Original Article

Acceptance and Commitment Therapy for Breast Cancer Survivors With Fear of Cancer Recurrence: A 3-Arm Pilot Randomized Controlled Trial

Shelley A. Johns, PsyD [1,2]; Patrick V. Stutz, BA [1]; Tasneem L. Talib, PhD[2]; Andrea A. Cohee, PhD [3]; Kathleen A. Beck-Coon, MD[1,3]; Linda F. Brown, PhD[1]; Laura R. Wilhelm, PhD[4]; Patrick O. Monahan, PhD[5]; Michelle L. LaPradd, MS[1]; Victoria L. Champion, PhD [3]; Kathy D. Miller, MD[1,6]; and R. Brian Giesler, PhD[7]

BACKGROUND: Fear of cancer recurrence (FCR) has a profound negative impact on quality of life (QOL) for many cancer survivors. Breast cancer survivors (BCS) are particularly vulnerable, with up to 70% reporting clinically significant FCR. To the authors' knowledge, evidence-based interventions for managing FCR are limited. Acceptance and commitment therapy (ACT) promotes psychological flexibility in managing life's stressors. The current study examined the feasibility and preliminary efficacy of group-based ACT for FCR in BCS. **METHODS:** Post-treatment BCS (91 patients with stage I-III disease) with clinical FCR randomly were assigned to ACT (6 weekly 2-hour group sessions), survivorship education (SE; 6 weekly 2-hour group sessions), or enhanced usual care (EUC; one 30-minute group coaching session with survivorship readings). FCR severity (primary outcome) and avoidant coping, anxiety, post-traumatic stress, depression, QOL, and other FCR-related variables (secondary outcomes) were assessed at baseline (T1), after the intervention (T2), 1 month after the intervention (T3), and 6 months after the intervention (T4) using intent-to-treat analysis. **RESULTS:** Satisfactory recruitment (43.8%) and retention (94.5%) rates demonstrated feasibility. Although each arm demonstrated within-group reductions in FCR severity over time, only ACT produced significant reductions at each time point compared with baseline, with between-group differences at T4 substantially favoring ACT over SE (Cohen *d* for effect sizes, 0.80; $P < .001$) and EUC (Cohen *d*, 0.61; $P < .01$). For 10 of 12 secondary outcomes, only ACT produced significant within-group reductions across all time points. By T4, significant moderate to large between-group comparisons favored ACT over SE and EUC with regard to avoidant coping, anxiety, depression, QOL, and FCR-related psychological distress. **CONCLUSIONS:** Group-based ACT is a feasible and promising treatment for FCR and associated outcomes in BCS that warrants testing in larger, fully powered trials. ***Cancer* 2020;126:211-218**. © *2019 American Cancer Society*.

KEYWORDS: acceptance and commitment therapy (ACT), anxiety, breast neoplasms, fear, quality of life, survivorship.

INTRODUCTION

Fear of cancer recurrence (FCR) is one of the most prevalent, persistent, and disruptive problems for cancer survivors.[1-3] Characterized by maladaptive coping, intrusive thoughts, and excessive distress,[4] clinically significant FCR disproportionally affects breast cancer survivors (BCS) compared with survivors of other common cancers.[5,6] Although approximately 90% of the 3.5 million American BCS are expected to survive ≥5 years after treament,[7] up to 70% of survivors report clinically significant FCR,[8,9] making it the most frequently reported unmet need of BCS.[1,10] Left untreated, debilitating fears may linger throughout survivorship,[1,2] thereby reducing quality of life (QOL).[1,2,8,11,12]

Many BCS manage FCR with maladaptive hypervigilant or avoidant coping.[11,13] Hypervigilant coping may result in excessive monitoring through daily breast self-examinations or requests for unnecessary scans, whereas avoidant coping involves attempts to ignore thoughts of cancer.[1,14] Although avoidance provides short-term stress reduction, such efforts often fail over time as thoughts of death become increasingly intrusive.[11,14]

Cognitive behavioral therapy (CBT) is a common psychotherapeutic intervention for patients with FCR.[15] Several CBT trials have included FCR as a primary[16-19] or secondary outcome.[20,21] Although CBT has proven superior to usual care in reducing FCR (reported effect sizes of −0.20 to −0.73),[16-18] CBT generally demonstrates limited advantage

Corresponding author: Shelley A. Johns, PsyD, Center for Health Services Research, Regenstrief Institute, Inc., 1101 W 10th St, RF-226, Indianapolis, IN 46202; sheljohn@iu.edu

[1]Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana; [2]Center for Health Services Research, Regenstrief Institute, Inc., Indianapolis, Indiana; [3]Indiana University School of Nursing, Indianapolis, Indiana; [4]Department of Behavioral Medicine and Psychiatry, West Virginia University School of Medicine, Charleston, West Virginia; [5]Department of Biostatistics, Indiana University School of Medicine, Indianapolis, Indiana; [6]Research and Clinical Trials, Indiana University Simon Cancer Center, Indianapolis, Indiana; [7]Department of Psychology, Butler University, Indianapolis, Indiana

We thank Dr. Catherine Mosher, Deborah Butt, Diane Monceski, Jill Dodson, and Katie Tremel for their contributions. We extend boundless gratitude to the cancer survivors for their participation.

Additional supporting information may be found in the online version of this article.

DOI: 10.1002/cncr.32518, **Received:** June 17, 2019; **Revised:** August 7, 2019; **Accepted:** August 23, 2019, **Published online** September 20, 2019 in Wiley Online Library (wileyonlinelibrary.com)

over active interventions (reported effect sizes of −0.10 to −0.57).[16,19-21] It is interesting to note that CBT produced a moderate effect (≥−0.50) in only 2 studies,[18,19] both of which tested individually delivered interventions in small samples (88 and 72 patients, respectively).

