



Published in final edited form as:

Cancer. 2020 January 01; 126(1): 211–218. doi:10.1002/cncr.32518.

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, BA¹, Tasneem L. Talib, PhD², Andrea A. Cohee, PhD³, Kathleen Beck-Coon, MD^{1,3}, Linda F. Brown, PhD¹, Laura Wilhelm, PhD⁴, Patrick O. Monahan, PhD¹, Michelle L. LaPradd, MS¹, Victoria L. Champion, PhD³, Kathy D. Miller, MD^{1,5}, R. Brian Giesler, PhD⁶

¹Indiana University School of Medicine

²Regenstrief Institute, Inc

³Indiana University School of Nursing

⁴West Virginia University School of Medicine

⁵Indiana University Simon Cancer Center

⁶Butler University

Abstract

Background: Fear of cancer recurrence (FCR) has a profound negative impact on many cancer survivors' quality of life (QoL). Breast cancer survivors (BCS) are particularly vulnerable with up to 70% reporting clinically-significant FCR. Evidence-based interventions for managing FCR are limited. Acceptance and Commitment Therapy (ACT) promotes psychological flexibility in managing life's stressors. This study examined feasibility and preliminary efficacy of group-based ACT for FCR in BCS.

Methods: Post-treatment BCS (N=91; stages I-III) with clinical FCR were randomly assigned to ACT (6 weekly 2-hour group sessions), survivorship education (SE; 6 weekly 2-hour group sessions), or enhanced usual care (EUC; 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), post-intervention (T2), 1 month post-intervention (T3), and 6 months post-intervention (T4) using intent-to-treat analysis.

Corresponding author: Shelley Johns, Regenstrief Institute, Inc., 1101 W 10th St RF-226, Indianapolis, IN 46202; 317-274-9127; sheljohn@iu.edu.

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

Conflicts of Interest: The authors made no disclosures.

Results: Satisfactory recruitment (43.8%) and retention (94.5%) demonstrated feasibility. Although each arm showed within-group FCR severity reductions over time, only ACT produced significant reductions at each time point relative to baseline, with between-group differences at T4 substantially favoring ACT over SE ($d=0.80$, $p<0.001$) and EUC ($d=0.61$, $p<0.01$). 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 on avoidant coping, anxiety, depression, QoL, and FCR-related psychological distress.

Conclusion: Group-based ACT is a feasible and promising treatment for FCR and associated outcomes in BCS that warrants testing in larger, fully-powered trials.

Precis:

Evidence-based interventions to treat survivors' fear of cancer recurrence are limited. This pilot study supports the feasibility and preliminary efficacy of Acceptance and Commitment Therapy for breast cancer survivors' fear of cancer recurrence.

Keywords

Acceptance and Commitment Therapy; survivorship; fear; breast neoplasms; anxiety; quality of life

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 disproportionately affects breast cancer survivors (BCS) compared to survivors of other common cancers.^{5,6} Although 90% of the 3.5 million American BCS are expected to survive 5 years post-treatment,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} 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-exams 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 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 (effect sizes -0.20 to -0.73),^{16–18} CBT generally shows limited advantage over active interventions (effect sizes -0.10 to -0.57).^{16,19–21} Notably, CBT produced a moderate effect (-0.50) in only two studies,^{18,19} and both tested individually-delivered interventions in small samples ($N=72–88$).

Acceptance and Commitment Therapy (ACT) is designed to maximize psychological flexibility in navigating life's challenges²² 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. While research suggests that ACT may improve distress symptoms and QoL in cancer,^{23–26} only three studies have applied ACT to FCR.^{27–29} Although effect sizes were promising (0.33 to 0.66), two studies were non-randomized,^{27,28} two used a resource-intensive individual format,^{27,29} and one was an ACT-metacognitive therapy hybrid.²⁹ The present randomized controlled pilot trial assessed feasibility and preliminary efficacy of group-based ACT for FCR in BCS compared to survivorship education (SE) and enhanced usual care (EUC).

