

Acceptability, feasibility, and efficacy potential of a multi-modal ACT intervention to address psychosocial and advance care planning needs among anxious and depressed adults with metastatic cancer

Running title: M-ACT for adults with advanced cancer

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Abstract

Background: Adults with metastatic cancer frequently report anxiety and depression symptoms, which may impact health behaviors such as advance care planning (ACP).

Objective: The study leveraged Acceptance and Commitment Therapy (ACT), an evidence-based approach for reducing distress and improving health behaviors, and adapted it into a multi-modal intervention (M-ACT) designed to address the psychosocial and ACP needs of anxious and depressed adults with metastatic cancer. The study evaluated M-ACT's acceptability, feasibility, and efficacy potential.

Design: The study was designed as a single-arm intervention development and pilot trial.

Setting/Subjects: The trial enrolled 35 anxious or depressed adults with stage IV cancer in community oncology clinics, with a referred-to-enrolled rate of 69% and eligible-to-enrolled rate of 95%.

Measurements: M-ACT alternated four in-person group sessions with three self-paced online sessions.

Acceptability and feasibility were assessed through enrollment, attendance, and satisfaction ratings. Outcomes and theorized intervention mechanisms were evaluated at baseline, mid-intervention, post-intervention, and 2-month follow-up.

Results: Participant feedback was used to refine the intervention. Of participants starting the intervention, 92% completed, reporting high satisfaction. One-quarter did not begin M-ACT due to health declines, moving, or death. Completers showed significant reductions in anxiety, depression, and fear of dying, and increases in ACP and sense of life meaning. In this pilot, M-ACT showed no significant impact on pain interference. Increases in two of three mechanism measures predicted improvement on 80% of significant outcomes.

Conclusions: The M-ACT intervention is feasible, acceptable, and shows potential for efficacy in community oncology settings; a randomized trial is warranted.

Keywords: Acceptance and Commitment Therapy; Advance Care Planning; Anxiety; Cancer; Metastatic; Depression; Palliative Care; Online

Introduction

Adults with metastatic cancer often report anxiety and depression symptoms, fear of dying, existential distress, and pain-related distress, which have been linked to lower quality of life and decreased survival time.¹⁻³ To exercise control over their future care, patients with metastatic cancer must engage in advance care planning (ACP), which involves “understanding and sharing [one’s] personal values, life goals, and preferences regarding future medical care”⁴ including legally designating and discussing these values, goals, and preferences with a healthcare proxy in preparation for the possibility of becoming too ill to speak for oneself. Previous interventions address only a limited number of these broad psychosocial and ACP needs,⁵ require regular access to palliative care specialists, of whom there is a serious shortage,⁶ or target patients in general^{7, 8} rather than the anxious or depressed patients most in need of support. Few interventions that do not rely on palliative care specialists have targeted this full range of needs and few have focused on metastatic patients with elevated anxiety or depression symptoms. This study designed, refined, and piloted a **multi-modal primary palliative care intervention based on Acceptance and Commitment Therapy (M-ACT)**, an evidence-based approach for reducing distress and improving health behaviors.⁹ The intervention aimed to address the psychosocial and initial ACP needs of adults with metastatic cancer reporting elevated anxiety or depression symptoms.

Adults with advanced cancer often experience declining health, intensive treatment schedules, and increasingly limited mobility, making it difficult to participate in lengthy in-person interventions.^{7, 10} Providing support through online platforms could remedy these issues, but trials of online-only interventions for patients with cancer have generally shown limited and inconsistent psychological benefits.¹¹ A meta-analysis found that online interventions are more efficacious and show higher retention rates when they include provider contact and support.¹² Further, studies evaluating group and individual formats of the same psychosocial intervention for adults with metastatic cancer have highlighted the benefits of group interaction,¹³ suggesting the importance

of face-to-face patient contact. We hypothesized that a blended or multi-modal approach that integrated offline and online intervention components,¹⁴ specifically, four face-to-face group sessions alternating with three self-paced online sessions, would reduce barriers to completing lengthy in-person interventions,^{7, 10} without sacrificing in-person connection. Interspersing online sessions with group sessions also holds participants accountable for completing the online sessions. While a blended approach has shown efficacy in reducing fear of cancer recurrence (FCR) among early stage cancer survivors,¹⁵ to our knowledge this is the first study to assess this blended or multi-modal approach for addressing psychosocial and ACP needs of adults with metastatic cancer.

M-ACT promotes forms of coping that predict positive psychosocial outcomes among cancer survivors: actively accepting emotions, reducing dominance of distressing thoughts, clarifying values, and committing to pursue activities/decisions that reflect values.^{16, 17} In a small trial of ACT vs. basic cognitive therapy for women with late-stage ovarian cancer, ACT led to superior psychosocial outcomes by large effects.¹⁸ However, this trial provided 12 individual ACT sessions, and a second small trial provided up to 8 individual sessions,¹⁹ requiring intensive resources that impede scalability.

We thus developed M-ACT to address patient needs in a more efficient manner by including a limited number of group sessions, which treats multiple patients at once and synergizes their collective experience, together with online sessions and check-ins completed on their own between group sessions. Targeting metastatic cancer patients with elevated anxiety or depression symptoms represents a triaging approach that is an efficient use of clinic resources. In contrast to previous ACT interventions for cancer survivors with various stages of cancer²⁰ or with no current evidence of disease,²¹ M-ACT included a focus on ACP completion and addressed concerns specific to metastatic cancer such as declining health, values regarding end-of-life care, and mortality/running out of time to live. Finally, M-ACT was developed and piloted in collaboration with community-based oncology care clinics. To further improve scalability within community settings and to serve

a broader range of patients, including those with less common forms of cancer, the intervention was designed to serve patients with various forms of metastatic cancer (see Methods and Table 1).