Acceptance and commitment therapy (ACT) is designed to maximize psychological flexibility in navigating life's challenges,[22] and may reduce maladaptive coping while facilitating adaptive management of FCR. Unlike CBT, which aims to change unhelpful thoughts and feelings, ACT emphasizes acceptance while living mindfully according to one's values. Although research has suggested that ACT may improve distress symptoms and QOL in patients with cancer,[23-26] to the best of our knowledge only 3 studies to date have applied ACT to FCR.[27-29] Although effect sizes were promising (range, 0.33-0.66), 2 studies were nonrandomized,[27,28] 2 studies used a resource-intensive individual format,[27,29] and 1 study was an ACT-metacognitive therapy hybrid.[29] The current randomized controlled pilot trial assessed the feasibility and preliminary efficacy of group-based ACT for FCR in BCS compared with survivorship education (SE) and enhanced usual care (EUC).

MATERIALS AND METHODS

Participants

Eligible subjects were aged ≥18 years, had stage I to stage III breast cancer, had completed curative treatment (ongoing endocrine therapy was allowed), had not experienced a cancer recurrence, and had clinically significant FCR (Fear of Cancer Recurrence Inventory–Short Form [FCRI-SF][8] score ≥13).[8] BCS with severe depression (Patient Health Questionnaire-8[30] score ≥20) or previous ACT or mindfulness training were excluded.

Procedures

The Indiana University institutional review board (#1507511085) approved study procedures. BCS receiving care at academic clinics in urban, suburban, and rural Indiana were identified through medical chart review and were systematically screened for eligibility. Interested and eligible BCS were invited to attend a group enrollment session to provide written informed consent, complete a baseline assessment (T1), and receive randomization to ACT, SE, or EUC. The allocation sequence was generated by the biostatistician in randomly varied block sizes of 3 or 6 and concealed in opaque, sequentially numbered envelopes. The ACT and SE groups contained 10 to 12 participants per cohort. Participants and research assistants were blinded to the allocation sequence, and participants were blinded to study hypotheses. Follow-up assessments occurred after the 6-week intervention period (T2), 1 month after the intervention (T3), and 6 months after the intervention (T4). A $25 gift card was provided for each completed assessment. The current study is registered with ClinicalTrials.gov (ClinicalTrials.gov identifier NCT02611544).

Interventions

Acceptance and commitment therapy

The group-based ACT intervention was designed to increase adaptive coping through acceptance, cognitive defusion, mindfulness, and perspective-taking exercises while supporting BCS in aligning behavior with their personal values. Over 6 weekly 2-hour sessions, ACT sought to reduce the impact of FCR by promoting adaptive strategies for responding to fear.[31] Led by a doctoral-level provider trained in mindfulness and acceptance-based therapies, each session included mindfulness exercises to deepen present-moment awareness. Participants self-reported the time spent completing assigned mindfulness home practices between sessions. Supporting Table 1 provides specific details concerning ACT session themes, content, experiential exercises, mindfulness practices, and assigned homework.

Survivorship education

Because FCR may arise from inadequate information,[32] SE was chosen as an active comparator to ACT. The group format and time commitment were equivalent between ACT and SE. SE covered relevant survivorship topics (eg, symptom management, weight management, physical activity, and survivorship care plans).[33,34] Didactic discussions were guided by masters-level oncology social workers. Between sessions, participants completed self-help assignments (eg, readings, a symptom log, and a food diary) and tracked the time spent doing each. Supporting Table 2 shows specific details regarding SE session themes, content, activities, and assigned homework.

Enhanced usual care

As in the ACT and SE arms, EUC participants continued receiving standard care from their health care providers. In addition, EUC participants received the National Cancer Institute booklet entitled *Facing Forward: Life After Cancer Treatment* and lists of supplemental resources (eg, websites). The survivorship booklet reviews follow-up care and strategies to manage physical changes, feelings, and social and working relationships. A doctoral-level oncology nurse delivered a 30-minute group coaching

session on creating a plan to help BCS achieve individual goals related to enhancing survivorship.

Treatment fidelity

ACT, SE, and EUC were delivered using standardized treatment manuals. Interventionists attended arm-specific training (5 hours for ACT or SE and 1 hour for EUC) that included didactics and role plays. Fidelity checklists were developed for ACT and SE sessions with 50% of the sessions reviewed and rated by external ACT or SE experts. Average fidelity ratings were 95.6% for ACT and 93.8% for SE.

Measures

Primary and secondary outcomes were assessed using valid and reliable self-report measures with the Cronbach's α ranging from .64 to .91. Across measures, higher scores indicated greater levels of each construct.

Primary outcome

The 9-item FCRI-SF[35] evaluates the presence and severity of FCR-associated thoughts or images. FCRI-SF items are rated on a 5-point scale (with 0 indicating never/not at all and 4 indicating all the time/a great deal), with higher scores indicating greater FCR.

Secondary outcomes

Other FCR-related outcomes were assessed using the remaining FCRI subscales rated on the same 5-point scale mentioned above. The Triggers subscale (8 items) assesses stimuli that activate FCR. The Psychological Distress subscale (4 items) and Functioning Impairments subscale (6 items) measure the consequences of FCR. The Insight subscale (3 items) assesses self-criticism toward FCR. The Reassurance Seeking subscale (3 items) and Coping Strategies subscale (9 items) measure coping responses that may influence FCR severity. Cancer-related avoidant coping was measured using the 17-item Cancer Acceptance and Action Questionnaire with items rated on a 7-point scale (with 1 indicating never true and 7 indicating always true).[28] Distress measures included the Generalized Anxiety Disorder 7-item scale[36] and 8-item Patient Health Questionnaire-8 depression scale,[30] both of which are rated on a 4-point scale (with 0 indicating not at all and 3 indicating nearly every day), and the 22-item Impact of Event Scale–Revised[37] to assess post-traumatic stress as rated on a 5-point scale (with 0 indicating not at all and 4 indicating extremely). Physical and mental QOL was assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Scale,[38] which contains physical (4 items) and mental (4 items) health subscales.