METHODS

Participants

Eligible subjects were 18 years old and had: stage I-III breast cancer; completed curative treatment (ongoing endocrine therapy was allowed); not experienced a cancer recurrence; clinically-significant FCR (Fear of Cancer Recurrence Inventory-SF [FCRI-SF]⁸ score ≥ 13).⁸ BCS with severe depression (Patient Health Questionnaire-8 [PHQ-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 systematically screened for eligibility. Interested and eligible BCS were invited to attend a group enrollment session to provide written informed consent, complete 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 three or six and concealed in opaque sequentially-numbered envelopes. ACT and SE groups contained 10–12 participants per cohort. Participants and research assistants were blinded to allocation sequence, and participants were blinded to study hypotheses. Follow-up assessments occurred after the 6-week intervention period (T2), 1 month post-intervention (T3), and 6 months post-intervention (T4). A \$25 gift card was provided for each completed assessment. This study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) ().

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 personal values. Over 6 weekly 2-hour sessions, ACT sought to reduce FCR's impact 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 time spent completing assigned mindfulness home practices between sessions. See Supporting Table 1 for specific

details on 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. Group format and time commitment between ACT and SE were equivalent. SE covered relevant survivorship topics (e.g., symptom management, weight management, physical activity, survivorship care plans).^{33,34} Didactic discussions were guided by masters-level oncology social workers. Between sessions, participants completed self-help assignments (e.g., readings, symptom log, food diary) and tracked time spent doing each. See Supporting Table 2 for specific details on 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 healthcare providers. Additionally, EUC participants received the NCI’s “Facing Forward: Life After Treatment” booklet and lists of supplemental resources (e.g., 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; 1 hour for EUC) that included didactics and role plays. Fidelity checklists were developed for ACT and SE sessions with 50% of 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, reliable self-report measures with Cronbach’s alphas ranging from 0.64–0.91. Across measures, higher scores indicate greater levels of each construct.

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

Secondary Outcomes.—Other FCR-related outcomes were assessed using remaining FCRI subscales rated on the 5-point scale above: Triggers (8 items) assesses stimuli that activate FCR; Psychological Distress (4 items) and Functioning Impairments (6 items) measure consequences of FCR; Insight (3 items) assesses self-criticism towards FCR; Reassurance Seeking (3 items) and Coping Strategies (9 items) measure coping responses that may influence FCR severity. Cancer-related avoidant coping was measured with the 17-item Cancer Acceptance and Action Questionnaire (Cancer-AAQ) with items rated on a 7-point scale (1=never true; 7=always true).²⁸ Distress measures included the 7-item Generalized Anxiety Disorder Scale (GAD-7)³⁶ and 8-item PHQ-8 depression scale,³⁰ both rated on a 4-point scale (0=not at all; 3=nearly every day), and the 22-item Impact of Events

Scale-Revised (IES-R)³⁷ to assess post-traumatic stress on a 5-point scale (0=not at all, 4=extremely). Physical and mental QoL was assessed using the 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 participants' attendance or adherence. Groups were compared on T1 demographic and medical characteristics (see Table 1). Descriptive statistics informed feasibility. Between-group differences on change scores of the outcomes were tested using a General Linear Model (GLM) while adjusting for theoretically-important covariates (i.e., age, stage of cancer, education)³⁹ and cancer treatments received, which differed significantly between arms at baseline. Treatment group, stage, 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 alpha at 0.05 for each outcome. A separate GLM was used for each change score (T1-T2, T1-T3, 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 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 with histograms and scatterplots. Between-group effect sizes for each pairwise comparison were computed using Cohen's *d*, the adjusted between-group difference on each outcome's mean change score (T2 minus T1; T3 minus T1; 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 (LSM) for the change score for each group was significantly different from zero. The 95% confidence interval or LSMs were reported with two-sided *p*-values <0.05. With 26 per arm, this pilot had 80% power to detect pairwise group differences on continuous outcomes with a GLM-based t-test.

RESULTS

Feasibility

Of 208 BCS assessed for eligibility, 91 (43.8%) enrolled and 117 were excluded (Figure 1). Retention was excellent (94.5%) and 89.0% of participants completed all four assessments. Attendance rates were similar across ACT (81.7%) and SE (86.7%; *p*=0.47) with 100% of EUC participants attending the single coaching session.

