Dear Editor,

This study assessed the acceptability, feasibility, and preliminary efficacy of a novel, theory-driven group intervention designed to address the psychological needs of cancer patients experiencing anxiety during the transition from cancer patient to post-treatment cancer survivor (the re-entry phase). Anxiety is particularly intense at re-entry [1,2] and predicts lower quality of life (e.g. [3]) and the overutilization of medical care (e.g. [4]). As highlighted by the Institute of Medicine [2] and others (e.g. [1,5]), the re-entry phase poses particular psychosocial challenges, many of which lead to elevated anxiety. Cancer survivors may experience uncertainty about the meaning and purpose of their lives following cancer, triggering anxiety. Additionally, they may worry: ‘Does this symptom mean that my cancer is back?’, ‘How can I live knowing that my cancer might return?’, and ‘Now that treatment is over, why am I not back to normal?’ [2,5,6]. Fear of cancer recurrence figures prominently, yet the focus of anxiety extends beyond it [2,5]. Moreover, anxiety often persists for a decade or more after cancer treatment, representing the largest mental health difference between long-term cancer survivors and community controls [7]. Further, evidence demonstrates that cancer patients with higher levels of anxiety (and distress in general) benefit most substantially from psychosocial interventions [8,9]. Yet to date, no interventions have been designed and demonstrated to specifically meet the needs of cancer survivors experiencing anxiety at re-entry [1,10]. By targeting anxiety at re-entry and potentially thwarting the development of chronic, costly anxiety, our intervention aims to address this unmet need.

Our intervention is founded on a theory-driven behavioral approach, Acceptance and Commitment Therapy (ACT), that as previous work from our team and others demonstrates, shows efficacy for treating elevated anxiety in general populations (e.g. [11]) and for reducing anxiety in cancer populations outside of the re-entry period [12,13]. ACT promotes forms of coping that predict positive psychosocial outcomes among cancer survivors: actively accepting cancer-related distress, reducing cancer-related avoidance, clarifying personal values, and committing to meaningful behavior change (e.g. [14]). ACT allows for rather than minimizes the distress of cancer and fear of recurrence—an approach that may authentically validate the fears of re-entry phase survivors, many of whom live with the real possibility of relapse and early mortality. Thus, ACT may help cancer survivors increase their capacity to live meaningfully and effectively even with persistent side effects and uncertainty about the future—a hypothesis supported by an ACT study in late-stage ovarian cancer patients and another in general cancer patients [12,13].

This study represents the first known effort to adapt and pilot an ACT intervention for cancer survivors experiencing anxiety at re-entry and the first to use ACT with cancer patients treated in a community cancer care setting (e.g. outside of a university setting). First, within the context of a community cancer care clinic, we adapted a group ACT intervention and investigated its feasibility by evaluating whether we could identify and recruit 40 cancer survivors with elevated anxiety using an evidence-based screener. Second, we assessed intervention acceptability by evaluating whether participants would attend the majority of ACT sessions and rate them highly. Third, we investigated preliminary efficacy by testing the hypothesis that ACT would increase reduce cancer-specific and broad negative outcomes, including the primary outcome of anxiety, and increase positive outcomes. Finally, we hypothesized that ACT would lead to increases in cancer-related psychological flexibility and that such increases would predict improvement in outcomes. We assessed
we hypothesized that the targeted outcomes would change following ACT but not during the (nearly) month-long multiple baseline period that preceded it.

**Methods**

**Participants**

Participants were English-fluent adults (18 years or older) who: (a) completed primary cancer treatment (surgery, chemotherapy, and/or radiation) within the previous 12 months; (b) indicated moderate to severe anxiety (with or without depression symptoms, see Screener); and (c) showed no evidence of cancer disease (NED) or had stable, chronic disease under ‘watchful waiting.’ Participants were recruited from Rocky Mountain Cancer Centers-Boulder in partnership with the University of Colorado Boulder. IRBs for both institutions approved the study; participants gave informed consent. Of the 157 patients screened, 71 were eligible, and 42 consented to participate. The four groups had 8–12 participants each, characterized in Table 1.