Statistical Analysis

Using an intent-to-treat design, all available data were analyzed regardless of the participants' attendance or adherence. Groups were compared based on T1 demographic and medical characteristics (Table 1). Descriptive statistics informed feasibility. Between-group differences regarding change scores of the outcomes were tested using a general linear model (GLM) while adjusting for theoretically important covariates (ie, age, stage of disease, and educational level)[39] and cancer treatments received, which differed significantly between arms at baseline. Treatment group, stage of disease, and categorical education were coded using reference cell–coded indicator variables. Post hoc Tukey-Kramer tests assessed pairwise differences between arms while controlling the family-wise α at .05 for each outcome. A separate GLM was used for each change score (T1-T2, T1-T3, and T1-T4) instead of a repeated measures mixed effects model because each follow-up time point was unique and conceptually different, group differences were variable across time, and the sample size yielded low power for group-by-time interaction tests for testing and estimating parameters for the repeated measures covariance matrix. Assumptions of normality and homogeneity of variances were satisfied and assessed using histograms and scatter plots. Between-group effect sizes for each pairwise comparison were computed using Cohen *d*, the adjusted between-group difference on each outcome's mean change score (T2 minus T1, T3 minus T1, and T4 minus T1) divided by the GLM-based pooled standard deviation. Within-group differences were tested using the GLM-based test of whether the least squares mean for the change score for each group was significantly different from zero. The 95% CI or least squares mean were reported with 2-sided *P* values $<.05$. With ≥ 26 participants per arm, this pilot study had $\geq 80\%$ power to detect pairwise group differences on continuous outcomes using a GLM-based Student *t* test.

RESULTS

Feasibility

Of 208 BCS assessed for eligibility, 91 (43.8%) were enrolled and 117 were excluded (Fig. 1). Retention was excellent (94.5%) and approximately 89.0% of participants completed all 4 assessments. Attendance rates were similar across ACT (81.7%) and SE (86.7%; $P = .47$) with 100% of EUC participants attending the single coaching session.

TABLE 1. Demographic and Clinical Characteristics

Characteristic	All N = 91	ACT N = 33	SE N = 32	EUC N = 26	*P*
Mean age (SD), y	58.70 (10.65)	59.84 (11.10)	57.53 (10.52)	58.68 (10.49)	.79
Race, no. (%)					.83
White	76 (83.52)	28 (84.84)	27 (84.38)	21 (80.77)	
Black	10 (10.99)	3 (9.09)	3 (9.38)	4 (15.38)	
Other	5 (5.50)	2 (6.06)	2 (6.25)	1 (3.85)	
Hispanic/Latina, no. (%)	2 (2.20)	0 (0.00)	0 (0.00)	2 (7.69)	.08
Marital status, no. (%)					.82
Married	65 (71.43)	23 (69.70)	23 (71.88)	19 (73.08)	
Divorced	15 (16.48)	6 (18.18)	5 (15.63)	4 (15.38)	
Never married	5 (5.49)	2 (6.06)	3 (9.38)	0 (0.00)	
Widowed	6 (6.59)	2 (6.06)	1 (3.13)	3 (11.54)	
Highest level of education attained, no. (%)					.61
<College graduate	32 (35.16)	13 (39.39)	10 (31.25)	9 (34.62)	
College graduate	33 (36.26)	13 (39.39)	13 (40.63)	7 (26.93)	
Master's degree, postgraduate, doctorate	26 (28.57)	7 (21.21)	9 (28.13)	10 (38.46)	
Income, no. (%)[a]					.70
<$15,000	5 (5.49)	1 (3.03)	3 (9.38)	1 (3.85)	
$15,000-$24,999	4 (4.40)	3 (9.09)	1 (3.13)	0 (0.00)	
$25,000-$49,999	13 (14.29)	5 (15.15)	3 (9.38)	5 (19.23)	
$50,000-$74,999	19 (20.88)	7 (21.12)	7 (21.88)	5 (19.23)	
$75,000-$99,999	20 (21.98)	6 (18.18)	6 (18.75)	8 (30.77)	
>$100,000	27 (29.67)	10 (30.30)	11 (34.38)	6 (23.08)	
Cancer history					
Mean mo since diagnosis (SD)	64.08 (56.64)	48.28 (28.16)	77.47 (76.57)	67.04 (51.11)	.61
Mean age at diagnosis (SD), y	52.84 (11.36)	54.91 (11.72)	50.58 (10.98)	52.81 (11.25)	.36
Stage of disease at diagnosis, no. (%)					.42
I	38 (41.76)	18 (54.55)	11 (34.38)	9 (34.62)	
II	39 (42.86)	10 (30.30)	16 (50.00)	13 (50.00)	
III	14 (15.38)	5 (15.15)	5 (15.63)	4 (15.38)	
Cancer treatments received, no. (%)					.03
Surgery only	12 (13.19)	6 (18.18)	3 (9.38)	3 (11.54)	
Surgery and RT	18 (19.78)	12 (36.36)	4 (12.50)	2 (7.69)	
Surgery and chemotherapy	19 (20.88)	3 (9.09)	7 (21.88)	9 (34.62)	
Surgery, chemotherapy, and RT	42 (46.15)	12 (36.36)	18 (56.25)	12 (46.15)	
Type of surgery, no. (%)					.33
Lumpectomy	46 (50.55)	19 (57.58)	16 (50.00)	11 (42.31)	
Mastectomy	39 (42.86)	14 (42.42)	13 (40.63)	12 (46.15)	
Both	6 (6.59)	0 (0.00)	3 (9.38)	3 (11.54)	
Current endocrine therapy, no. (%)					.47
Yes	41 (45.05)	17 (51.52)	11 (34.38)	13 (50.00)	
No	50 (54.95)	16 (48.48)	21 (65.63)	13 (50.00)	

Abbreviations: ACT, acceptance and commitment therapy; EUC, enhanced usual care; RT, radiotherapy; SE, survivorship education.
P values for continuous variables were calculated using either analysis of variance or the Student *t* test depending on whether 2 groups or 3 groups were being compared. *P* values for frequency analyses were calculated using the Pearson chi-square test unless the expected frequency for 25% of cells was ≤5, in which case a 2-sided Fisher exact test was used. The *P* value for combined income categories (<$50,000, $50,000-$99,999, and >$100,000) was .87.
[a]Three participants skipped this question.