Participant Characteristics

Mean participant age was 58.7 years (see Table 1). Most participants were White (84%) college graduates (65%) earning \$50,000 annually (73%). Mean time since diagnosis was 64 months, and over half had undergone lumpectomy. Except for cancer treatments received, groups were similar on demographic and clinical characteristics.

Primary Outcome

Table 2 shows within- and between-group differences on FCR severity. Each group showed within-group reductions in FCR severity by T4, but only ACT produced significant

improvement at each time point. Moreover, compared to SE, ACT showed significantly larger FCR severity reductions with a moderate effect at T2 ($d=0.68$, $p<0.05$) and large effect by T4 ($d=0.80$, $p<0.001$). At T4, ACT became superior to EUC on FCR severity ($d=0.61$, $p<0.01$). No differences between SE and EUC on FCR severity were observed.

Secondary Outcomes

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

DISCUSSION

This pilot was the first randomized controlled trial to assess feasibility and preliminary efficacy of a six-session ACT group for BCS with clinical FCR. ACT showed strong evidence of feasibility with high accrual (43.8% of BCS screened; 60.7% of eligible BCS), attendance (81.7%), and retention (94.5%) rates. Compelling evidence of preliminary efficacy was also obtained. Relative to baseline, ACT showed significant within-group improvement on FCR severity and nearly all secondary outcomes at all follow-ups, whereas SE and EUC showed minimal change across outcomes. Between-group differences at each time point favored ACT, most obviously at T4; six months after intervention, ACT participants reported greater reductions in FCR severity relative to both SE and EUC with differences large enough to be considered clinically significant.⁴⁰ Moderate-to-large improvements on most secondary outcomes were also observed favoring ACT by T4. Only two FCRI subscales (i.e., Reassurance Seeking, Coping Strategies) failed to show significant differences, consistent with reports from other recent studies.^{18,41}

While preliminary, our results are promising for several reasons. First, ACT can be delivered efficaciously to a group, potentially reducing costs and increasing the number of those served over individually-delivered interventions.^{27,29} Second, it appears 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. While 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 ACT's impact 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 ACT participants' reported physical and mental QoL improvement, which likely resulted from a combination of reduced anxiety and increased psychological flexibility.²³⁻²⁶ Both SE

and EUC groups showed relatively weak reductions in FCR severity and secondary outcomes compared to ACT. 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, our findings suggest that providing information alone is inadequate in lessening FCR's impact.

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

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements:

The authors 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.

Funding: This study was funded by an Indiana University Health Values Grant (0952) and the Walther Cancer Foundation (0175.01). Drs. Champion, Johns, and Cohee were supported by K05CA175048 from the NCI (PI: Champion).

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(3):300–322. [PubMed: 23475398]
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): 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(4):354–360. [PubMed: 23497839]
4. Lebel S, Ozakinci G, Humphris G, et al. From normal response to clinical problem: definition and clinical features of fear of cancer recurrence. *Support Care Cancer.* 2016;24(8):3265–3268. [PubMed: 27169703]
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(12): 1329–1333. [PubMed: 27175578]

6. Simard S, Savard J, Ivers H Fear of cancer recurrence: specific profiles and nature of intrusive thoughts. *J Cancer Surviv.* 2010;4(4):361–371. [PubMed: 20617394]
7. Siegel RL, Miller KD, Jemal A Cancer statistics, 2019. *CA Cancer J Clin.* 2019;69(1):7–34. [PubMed: 30620402]
8. Simard S, Savard J Screening and comorbidity of clinical levels of fear of cancer recurrence. *J Cancer Surviv.* 2015;9(3):481–491. [PubMed: 25603948]
9. Thewes B, Butow P, Bell ML, et al. 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(11):2651–2659. [PubMed: 22328003]
10. Harrison SE, Watson EK, Ward AM, et al. Primary health and supportive care needs of long-term cancer survivors: a questionnaire survey. *Journal Clin Oncol.* 2011;29(15):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(12):1273–1280. [PubMed: 19267364]
12. Tewari A, Chagpar AB Worry about breast cancer recurrence: a population-based analysis. *Am Surg.* 2014;80(7):640–645. [PubMed: 24987893]
13. Crist JV, Grunfeld EA Factors reported to influence fear of recurrence in cancer patients: a systematic review. *Psychooncology.* 2013;22(5):978–986. [PubMed: 22674873]
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(5):2269–2276. [PubMed: 26581900]
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(11):2546–2558. [PubMed: 29744965]
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(4):471–479. [PubMed: 19865833]
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(36):4405–4414. [PubMed: 27998215]
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(19):2173–2183. [PubMed: 28471726]
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(2):239–252. [PubMed: 22037965]
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(1):82–92. [PubMed: 23269773]
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(8):1147–1154. [PubMed: 27718533]
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(2):71–76. [PubMed: 25960844]
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(2):229–252. [PubMed: 28836916]
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(2):459–464. [PubMed: 23382134]