**Intervention adaptation and content**

Based on an iterative process of soliciting feedback from outside ACT experts and written weekly ratings from participants, we developed and successively refined a group manual and participant workbook for 7 weekly 2-h sessions. Using experiential exercises, metaphors, discussion, and homework, the intervention aimed to help participants: (a) Cultivate awareness and acceptance of thoughts and emotions about cancer and themselves, by cultivating flexibility in relating to such thoughts/beliefs; and (c) Clarify personal values and commit to pursue meaningful activities aligned with those values.

We selected ACT metaphors and exercises using the rationale that they appeared particularly relevant to addressing the psychosocial struggles of cancer survivors experiencing anxiety at re-entry and could be readily taught and disseminated within a community cancer care setting. In the first three sessions we employed the Matrix [15], a simple tool for teaching the ACT model. Figure 2 (see Supporting Information) illustrates how we applied the Matrix to address the psychosocial challenges of re-entry, using sample content from our group participants. Specifically, we provided the Matrix outline and asked group members to discuss their challenging thoughts and feelings related to cancer and the actions they take to get rid of or escape those feelings (struggle actions). Next we had them share who and what are most important to them (values) and what they do (or could do) to flexibly enact their values (valued actions). Whenever challenging cancer-related thoughts, feelings, or physical sensations arose in daily life, they then tracked how they responded and whether their response moved them towards versus away from their values. In the remaining sessions, participants learned how to skillfully respond to cancer-related thoughts and feelings and move towards valued actions, rather than remain stuck in struggle actions. A central tool employed in later sessions was the Passengers on the Bus metaphor [16], which invited participants to identify persistently challenging thoughts, feelings, and memories/images about cancer, labeled ‘passengers’. We experientially taught skills in how to actively accept, defuse (develop flexibility in how one relates to them), and compassionately respond to passengers, while not allowing them to dominate their life. The most common ‘passengers’ focused on anxiety and fear of various issues related to cancer, e.g. fear of dying, cancer recurrence, or being diagnosed with a new cancer, fear of failing to reintegrate into ‘regular’ life, fear of coming to terms with shifted personal priorities, fear of being treated differently or misunderstood by others. Thus we spent the majority of time focused on skillful responding to anxiety and fear related to cancer and survivorship. In addition to these two central tools, we employed various smaller exercises and metaphors adapted from previous ACT protocols (e.g. [16–18]) to address other cancer-specific psychosocial content.

**Facilitators and supervision**

The groups were jointly facilitated by a clinical psychologist with 10 years of experience with ACT (J.J.A.) and an experienced oncology social worker trained in ACT (J.L.M.). Outside ACT experts provided weekly supervision.

**Measures**

**Screener**

The screener aimed to identify cancer survivors who were anxious or depressed in their daily lives and anxious about

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**Table 1.** Participant sociodemographic and cancer profiles

<table>
<thead>
<tr>
<th>Variable</th>
<th>Breast</th>
<th>Gastrointestinal</th>
<th>Gynecologic</th>
<th>Leukemia/lymphoma</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>% (N/42)</td>
<td>59.52% (25/42)</td>
<td>14.29% (6/42)</td>
<td>9.52% (4/42)</td>
<td>7.14% (3/42)</td>
<td>9.52% (4/42)</td>
</tr>
</tbody>
</table>

**Cancer stage (solid tumor cancers)**

<table>
<thead>
<tr>
<th>Stage</th>
<th>% (N/33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3.03% (1/33)</td>
</tr>
<tr>
<td>I</td>
<td>27.27% (9/33)</td>
</tr>
<tr>
<td>II</td>
<td>27.27% (9/33)</td>
</tr>
<tr>
<td>III</td>
<td>39.39% (13/33)</td>
</tr>
<tr>
<td>IV</td>
<td>6.06% (2/33)</td>
</tr>
</tbody>
</table>

**Sociodemographics**

<table>
<thead>
<tr>
<th></th>
<th>% (N/42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>92.86% (39/42)</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>53.52 (SD = 11.05)</td>
</tr>
<tr>
<td>Range: 20s–70s</td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>97.44% (38/39)</td>
</tr>
<tr>
<td>Married or partnered</td>
<td>61.54% (24/39)</td>
</tr>
<tr>
<td>Have children</td>
<td>51.28% (21/41)</td>
</tr>
<tr>
<td>Education (median)</td>
<td>Bachelor's degree</td>
</tr>
<tr>
<td>Household income (median)</td>
<td>$41,000–60,000</td>
</tr>
</tbody>
</table>