Participant Characteristics

The mean age of the participants was 58.7 years (Table 1). The majority of participants were white (84%), college graduates (65%), and earned ≥$50,000 annually (73%). The mean time since diagnosis was 64 months, and greater than one-half of the sample had undergone lumpectomy. With the exception of cancer treatments received, the groups were similar with regard to demographic and clinical characteristics.

Primary Outcome

Table 2 shows within-group and between-group differences concerning FCR severity. Each group demonstrated within-group reductions in FCR severity by T4, but only ACT produced significant improvements at each time point. Moreover, compared with SE, ACT demonstrated significantly larger reductions in FCR severity with a moderate effect at T2 (Cohen *d*, 0.68; $P < .05$) and a large effect by T4 (Cohen *d*, 0.80; $P < .001$). At T4, ACT became superior to EUC with regard to FCR severity (Cohen *d*, 0.61; $P < .01$). No differences were observed between SE and EUC with regard to FCR severity.

Secondary Outcomes

At each time point, ACT participants reported significant within-group improvements with regard to all secondary

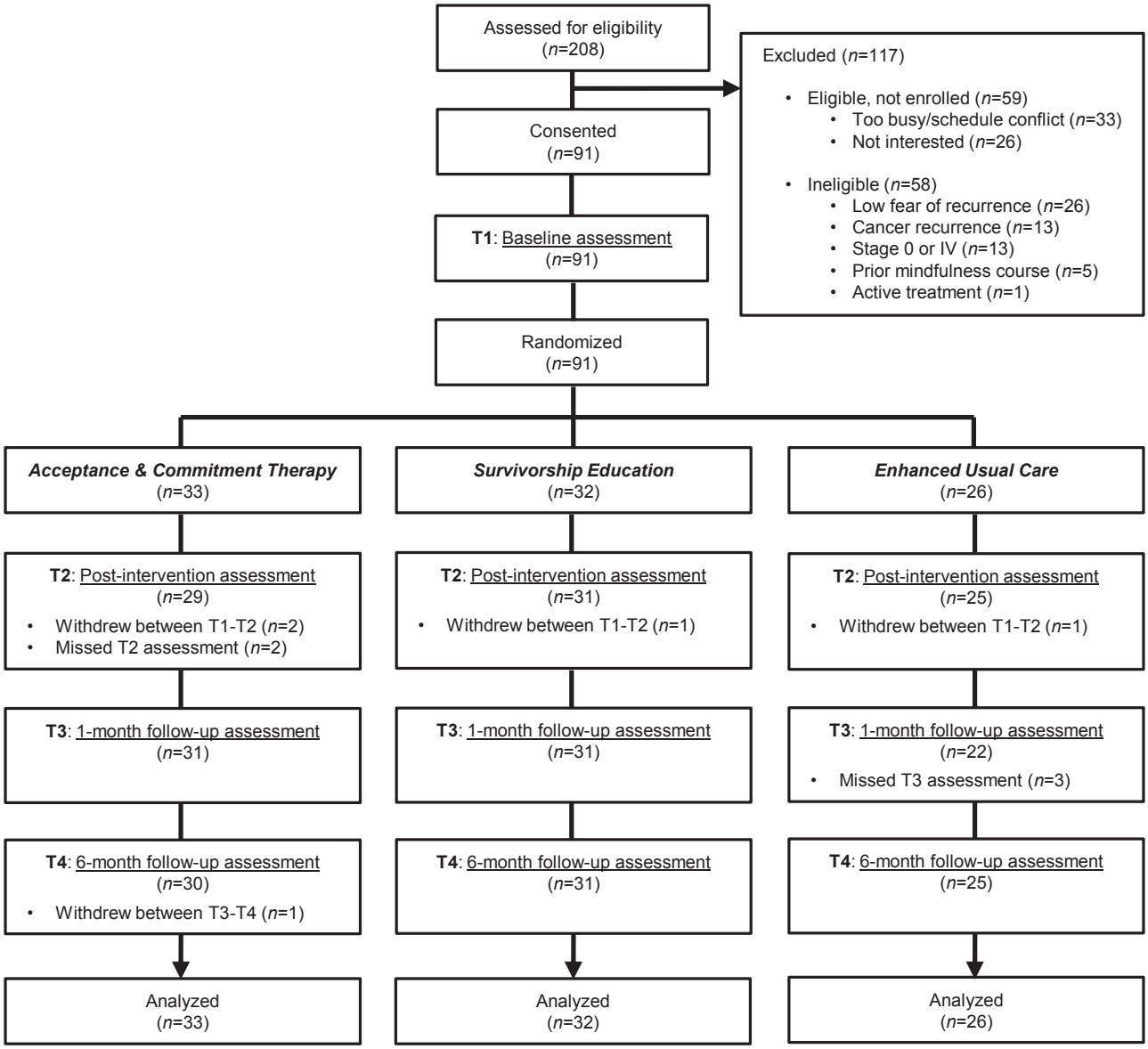

Figure 1. Consolidated Standards Of Reporting Trials (CONSORT) diagram. T1 indicates baseline; T2, after the intervention; T3, 1 month after the intervention; T4, 6 months after the intervention.

outcomes except for FCRI-Reassurance Seeking and FCRI-Coping Strategies (Table 2). Conversely, SE and EUC participants reported significant within-group improvements for only a fraction of the secondary outcomes. Although there was some variation across time points, on pairwise comparisons across groups, by T4 ACT was found to be superior to SE with regard to 10 of 12 secondary outcomes and superior to EUC concerning 7 of 12 secondary outcomes with moderate to large effect sizes, thereby indicating clinical significance. No differences between SE and EUC were observed with regard to secondary outcomes. Descriptive statistics for all continuous variables are provided in Supporting Table 3.