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. [PubMed: 27176925]
27. Montesinos F, Luciano F Acceptance of relapse fears in breast cancer patients: Effects of an act-based abridged intervention. *Psicooncologia.* 2016;13(1):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(5):610–615. [PubMed: 26130586]
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(36):4066–4077. [PubMed: 29095681]
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(1–3):163–173. [PubMed: 18752852]
31. Hayes SC, Levin ME, Plumb-Villardaga 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(2):180–198. [PubMed: 23611068]
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(2):314–320. [PubMed: 28093034]
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(9):704–717. [PubMed: 15651055]
34. Chung LK, Cimprich B, Janz NK, Mills-Wisneski SM Breast cancer survivorship program: testing for cross-cultural relevance. *Cancer Nurs.* 2009;32(3):236–245. [PubMed: 19295427]
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(3):241–251. [PubMed: 18414902]
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(10):1092–1097. [PubMed: 16717171]
37. Weiss D, Marmar C The Impact of Event Scale-Revised In: Wilson J, Keane T, eds. *Assessing psychological trauma and PTSD: A practitioner's handbook.* New York: 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(7):873–880. [PubMed: 19543809]
39. Senn S Testing for baseline balance in clinical trials. *Stat Med.* 1994;13(17):1715–1726. [PubMed: 7997705]
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(5):581–585. [PubMed: 19807551]
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(7):832–838. [PubMed: 26489770]
42. Wegner DM Ironic processes of mental control. *Psychol Rev.* 1994;101(1):34–52. [PubMed: 8121959]
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(1):15–27. [PubMed: 25100576]