Note that we lacked medical chart-confirmed cancer staging for six participants with solid tumor cancer, and full sociodemographic data for three participants.
cancer, based on: (a) a validated six-item version of the State-Trait Anxiety Inventory (STAI; [19]) referencing the past month; (b) a four-item Patient Health Questionnaire for Anxiety and Depression (PHQ-4; [20]); and (c) a 0–10 rating on a ‘your current anxiety about cancer’ scale. To be eligible, patients had to score (a) 14+ on the STAI [21] or (b) 3+ on either the depression or anxiety scales of the PHQ-4 [20] and endorse a 5+ regarding ‘current anxiety about cancer’. In total, 100% (71/71) of patients who met the eligibility criteria screened positively for anxiety symptoms in daily life (e.g. on the PHQ-4 anxiety scale or STAI) whereas 52.11% (37/71) screened positively for both anxiety and depression symptoms in daily life.

Outcome measures

Participants completed outcome questionnaires confidentially online at three baseline points (3.5, 2, and .5 week[s] prior to the group2), mid-intervention (Mid), 1 week following the last group session (Post), and 3-months following Post (FU). With the exception of the study mediator measure (see below), we employed widely validated outcome measures used extensively in previous studies. Participants were paid $20–25 per assessment.

The state STAI (full 20-item version; [21]) and Center for Epidemiological Studies Depression scale [22] measured anxiety and depressive symptoms, respectively. Two RAND SF-36 scales assessed each physical pain and vitality (the reverse of fatigue; [23]). An adapted version (for all cancer types) of the Overall Fear scale from the Concerns about Recurrence Scale [24] assessed fear of recurrence. The Revised Impact of Events Scale [25] assessed cancer-related trauma symptoms. The Orientation to Life Questionnaire [26] assessed life meaning, comprehensibility, and manageability. Change in ACT processes (e.g. psychological flexibility) was measured by the 15-item Cancer Acceptance and Action Cancer Questionnaire (baseline $\alpha$’s = .91–.95), a scale adapted for this study by focusing items from the widely validated AAQ-II [27] and diabetes-adapted AAQ [28] towards cancer. Adapting AAQ items towards a specific clinical target (e.g. diabetes, social anxiety, chronic pain, and weight maintenance) has been shown across numerous studies to yield valid measures (e.g. [29,30]) that mediate ACT outcomes for the relevant population [28,31–34]. Cancer-related information was confirmed by medical chart review.

Statistical approach

Within hierarchical linear models using all available data (HLM 6.08), we employed a piecewise coding approach [35] to separately assess change across the three baseline assessments and change from the baselines through each Post and FU. Change across baseline is reported while change from the baselines through Post is held constant and vice versa. Findings were consistent across two-level and three-level HLMs, the latter of which accounted for group clustering. Three-level HLMs showed that clustering was non-significant across all group outcome slopes and led to insufficient df/s to estimate random intercepts; we thus report findings from the two-level HLMs.3 Dropouts (n=4) were encouraged to complete all assessments (n=1 obliged) and, regardless, were included in all analyses. The one patient whose cancer relapsed mid-study was excluded from analysis.

Results

Feasibility

As the Supplemental Figure 1 illustrates, nearly half (45.22%; 71/157) of screened cancer survivors were study-eligible, and 59.15% (42/71) of study eligible participants were recruited to the study. All attended at least one group session; median attendance was six of seven sessions.

Acceptability

Session-by-session participant ratings of ‘how valuable was this session’ yielded a mean of 4.35 (SD=.68, Range=3.91–4.83) on a 1–5 scale in which 1 = not valuable, 3 = somewhat valuable, and 5 = extremely valuable.

ACT group outcomes

Reduced broad negative effects: primary outcomes

As Figure 1 and Supplemental Table 1 present, anxiety declined significantly following the group through Post, $p < .001$, $d = .75$, and FU, $p < .001$, $d = 1.00$, but did not change significantly during the month-long baseline period, $p = .68$, $d = .06$. Depression symptoms declined significantly following the group through Post, $p < .001$, $d = .78$, and FU, $p < .001$, $d = .95$, but not during baseline, $p = .18$, $d = .16$.

