope with the distress that evokes thoughts, images, or memories related to FCR.

In relation to self-compassion domains, CBCT proved to improve the ability to be kind in the face of one's own inadequacies and vulnerabilities, not feel alienated when experiencing difficulties (self-kindness and common humanity, self-compassion traits), and aid overall self-compassion. These self-compassion dimensions have been strongly related to well-being, happiness, and resilience in different studies. 15,36,73-78 According to Neff and colleagues, 53,79 the constituents of self-compassion that have been highlighted in their studies are central to fostering a self-compassionate mindset when coping with one's own inadequacies, personal failures, and external circumstances that are hard to bear. This perspective realizes imperfection as part of the shared human condition, so that one's weaknesses are seen from a broad, inclusive perspective. Similarly, difficult life circumstances are framed in light of the shared human experience, fostering connection instead of disconnection

and isolation when experiencing suffering. In this sense, when assuming a non–self-compassionate outlook, people tend to feel isolated, harsh, and emotionally reactive when considering personal flaws, weaknesses, or hardship.

CBCT was not seen to be efficacious compared with TAU in the increase of compassion scores; however, data show significant improvements in compassion at posttest for the CBCT group with medium effect size, and no significant improvements for TAU. These findings are in line with previous results in compassion measures related to CBIs. 80,81 These results could be explained by several factors, such as the length of the intervention; other CBCT studies have been done with an extended format.⁶⁷ This extension is relevant given the complex and numerous psychosocial and physiological impairments in survivorship when trying to adapt CBCT in future studies. Furthermore, more efforts should be focused on adapting the CBCT program to Latin-Mediterranean-Catholic cultural contexts. In these contexts, compassion as proposed by CBIs is relatively new and needs a longer time to be integrated into the individual and collective schema.

Regarding mindfulness facets, data reveal that CBCT is an effective intervention that fosters abilities to observe external and internal phenomena or stimuli with awareness (mindful observation factor, FFMQ trait) and act mindfully in daily activities (acting with awareness scores, FFMQ trait). Although CBCT is a protocol that uses meditation to generate mindsets and skillsets related to well-being, no other interaction in mindfulness facets were reported as significant in this study. This may be a result of the orientation of this program, which pays special attention and care to the cognitive strategies and techniques that have been tested to enhance well-being.* However, efforts to accurately assess mindfulness facets are highly needed in contemplative training programs that include analytical approaches that enhance well-being. 84-87 We think that this point is relevant because of the importance of the cognitive constituents that have been highlighted as central in compassion mind training.^{88,89}

To sum up, results from this RCT study also suggest that CBCT is a feasible and highly satisfactory 8-week intervention among BCSs. Moreover, the adherence rate was higher than in previous studies with CBCT and BCSs. ¹⁷ In this previous study, adherence was assessed in 2 ways: logged home practice time between participant and attendance at weekly classes as recorded by the teacher. In the present study, data suggest that CBCT has high rates of attendance, high rates of adherence to home practice, and high scores in minutes of practice between sessions. Moreover, most of the participants had a high rate of practice frequency a day after finishing each session. A high percentage of these participants wish to continue with CBCT training if offered and would recommend CBCT to other patients. Data

confirm a high level of satisfaction with the program. Finally, most of the participants intend to continue practicing CBCT on a daily basis.

Several limitations and methodological issues with this study should be mentioned: (1) The results might be influenced by participants' contemplative experience prior to the study, and this is one variable that should be taken into account in future studies; (2) considering that this is the first CBCT study conducted outside an Anglo-Saxon context, refinement in the adaptation process to Latin-Mediterranean-Catholic cultural contexts must be examined. This will be included in future analyses with samples of Spanish BCSs and CBCT.

However, caution must be exercised when considering the effects of compassion training in this study; results suggest that CBCT could be considered as a promising protocol that aids BCSs in coping with the stress evoked by FCR, fosters self-compassion facets that promote well-being and resilience, and nurtures mindful abilities.

This research is another call for deepening scientific knowledge and paying more attention to the mechanisms and implications of training in compassion. One of the main goals of compassion programs is to cultivate skills to cope with internal (feelings, thoughts, sensations, memories, selfcriticism, etc) and external (lost, sickness, death, criticism) difficulties and turn them into opportunities for growth from the basis of a selflessness perspective. According to a theoretical construct discussed by some authors, 90,91 the abilities embedded in CBIs offer a selflessness perspective that cultivate conative, attentional, cognitive, and affective abilities that enhance authentic and lasting well-being. 92 Moreover, as far as we know, this is one of the first studies to evaluate the effects of a CBI in an oncological survivor sample and the first study to measure the efficacy of CBCT in a Latin-Mediterranean-Catholic setting.

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Declaration of Conflicting Interests

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