DISCUSSION

To our knowledge, the current pilot study is the first randomized controlled trial to assess the feasibility and preliminary efficacy of a 6-session ACT group for BCS with clinical FCR. ACT demonstrated strong evidence of feasibility with high accrual (43.8% of screened BCS;

TABLE 2. Within-Group and Between-Group Changes in Primary and Secondary Outcomes From T1 to T2, T1 to T3, and T1 to T4 and Effect Sizes

	ACT (N = 33) LSM (95% CI)	SE (N = 32) LSM (95% CI)	EUC (N = 26) LSM (95% CI)	ACT Versus SE Cohen *d*	ACT Versus EUC Cohen *d*	SE Versus EUC Cohen *d*
Primary Outcome Measure						
FCRI-Severity						
T1-T2	−4.03 (−5.57 to −2.49)[a]	−0.97 (−2.57 to 0.63)	−1.72 (−3.54 to 0.09)	0.68[c]	0.58	−0.19
T1-T3	−4.06 (−5.69 to −2.43)[a]	−1.43 (−3.16 to 0.30)	−2.84 (−4.95 to −0.73)[b]	0.53	0.27	−0.32
T1-T4	−5.04 (−6.05 to −4.03)[a]	−1.94 (−2.98 to −0.91)[b]	−3.39 (−4.56 to −2.22)[a]	0.80[a]	0.61[b]	−0.36
Secondary outcome measures						
FCRI-Triggers						
T1-T2	−3.41 (−5.29 to −1.53)[a]	−0.35 (−2.31 to 1.61)	−0.48(−2.70 to 1.74)	0.61	0.60	−0.06
T1-T3	−3.55 (−5.42 to −1.69)[a]	−1.66 (−3.63 to 0.31)	−3.74 (−6.15 to −1.33)[b]	0.34	−0.04	−0.39
T1-T4	−5.04 (−6.05 to −4.03)[a]	−1.94 (−2.98 to −0.91)[a]	−3.39 (−4.56 to −2.22)[a]	0.64[a]	0.33	−0.31
FCRI-Psychological Distress						
T1-T2	−2.14 (−3.19 to −1.09)[a]	−0.43 (−1.52 to 0.32)	0.18 (−1.05 to 1.42)	0.67	0.81[c]	0.22
T1-T3	−2.44 (−3.35 to −1.53)[a]	−0.99 (−1.95 to −0.02)[c]	−0.45 (−1.63 to 0.73)	0.60	0.75[c]	0.23
T1-T4	−2.62 (−3.23 to −2.02)[a]	−0.81 (−1.43 to −0.20)[c]	−1.05 (−1.75 to −0.34)[b]	0.66[a]	0.52[b]	−0.08
FCRI-Functioning Impairments						
T1-T2	−1.87 (−3.02 to −0.73)[b]	0.13 (−0.07 to 0.33)	−0.99 (−2.35 to 0.36)	0.97[b]	0.23	−0.56
T1-T3	−2.47 (−3.62 to −1.32)[a]	−0.28 (−1.50 to 0.93)	−0.59 (−2.08 to 0.90)	0.75[c]	0.48	−0.09
T1-T4	−2.28 (−3.04 to −1.53)[a]	0.20 (−0.57 to 0.97)	−0.96 (−1.84 to −0.08)[c]	0.69[a]	0.35	−0.30
FCRI-Insight						
T1-T2	−0.89 (−1.57 to −0.21)[c]	−0.12 (−0.83 to 0.59)	−0.87 (−1.68 to −0.07)[c]	0.41	0.01	−0.50
T1-T3	−1.27 (−1.89 to −0.65)[a]	−0.54 (−1.20 to 0.12)	−0.45 (−1.26 to 0.35)	0.41	0.44	0.07
T1-T4	−1.18 (−1.62 to −0.74)[a]	0.03 (−0.43 to 0.48)	−0.57 (−1.09 to −0.06)[c]	0.54[a]	0.31	−0.32
FCRI-Reassurance Seeking						
T1-T2	−0.10 (−0.95 to 0.75)	0.08 (−0.80 to 0.96)	0.18(−0.82 to 1.18)	0.08	0.13	0.05
T1-T3	0.15 (−0.69 to 0.99)	0.21 (−0.67 to 1.10)	0.28 (−0.80 to 1.36)	0.02	0.06	0.04
T1-T4	−0.55 (−1.13 to 0.03)	0.10 (−0.50 to 0.70)	−0.17 (−0.85 to 0.51)	0.23	0.15	−0.11
FCRI-Coping Strategies						
T1-T2	0.39 (−1.85 to 2.64)	−0.07 (−0.60 to 2.28)	−0.41 (−3.07 to 2.24)	−0.08	−0.14	−0.06
T1-T3	−0.55 (−2.50 to 0.03)	1.76 (−0.30 to 3.80)	−1.23 (−3.80 to 0.35)	0.44	−0.14	−0.56
T1-T4	−0.48 (−1.79 to 0.82)	0.42 (−0.98 to 1.81)	−1.02 (−2.54 to 0.51)	0.14	−0.08	−0.25
Cancer Acceptance and Action Questionnaire						
T1-T2	−0.45 (−0.67 to −0.23)[a]	−0.05 (−0.28 to 0.18)	−0.03 (−0.29 to 0.23)	0.66[c]	0.68[c]	0.04
T1-T3	−0.53 (−0.73 to −0.32)[a]	−0.01 (−0.22 to 0.21)	−0.15 (−0.42 to 0.11)	0.83[b]	0.59	−0.30
T1-T4	−0.69 (−0.82 to −0.56)[a]	−0.05 (−0.18 to 0.09)	−0.22 (−0.37 to −0.07)[b]	0.97[a]	0.80[a]	−0.32
Impact of Events Scale-Revised						
T1-T2	−5.34 (−9.05 to −1.64)[b]	−2.12 (−6.02 to 1.78)	−1.10 (−5.48 to 3.27)	0.33	0.42	0.12
T1-T3	−7.96 (−11.42 to −4.50)[a]	−3.46 (−7.16 to 0.25)	0.22 (−4.26 to 4.70)	0.44	0.80[c]	0.34
T1-T4	−7.91 (−9.90 to −5.91)[a]	−3.90 (−5.98 to −1.82)[a]	−5.98 (−8.31 to −3.65)[a]	0.41[c]	0.19	−0.19
Generalized Anxiety Disorder-7						
T1-T2	−2.36 (−4.06 to −0.66)[b]	−0.32 (−2.09 to 1.45)	−0.25 (−2.26 to 1.76)	0.44	0.52	0.02
T1-T3	−3.04 (−4.64 to −1.43)[a]	0.31 (−1.39 to 2.01)	−0.38 (−2.46 to 1.70)	0.73[c]	0.73	−0.17
T1-T4	−3.25 (−4.05 to −2.46)[a]	0.43 (−0.39 to 1.25)	−0.63 (−1.56 to 0.30)	0.95[a]	0.75[a]	−0.30
Patient Health Questionnaire-8						
T1-T2	−1.55 (−2.81 to −0.28)[c]	−0.07 (−1.39 to 1.25)	−0.58 (−2.08 to 0.91)	0.39	0.31	−0.15
T1-T3	−1.77 (−2.90 to −0.63)[b]	−0.65 (−1.85 to 0.56)	0.01 (−1.46 to 1.48)	0.32	0.57	0.23
T1-T4	−1.72 (−2.42 to −1.03)[a]	−0.42 (−1.13 to 0.30)	−0.29 (−1.10 to 0.52)	0.38[c]	0.50[c]	0.04
PROMIS Global Health-Physical						
T1-T2	1.31 (0.68 to 1.94)[a]	0.00 (−0.68 to 0.68)	−0.34 (−1.13 to 0.45)	0.72[a]	0.95[a]	0.23
T1-T3	1.25 (0.60 to 1.91)[a]	−0.20 (−0.92 to 0.51)	−0.20 (−1.11 to 0.71)	0.75[a]	0.76[a]	0.00
T1-T4	1.32 (0.93 to 1.71)[a]	0.07 (−0.34 to 0.48)	−0.51 (−0.99 to −0.03)[c]	−0.62[a]	−0.82[a]	0.32
PROMIS Global Health-Mental						
T1-T2	1.36 (0.52 to 2.19)[b]	−0.26 (−1.18 to 0.67)	0.18 (−0.80 to 1.15)	0.68[a]	0.55[b]	−0.24
T1-T3	1.43 (0.63 to 2.24)[a]	−0.10 (−0.97 to 0.77)	0.25 (−0.78 to 1.28)	0.68[a]	0.58[b]	−0.19
T1-T4	1.28 (0.83 to 1.72)[a]	0.11 (−0.36 to 0.58)	0.03 (−0.49 to 0.54)	−0.52[b]	−0.58[b]	−0.04