Reduced cancer-specific negative effects

Fear of cancer recurrence decreased through Post, $p < .05$, $d = .34$, and FU, $p = .001$, $d = .66$, but not during the month-long baseline period, $p = .43$, $d = .11$.

Physical pain decreased through Post, $p = .05$, $d = .36$, and FU, $p < .01$, $d = .54$, but not during baseline, $p = .64$, $d = .07$.

Trauma symptoms related to cancer diminished at Post, $p = .001$, $d = .58$, and FU, $p < .001$, $d = .84$, but not during baseline, $p = .99$, $d = .00$. Reductions were evident on each subscale: intrusiveness (Post: $p < .001$, $d = .68$; FU: $p < .001$, $d = .86$), hyperarousal (Post: $p = .005$, $d = .48$; FU: $p < .001$, $d = .79$), and avoidance at FU (Post: $p = .16$, $d = .17$; FU: $p = .03$, $d = .32$).

Increased positive effects

Vitality increased from baseline to Post, $p = .001$, $d = .52$, and FU, $p < .001$, $d = .77$, but also increased during baseline, $p = .01$, $d = .29$; see Figure 1.
From baseline to Post and FU, increases were evident in sense of life meaning (Post: \( p < .001, d = .38 \); FU: \( p < .001, d = .49 \)), comprehensibility (Post: \( p = .02, d = .32 \); FU: \( p < .001, d = .61 \)), and manageability (Post: \( p = .05, d = .21 \); FU: \( p = .003, d = .37 \)). Across the month-long baseline period, life meaning, \( p = .17, d = .13 \), comprehensibility, \( p = .58, d = .07 \), and manageability, \( p = .82, d = .02 \), did not change significantly.

**Prediction by psychological flexibility**

Using time-lagged models in HLM, we assessed whether change in cancer-related psychological flexibility from Baseline (mean of Baselines 1–3), Mid, and Post, predicted subsequent change in outcomes from Mid, Post, and FU. On Level 2 intercept (and slope, when significant), we controlled for mean baseline levels of the outcome.

Change in cancer-related psychological flexibility predicted subsequent change in most outcomes: depression, \( p = .04 \); physical pain, \( p = .03 \); traumatic impact of cancer, \( p = .01 \); vitality, \( p = .03 \); life meaning \( p = .03 \); and life manageability \( p = .04 \). It also nearly predicted change in anxiety, \( p = .06 \), and life comprehensibility, \( p = .08 \), but not fear of recurrence, \( p = .33 \). In summary, increases in cancer-related psychological flexibility predicted or nearly predicted subsequent improvement on 8 of 9 outcomes, consistent with the role of a partial mediator.

**Moderation by depressive symptoms**

All participants screened positively for at least one domain of elevated daily anxiety symptoms (in addition to endorsing moderate to high anxiety about cancer) but only about half (52.11%) screened positively for depression symptoms as well (see Screener). Within multivariate ANOVA, screening positively for depression (using the \( \geq 3 \) cutoff; [20]) predicted lower anxiety scores at Post, \( p = .04 \), but not at FU, \( p = .85 \). However, screening positively for depression failed to moderate negative cancer-specific effects or positive effects, \( p_s > .15 \). Thus generally, participants who screened positively versus negatively for depression benefitted similarly.

**Discussion**

This study represents the first to adapt and pilot an ACT-based group intervention for anxious cancer survivors at re-entry. Within a community-based cancer care setting, we examined ACT’s preliminary feasibility, acceptability, efficacy, and mediation by psychological flexibility. The multiple baseline design permitted comparing change across (brief) time alone to change following the intervention. Findings generally supported the research questions and hypotheses, demonstrating the initial promise of an
ACT intervention for anxious cancer survivors

ACT group approach for addressing the psychological needs of cancer survivors with elevated anxiety at re-entry.

Specifically, compared to the month-long baseline period, participants reported significant improvements across all outcomes, including our primary outcome of anxiety, following the ACT group. By follow-up, the magnitude of improvement was large for anxiety, depression, and vitality (fatigue), medium to large for fear of cancer recurrence, trauma-related symptoms, physical pain, and sense of life comprehensibility, medium for sense of life meaning, and small to medium for sense of life manageability. Our mediation hypothesis was largely supported in that cancer-related psychological flexibility predicted or nearly predicted subsequent change in 8 of the 9 outcomes. Findings are consistent with studies demonstrating the benefits of ACT-based interventions for cancer patients at different stages of treatment [12] and late-stage ovarian cancer patients [13].