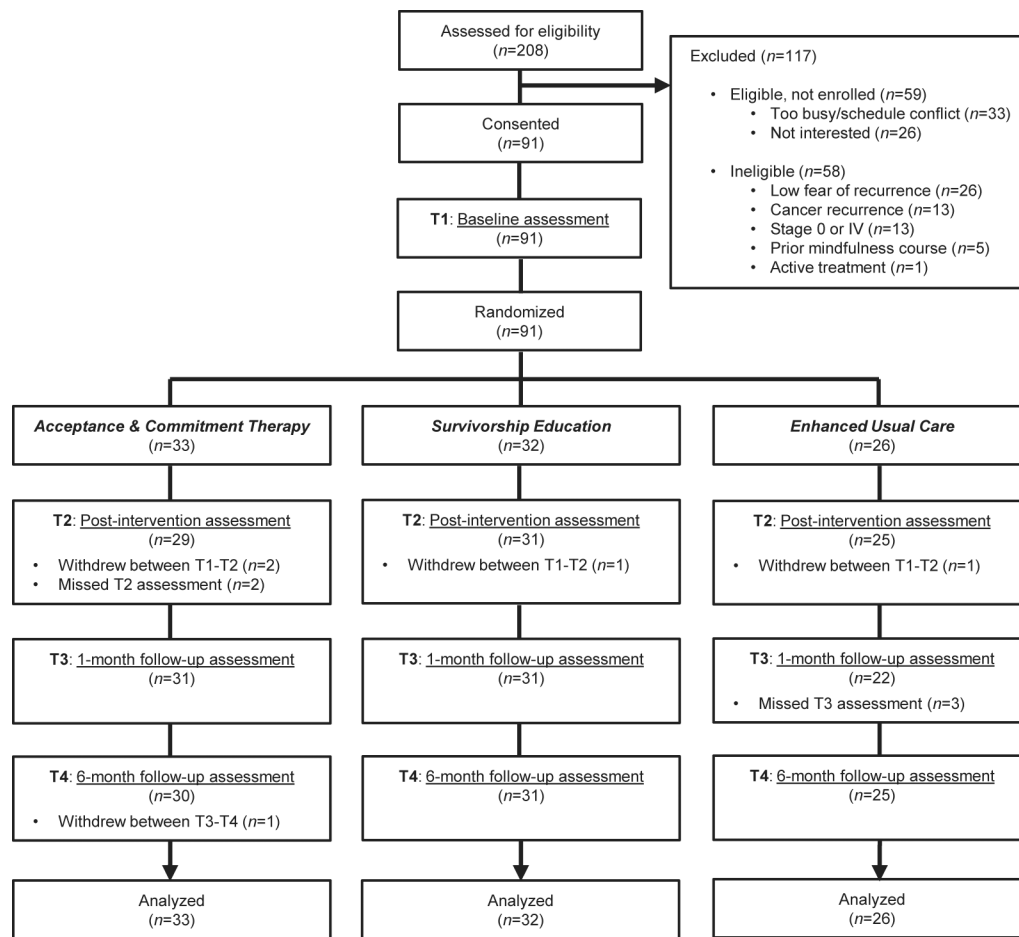


Figure 1.
Consolidated Standards Of Reporting Trials (CONSORT) Diagram

Table 1.

Demographic and clinical characteristics

	All (N=91)	ACT (N=33)	SE (N=32)	EUC (N=26)	p value
Age, mean (SD)	58.70 (10.65)	59.84 (11.10)	57.53 (10.52)	58.68 (10.49)	0.79
Race, n (%)					0.83
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, n (%)	2 (2.20)	0 (0.00)	0 (0.00)	2 (7.69)	0.08
Marital Status, n (%)					0.82
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, n (%)					0.61
Not a 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, post-grad, doctorate	26 (28.57)	7 (21.21)	9 (28.13)	10 (38.46)	
Income, n (%) ^I					0.70
<\$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 (SD)					
Months since diagnosis	64.08 (56.64)	48.28 (28.16)	77.47 (76.57)	67.04 (51.11)	0.61
Age at diagnosis	52.84 (11.36)	54.91 (11.72)	50.58 (10.98)	52.81 (11.25)	0.36
Stage at diagnosis, n (%)					0.42
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, n (%)					0.03
Surgery only	12 (13.19)	6 (18.18)	3 (9.38)	3 (11.54)	
Surgery and Radiation	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 Radiation	42 (46.15)	12 (36.36)	18 (56.25)	12 (46.15)	
Type of Surgery, n (%)					0.33
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)	

	All (N=91)	ACT (N=33)	SE (N=32)	EUC (N=26)	<i>p</i> value
Current Endocrine Therapy, <i>n</i> (%)					0.47
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)	

Notes. ACT=Acceptance and Commitment Therapy; SE=survivorship education; EUC=enhanced usual care; SD=standard deviation. P-values for continuous variables were calculated using either ANOVA or t-test depending on if two groups or three 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 or less, in which case a two-sided Fisher's exact test was used. The p-value for combined income categories (<\$50,000, \$50,000–\$99,999, >\$100,000) is 0.87.

¹Three participants skipped this question

Table 2.

Within- and between-group changes in primary and secondary outcomes from Baseline to Post-Intervention (T1-T2), 1 Month Follow-Up (T1-T3), 6 Month Follow-Up (T1-T4), and Effect Sizes (Cohen's *d*)