Abbreviations: ACT, acceptance and commitment therapy; EUC, enhanced usual care; FCRI, Fear of Cancer Recurrence Inventory; LSM, least squares mean; PROMIS, Patient-Reported Outcomes Measurement Information System; SE, survivorship education; T1, baseline; T2, after the intervention; T3, 1 month after the intervention; T4, 6 months after the intervention; T1-TX, T1 to TX change calculated as the TX outcome score minus the T1 outcome score.
[a]$P < .001$.
[b]$P < .01$.
[c]$P < .05$.

60.7% of eligible BCS), attendance (81.7%), and retention (94.5%) rates. Compelling evidence of preliminary efficacy also was obtained. Compared with baseline, ACT demonstrated significant within-group improvement regarding FCR severity and nearly all secondary outcomes at all follow-up time points, whereas SE and EUC

demonstrated minimal change across outcomes. Between-group differences at each time point favored ACT, most obviously at T4; 6 months after the intervention, ACT participants reported greater reductions in FCR severity compared with both SE and EUC participants, with differences large enough to be considered clinically significant.[40] Moderate to large improvements in the majority of secondary outcomes were also observed favoring ACT by T4. Only 2 FCRI subscales (ie, Reassurance Seeking and Coping Strategies) failed to demonstrate significant differences, a finding that is consistent with reports from other recent studies.[18,41]

Although preliminary, the results of the current study are promising for several reasons. First, ACT can be delivered efficaciously to a group, thereby potentially reducing costs and increasing the number of those served compared to individually delivered interventions.[27,29] Second, it appears that targeting FCR while reducing maladaptive coping may promote concomitant reductions in distress outcomes. Reducing avoidant coping in particular may be pivotal in managing FCR and its correlates throughout survivorship. Although avoidant coping allows survivors to escape anxiety-provoking thoughts about cancer in the short term, rebound effects produce sustained, elevated levels of FCR over time.[42] This may explain why the impact of ACT was greatest at T4. As more time passed, ACT became more efficacious. Theoretically, reducing avoidant coping promotes psychological flexibility, allowing individuals to pursue more adaptive strategies to handle cancer-related and other challenges.[43] This interpretation is supported by the improvements in physical and mental QOL reported by ACT participants, which likely resulted from a combination of reduced anxiety and increased psychological flexibility.[23-26] Both the SE and EUC groups demonstrated relatively weak reductions in FCR severity and secondary outcomes compared with individuals in the ACT group. Both offered resources to indirectly manage FCR but did not directly promote adaptive coping with fearful thoughts and emotions, which may be key in addressing comorbid distress and FCR. Taken together, the findings of the current study suggest that providing information alone is inadequate for lessening the impact of FCR.