Strengths and limitations

Conducting the study in the community, where the vast majority of cancer patients receive care, using a resource-efficient group model, and refining the intervention based on an iterative process of patient-centered feedback, represent study strengths.

Study limitations include the modest sample and single-arm design. However, it can be argued that a single-arm design was appropriate for a pilot study conducted in the community, as we aimed to demonstrate feasibility and assess the promise of the intervention prior to more intensive community investment. Further, the one-month multiple baseline period and piecewise statistical approach demonstrated that change following the intervention was significant whereas change during time alone generally was not. A major review demonstrated that anxiety symptoms often remain elevated over an extended time period among cancer survivors (>10 years post-treatment; 7), bolstering the current finding that (briefer) time alone did not significantly reduce anxiety. Randomized trials are nonetheless needed to draw the definitive conclusion that the intervention is superior to time alone. Finally, future studies should focus on recruiting more men and a more sociodemographically diverse patient population.

Conclusions

This study represents the first adaptation and investigation of an ACT intervention for anxious cancer survivors at re-entry. Findings demonstrate that relative to a month-long baseline period, ACT led to moderate to large improvements in cancer-specific and broader outcomes. The promise of this approach warrants further investigation.

Acknowledgements

This project was funded by an American Cancer Society Institutional Research Grant through the University of Colorado Cancer Center and an Innovative Seed Grant through the University of Colorado Boulder, to PI-Arch. We thank Drs. Kelly Wilson, Jennifer Plumb Vilaradaga, and Joanne Steinwachs, for sharing their ACT expertise, training, and supervision. Dr. Albert Marcus for his early support, Susan Ash-Lee, LCSW, and Drs. David Andorsky, John Fleagle, and Robert Fisher for organizational support, Dr. Charles Judd for statistical advice. Kelsee Henningsen, Alaina Carr, and Kevin McGuire for study coordination, and Lauren Landy for assistance in many domains. Above all, thank you to the courageous adults who participated in this study.

Conflict of interest

The authors have declared no conflicts of interest.

Key Points

- This pilot study investigated the preliminary feasibility and efficacy of an Acceptance and Commitment Therapy (ACT) group intervention for cancer survivors experiencing anxiety during the transition from active treatment to post-treatment (the re-entry phase).
- Cancer survivors experiencing significant anxiety at re-entry (n=42) participated in a group ACT intervention within 12 months of finishing primary cancer treatment.
- We assessed improvement on broad negative effects (anxiety and depression symptoms), which included our main outcome of anxiety, cancer-specific negative effects (fear of recurrence, cancer-related trauma symptoms, and physical pain), and positive effects (vitality, sense of life meaning/comprehensibility/manageability). Outcomes were assessed across a month-long multiple baseline period, mid- and post-intervention (Post), and 3-month follow-up (FU). Cancer-related psychological flexibility was tested as a putative mediator.
- Intent-to-treat analyses demonstrated robust improvement across all outcomes from the multiple baseline to Post, ps ≤.05, ds = .21–.78, and FU, ps ≤.01, ds = .37–1.00, with anxiety and depression symptoms showing the largest improvements across both Post (p <.001, ds = .75–.78) and FU (p <.001, ds = .95–1.00). Change in cancer-related psychological flexibility predicted or nearly predicted subsequent change in 8 of 9 outcomes. High attendance and session ratings indicated strong feasibility.
- ACT, delivered as a group intervention within a community cancer care setting, appeared to produce broad and substantial psychosocial improvements among anxious cancer survivors at re-entry, warranting further investigation.

Notes

1. Specifically, limited efforts have addressed fears of recurrence in select cancers, but none have
addressed the broad anxiety that often emerges following cancer treatment, including yet going beyond fear of recurrence, with relevance across cancer types.

2. To accommodate last-minute participants, the fourth group completed only the second and third baselines.

3. Findings between two- and three-level HLMs did not significantly differ.

References


Supporting information

Additional supporting information may be found in the online version of this article at the publisher’s web site.