	ACT (N=33) LSM [95% CI]	SE (N=32) LSM [95% CI]	EUC (N=26) LSM [95% CI]	ACT vs SE <i>d</i>	ACT vs EUC <i>d</i>	SE vs EUC <i>d</i>
Primary Outcome Measure						
FCRI-Severity						
T1-T2	-4.03 [-5.57, -2.49]***	-0.97 [-2.57, 0.63]	-1.72 [-3.54, 0.09]	0.68*	0.58	-0.19
T1-T3	-4.06 [-5.69, -2.43]***	-1.43 [-3.16, 0.30]	-2.84 [-4.95, -0.73]**	0.53	0.27	-0.32
T1-T4	-5.04 [-6.05, -4.03]***	-1.94 [-2.98, -0.91]**	-3.39 [-4.56, -2.22]***	0.80***	0.61**	-0.36
Secondary Outcome Measures						
FCRI-Triggers						
T1-T2	-3.41 [-5.29, -1.53]***	-0.35 [-2.31, 1.61]	-0.48[-2.70, 1.74]	0.61	0.60	-0.06
T1-T3	-3.55 [-5.42, -1.69]***	-1.66 [-3.63, 0.31]	-3.74 [-6.15, -1.33]**	0.34	-0.04	-0.39
T1-T4	-5.04[-6.05, -4.03]***	-1.94 [-2.98, -0.91]***	-3.39 [-4.56, -2.22]***	0.64***	0.33	-0.31
FCRI-Psychological Distress						
T1-T2	-2.14 [-3.19, -1.09]**	-0.43 [-1.52, 0.32]	0.18 [-1.05, 1.42]	0.67	0.81*	0.22
T1-T3	-2.44 [-3.35, -1.53]**	-0.99 [-1.95, -0.02]*	-0.45 [-1.63, 0.73]	0.60	0.75*	0.23
T1-T4	-2.62 [-3.23, -2.02]**	-0.81 [-1.43, -0.20]*	-1.05 [-1.75, -0.34]**	0.66***	0.52**	-0.08
FCRI-Functioning Impairments						
T1-T2	-1.87 [-3.02, -0.73]**	0.13 [-0.07, 0.33]	-0.99 [-2.35, 0.36]	0.97**	0.23	-0.56
T1-T3	-2.47 [-3.62, -1.32]**	-0.28 [-1.50, 0.93]	-0.59 [-2.08, 0.90]	0.75*	0.48	-0.09
T1-T4	-2.28 [-3.04, -1.53]**	0.20 [-0.57, 0.97]	-0.96 [-1.84, -0.08]*	0.69***	0.35	-0.30
FCRI-Insight						
T1-T2	-0.89 [-1.57, -0.21]*	-0.12 [-0.83, 0.59]	-0.87 [-1.68, -0.07]*	0.41	0.01	-0.50
T1-T3	-1.27 [-1.89, -0.65]**	-0.54 [-1.20, 0.12]	-0.45 [-1.26, 0.35]	0.41	0.44	0.07
T1-T4	-1.18 [-1.62, -0.74]**	0.03 [-0.43, 0.48]	-0.57 [-1.09, -0.06]*	0.54***	0.31	-0.32
FCRI-Reassurance Seeking						
T1-T2	-0.10 [-0.95, 0.75]	0.08 [-0.80, 0.96]	0.18[-0.82, 1.18]	0.08	0.13	0.05