A limitation of the current study was the largely White, affluent, college-educated sample, which may limit generalizability to other groups. Second, this pilot was not a fully powered efficacy trial, thereby necessitating a larger randomized trial to confirm the results. Although intended to assess the long-term effects of treatment, the 6-month follow-up of the current pilot study was only modestly rigorous compared with a 12-month or 24-month follow-up assessment; future trials should implement longer-term follow-up assessments to more accurately gauge maintenance or attenuation of the intervention effect. Finally, using different measures may have provided greater insight into the mechanisms of ACT's effect. Although the Cancer Acceptance and Action Questionnaire captured avoidant coping, the FCRI-Coping Strategies subscale is essentially a count measure of adaptive and maladaptive coping strategies and appeared to provide little insight into specific coping styles; thus, other coping styles (eg, hypervigilance) that may fuel recurrence anxiety were not comprehensively assessed. Despite these limitations, the results of the current study suggest that ACT is a promising treatment for reducing FCR in BCS. Unlike SE or EUC, ACT may reduce maladaptive avoidant coping, thereby contributing to the long-term management of FCR and associated distress.

FUNDING SUPPORT

This study was funded by an Indiana University Health Values Grant (grant 0952) and the Walther Cancer Foundation (0175.01).

CONFLICT OF INTEREST DISCLOSURES

Shelley A. Johns, Andrea A. Cohee, and Victoria L. Champion were supported by National Cancer Institute grant K05CA175048 for work performed as part of the current study (PI: Victoria L. Champion). The other authors made no disclosures.

AUTHOR CONTRIBUTIONS

Shelley A. Johns: Conceptualization, funding acquisition, supervision, writing–original draft, and writing–review and editing. **Patrick V. Stutz:** Project administration, writing–original draft, and writing–review and editing. **Tasneem L. Talib:** Project administration, writing–original draft, and writing–review and editing. **Andrea A. Cohee:** Data curation, writing–original draft, and writing–review and editing. **Kathleen A. Beck-Coon:** Conceptualization and writing–review and editing. **Linda F. Brown:** Conceptualization and writing–review and editing. **Laura R. Wilhelm:** Conceptualization and writing–review and editing. **Patrick O. Monahan:** Data analysis, writing–original draft, and writing–review and editing. **Michelle L. LaPradd:** Data analysis. **Victoria L. Champion:** Conceptualization and writing–review and editing. **Kathy D. Miller:** Methodology and writing–review and editing. **R. Brian Giesler:** Data curation, methodology, writing–original draft, and writing–review and editing.

REFERENCES

1. Simard S, Thewes B, Humphris G, et al. Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *J Cancer Surviv*. 2013;7:300-322.
2. Koch L, Jansen L, Brenner H, Arndt V. Fear of recurrence and disease progression in long-term (≥ 5 years) cancer survivors–a systematic review of quantitative studies. *Psychooncology*. 2013;22:1-11.
3. Savard J, Ivers H. The evolution of fear of cancer recurrence during the cancer care trajectory and its relationship with cancer characteristics. *J Psychosom Res*. 2013;74:354-360.