	ACT (N=33) LSM [95% CI]	SE (N=32) LSM [95% CI]	EUC (N=26) LSM [95% CI]	ACT vs SE <i>d</i>	ACT vs EUC <i>d</i>	SE vs EUC <i>d</i>
T1-T3	0.15 [-0.69, 0.99]	0.21 [-0.67, 1.10]	0.28 [-0.80, 1.36]	0.02	0.06	0.04
T1-T4	-0.55 [-1.13, 0.03]	0.10 [-0.50, 0.70]	-0.17 [-0.85, 0.51]	0.23	0.15	-0.11
FCRI-Coping Strategies						
T1-T2	0.39 [-1.85, 2.64]	-0.07 [-0.60, 2.28]	-0.41 [-3.07, 2.24]	-0.08	-0.14	-0.06
T1-T3	-0.55 [-2.50, 0.03]	1.76 [-0.30, 3.80]	-1.23 [-3.80, 0.35]	0.44	-0.14	-0.56
T1-T4	-0.48 [-1.79, 0.82]	0.42 [-0.98, 1.81]	-1.02 [-2.54, 0.51]	0.14	-0.08	-0.25
Cancer Acceptance and Action Questionnaire						
T1-T2	-0.45 [-0.67, -0.23]***	-0.05 [-0.28, 0.18]	-0.03 [-0.29, 0.23]	0.66*	0.68*	0.04
T1-T3	-0.53 [-0.73, -0.32]***	-0.01 [-0.22, 0.21]	-0.15 [-0.42, 0.11]	0.83**	0.59	-0.30
T1-T4	-0.69 [-0.82, -0.56]***	-0.05 [-0.18, 0.09]	-0.22 [-0.37, -0.07]**	0.97***	0.80***	-0.32
Impact of Events Scale-Revised						
T1-T2	-5.34 [-9.05, -1.64]**	-2.12 [-6.02, 1.78]	-1.10 [-5.48, 3.27]	0.33	0.42	0.12
T1-T3	-7.96 [-11.42, -4.50]***	-3.46 [-7.16, 0.25]	0.22 [-4.26, 4.70]	0.44	0.80*	0.34
T1-T4	-7.91 [-9.90, -5.91]***	-3.90 [-5.98, -1.82]***	-5.98 [-8.31, -3.65]***	0.41*	0.19	-0.19
Generalized Anxiety Disorder-7						
T1-T2	-2.36 [-4.06, -0.66]**	-0.32 [-2.09, 1.45]	-0.25 [-2.26, 1.76]	0.44	0.52	0.02
T1-T3	-3.04 [-4.64, -1.43]***	0.31 [-1.39, 2.01]	-0.38 [-2.46, 1.70]	0.73*	0.73	-0.17
T1-T4	-3.25 [-4.05, -2.46]***	0.43 [-0.39, 1.25]	-0.63 [-1.56, 0.30]	0.95***	0.75***	-0.30
Patient Health Questionnaire-8						
T1-T2	-1.55 [-2.81, -0.28]*	-0.07 [-1.39, 1.25]	-0.58 [-2.08, 0.91]	0.39	0.31	-0.15
T1-T3	-1.77 [-2.90, -0.63]**	-0.65 [-1.85, 0.56]	0.01 [-1.46, 1.48]	0.32	0.57	0.23
T1-T4	-1.72 [-2.42, -1.03]***	-0.42 [-1.13, 0.30]	-0.29 [-1.10, 0.52]	0.38*	0.50*	0.04
PROMIS Global Health-Physical						
T1-T2	1.31 [0.68, 1.94]***	0.00 [-0.68, 0.68]	-0.34 [-1.13, 0.45]	0.72***	0.95***	0.23
T1-T3	1.25 [0.60, 1.91]***	-0.20 [-0.92, 0.51]	-0.20 [-1.11, 0.71]	0.75***	0.76***	0.00
T1-T4	1.32 [0.93, 1.71]***	0.07 [-0.34, 0.48]	-0.51 [-0.99, -0.03]*	-0.62***	-0.82***	0.32
PROMIS Global Health-Mental						
T1-T2	1.36 [0.52, 2.19]**	-0.26 [-1.18, 0.67]	0.18 [-0.80, 1.15]	0.68***	0.55**	-0.24

	ACT (N=33) LSM [95% CI]	SE (N=32) LSM [95% CI]	EUC (N=26) LSM [95% CI]	ACT vs SE <i>d</i>	ACT vs EUC <i>d</i>	SE vs EUC <i>d</i>
T1-T3	1.43 [0.63, 2.24] ***	-0.10 [-0.97, 0.77]	0.25 [-0.78, 1.28]	0.68 ***	0.58 **	-0.19
T1-T4	1.28 [0.83, 1.72] ***	0.11 [-0.36, 0.58]	0.03 [-0.49, 0.54]	-0.52 **	-0.58 **	-0.04

Note: ACT=Acceptance and Commitment Therapy; SE=survivorship education; EUC=enhanced usual care; LSM=least squares mean, from the general linear model. T1-T2 refers to T1 to T2 change calculated as T2 outcome score minus T1 outcome score. CI=confidence interval; FCRI=Fear of Cancer Recurrence Inventory; PROMIS=Patient-Reported Outcomes Measurement Information System

* $p < .05$

** $p < .01$

*** $p < .001$