4. Lebel S, Ozakinci G, Humphris G, et al; University of Ottawa Fear of Cancer Recurrence Colloquium attendees. From normal response to clinical problem: definition and clinical features of fear of cancer recurrence. *Support Care Cancer*. 2016;24:3265-3268.
5. Koch-Gallenkamp L, Bertram H, Eberle A, et al. Fear of recurrence in long-term cancer survivors–do cancer type, sex, time since diagnosis, and social support matter? *Health Psychol*. 2016;35:1329-1333.
6. Simard S, Savard J, Ivers H. Fear of cancer recurrence: specific profiles and nature of intrusive thoughts. *J Cancer Surviv*. 2010;4:361-371.
7. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. *CA Cancer J Clin*. 2019;69:7-34.
8. Simard S, Savard J. Screening and comorbidity of clinical levels of fear of cancer recurrence. *J Cancer Surviv*. 2015;9:481-491.
9. Thewes B, Butow P, Bell ML, et al; FCR Study Advisory Committee. Fear of cancer recurrence in young women with a history of early-stage breast cancer: a cross-sectional study of prevalence and association with health behaviours. *Support Care Cancer*. 2012;20:2651-2659.
10. Harrison SE, Watson EK, Ward AM, et al. Primary health and supportive care needs of long-term cancer survivors: a questionnaire survey. *J Clin Oncol*. 2011;29:2091-2098.
11. Mehnert A, Berg P, Henrich G, Herschbach P. Fear of cancer progression and cancer-related intrusive cognitions in breast cancer survivors. *Psychooncology*. 2009;18:1273-1280.
12. Tewari A, Chagpar AB. Worry about breast cancer recurrence: a population-based analysis. *Am Surg*. 2014;80:640-645.
13. Crist JV, Grunfeld EA. Factors reported to influence fear of recurrence in cancer patients: a systematic review. *Psychooncology*. 2013;22:978-986.
14. Thewes B, Lebel S, Seguin Leclair C, Butow P. A qualitative exploration of fear of cancer recurrence (FCR) amongst Australian and Canadian breast cancer survivors. *Support Care Cancer*. 2016;24:2269-2276.
15. Hall DL, Luberto CM, Philpotts LL, Song R, Park ER, Yeh GY. Mind-body interventions for fear of cancer recurrence: a systematic review and meta-analysis. *Psychooncology*. 2018;27:2546-2558.
16. Herschbach P, Book K, Dinkel A, et al. Evaluation of two group therapies to reduce fear of progression in cancer patients. *Support Care Cancer*. 2010;18:471-479.
17. Dieng M, Butow PN, Costa DS, et al. Psychoeducational intervention to reduce fear of cancer recurrence in people at high risk of developing another primary melanoma: results of a randomized controlled trial. *J Clin Oncol*. 2016;34:4405-4414.
18. van de Wal M, Thewes B, Gielissen M, Speckens A, Prins J. Efficacy of blended cognitive behavior therapy for high fear of recurrence in breast, prostate, and colorectal cancer survivors: the SWORD Study, a randomized controlled trial. *J Clin Oncol*. 2017;35:2173-2183.
19. Heinrichs N, Zimmermann T, Huber B, Herschbach P, Russell DW, Baucom DH. Cancer distress reduction with a couple-based skills training: a randomized controlled trial. *Ann Behav Med*. 2012;43:239-252.
20. Germino BB, Mishel MH, Crandell J, et al. Outcomes of an uncertainty management intervention in younger African American and Caucasian breast cancer survivors. *Oncol Nurs Forum*. 2013;40:82-92.
21. Merckaert I, Lewis F, Delevallez F, et al. Improving anxiety regulation in patients with breast cancer at the beginning of the survivorship period: a randomized clinical trial comparing the benefits of single-component and multiple-component group interventions. *Psychooncology*. 2017;26:1147-1154.
22. Hayes SC, Strosahl KD, Wilson KG. Acceptance and Commitment Therapy: The Process and Practice of Mindful Change. Guilford Press; 2011.
23. Mohabbat-Bahar S, Maleki-Rizi F, Akbari M, Moradi-Joo M. Effectiveness of group training based on acceptance and commitment therapy on anxiety and depression of women with breast cancer. *Iran J Cancer Prev*. 2015;8:71-76.
24. Fashler SR, Weinrib AZ, Azam MA, Katz J. The use of acceptance and commitment therapy in oncology settings: a narrative review. *Psychol Rep*. 2018;121:229-252.
25. Feros DL, Lane L, Ciarrochi J, Blackledge JT. Acceptance and Commitment Therapy (ACT) for improving the lives of cancer patients: a preliminary study. *Psychooncology*. 2013;22:459-464.
26. Graham CD, Gouick J, Krahe C, Gillanders D. A systematic review of the use of Acceptance and Commitment Therapy (ACT) in chronic disease and long-term conditions. *Clin Psychol Rev*. 2016;46:46-58.
27. Montesinos F, Luciano C. Acceptance of relapse fears in breast cancer patients: effects of an ACT-based abridged intervention. *Psicooncologia*. 2016;13:7-21.
28. Arch JJ, Mitchell JL. An Acceptance and Commitment Therapy (ACT) group intervention for cancer survivors experiencing anxiety at re-entry. *Psychooncology*. 2016;25:610-615.
29. Butow PN, Turner J, Gilchrist J, et al. Randomized trial of ConquerFear: a novel, theoretically based psychosocial intervention for fear of cancer recurrence. *J Clin Oncol*. 2017;35:4066-4077.
30. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord*. 2009;114:163-173.
31. Hayes SC, Levin ME, Plumb-Vilardaga J, Villatte JL, Pistorello J. Acceptance and commitment therapy and contextual behavioral science: examining the progress of a distinctive model of behavioral and cognitive therapy. *Behav Ther*. 2013;44:180-198.
32. Ellegaard MB, Grau C, Zachariae R, Bonde Jensen A. Fear of cancer recurrence and unmet needs among breast cancer survivors in the first five years. A cross-sectional study. *Acta Oncol*. 2017;56:314-320.
33. Cimprich B, Janz NK, Northouse L, Wren PA, Given B, Given CW. Taking CHARGE: a self-management program for women following breast cancer treatment. *Psychooncology*. 2005;14:704-717.
34. Chung LK, Cimprich B, Janz NK, Mills-Wisneski SM. Breast cancer survivorship program: testing for cross-cultural relevance. *Cancer Nurs*. 2009;32:236-245.
35. Simard S, Savard J. Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence. *Support Care Cancer*. 2009;17:241-251.
36. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166:1092-1097.
37. Weiss D, Marmar C. The Impact of Event Scale-revised. In: Wilson J, Keane T, eds. Assessing Psychological Trauma and PTSD: A Practioner's Handbook. Guilford Press; 1997:339-411.
38. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res*. 2009;18:873-880.
39. Senn S. Testing for baseline balance in clinical trials. *Stat Med*. 1994;13:1715-1726.
40. Norman GR, Sloan JA, Wyrwich KW. The truly remarkable universality of half a standard deviation: confirmation through another look. *Expert Rev Pharmacoecon Outcomes Res*. 2004;4:581-585.
41. Costa DS, Dieng M, Cust AE, Butow PN, Kasparian NA. Psychometric properties of the Fear of Cancer Recurrence Inventory: an item response theory approach. *Psychooncology*. 2016;25:832-838.
42. Wegner DM. Ironic processes of mental control. *Psychol Rev*. 1994;101:34-52.
43. Hulbert-Williams NJ, Storey L, Wilson KG. Psychological interventions for patients with cancer: psychological flexibility and the potential utility of Acceptance and Commitment Therapy. *Eur J Cancer Care (Engl)*. 2015;24:15-27.