This study also explored intervention mechanisms, defined as the core therapeutic processes that are purported to achieve change and thus to predict intervention outcomes.²² Previous research has identified two core ACT mechanisms:^{22, 23} (1) opening up toward internal experience through acceptance and cognitive defusion (observing thoughts in a more objective manner), and (2) moving in meaningful life directions by clarifying personal values and pursuing activities and decisions that reflect those values. We thus explored the extent to which the M-ACT intervention was associated with change in these core mechanisms, and whether change in mechanisms predicted subsequent change in outcomes.

This study aimed to develop and refine M-ACT in response to participant and provider feedback, and to conduct a single-arm pilot trial to assess feasibility, acceptability, and potential for efficacy in anxiety and depression symptoms (primary outcomes), ACP, fear of dying, pain interference, and life meaning (secondary outcomes), and explore intervention mechanisms.

Methods

Participants

Participants (see Table 1) were English-fluent adults who were: (a) 18 years or older, (b) diagnosed with Stage IV solid tumor cancer (any type) or incurable, life-threatening hematologic malignancy; and had: (c) an Eastern Cooperative Group Performance Status of 0 to 2,²⁴ i.e., physically well enough to participate, (d) moderate to severe anxiety or depression symptoms (see Screener). Participants were recruited from Rocky Mountain Cancer Centers in Colorado (Supplemental Figure 1); groups were run onsite in four cohorts of 5 to 9 participants. The University of Colorado Boulder IRB approved the study (protocol #16-0357) and participants gave informed consent.

Intervention Development and Refinement

M-ACT content was developed through an iterative process of adaptation from previous ACT interventions for anxious post-treatment cancer survivors,²¹ with new online content and delivery, and a specific focus on ACP and concerns related to metastatic disease and end-of-life (e.g., fear of running out of time, declining health). We refined M-ACT in response to feedback from stakeholder clinicians ($n=11$) and participants (see Supplement).

The M-ACT Intervention Delivery and Content

As outlined in the Supplemental Materials, the final M-ACT intervention consisted of: a) four manualized 2-hour group sessions co-led by an onsite oncology social worker and a clinical psychologist (X.X.X.), interspersed with: b) three 45-minute self-paced online sessions that participants completed on their own, and c) daily 5 to 7-minute online check-ins throughout. Online sessions, programmed in Qualtrics,²⁵ applied skills learned in group to daily life and to ACP through interactive exercises that dynamically adapted content to individual's values/goals identified earlier in the session or previous sessions.

Measures

Screener. Participants were study-eligible if they scored 3+ on either the anxiety or depression symptom (anx/dep) scale of the 4-item Patient Health Questionnaire,²⁶ indicating anx/dep in daily life, *and* 5+ on either a 0-10 cancer-related anxiety scale or parallel depression scale, indicating anx/dep about cancer.

Assessments were completed in REDCap¹ at baseline (Pre), mid-intervention (after 2nd group), 1-week post-intervention (Post) and 2-months post-intervention (FU).

Outcomes. The primary outcomes were anxiety symptoms and depression symptoms (anx/dep) evaluated with the widely used and validated Hospital Anxiety and Depression Scale;²⁸ baseline α s=.81 and .84 for the anxiety and depression scales. Secondary outcomes included fear of dying, pain interference, sense of

¹ REDCap is a secure, widely-used, web-based platform that supports data capture for research studies [27].

life meaning, and completion of initial ACP steps. The first three were assessed with the validated Death and Dying Distress Scale²⁹ (baseline $\alpha=.94$), which assesses fear of dying and shows good convergent and discriminant validity; the widely-used, validated Rand Short Form Health Survey-36 single-item pain-interference question,^{30, 31} which assesses the degree to which pain interferes normal work including housework; and the widely-used Functional Assessment of Chronic Illness Therapy-Spirituality³² peace/meaning scale (baseline $\alpha=.92$), which assesses sense of life meaning and inner peace, and shows good convergent and discriminant validity and test-retest reliability.³³ Three yes/no questions were summed to assess initial ACP steps: (1) reflected on your personal values related to advance care planning; (2) identified a health care agent; and (3) completed a Medical Durable Power of Attorney form to legally appoint your healthcare agent.

Mechanisms. The theorized M-ACT mechanism of opening up toward internal experience via acceptance and cognitive defusion was assessed with the Experiences Questionnaire-Decentering scale³⁴ (EQ; baseline $\alpha=.93$) which measures acceptance and defusion generally, and the Cancer Acceptance and Action Questionnaire³⁵ (baseline $\alpha=.90$), which measures acceptance/defusion specifically for thoughts and feelings about cancer. The theorized M-ACT mechanism of aligning behavior with personal values was assessed with the Bulls Eye Values Survey³⁶ (baseline $\alpha=.86$).

Acceptability. On the Client Satisfaction Questionnaire,³⁷ modified for M-ACT (e.g., changing references to “service” to “program”), at Post ($\alpha=.81$), we aimed for a mean above 3.00 (Good-Excellent) on the 0-4 scale, and on the piloted Session Feedback Questionnaire³⁵, aimed for a mean of 4.00 on a “How valuable was today’s session for you?” scale with 1=not valuable, 3=somewhat valuable, and 5=extremely valuable.

Feasibility. The goal was a $\geq 50\%$ referred-to-enrolled rate and 70% study completion rate through FU.

Statistical Approach

We analyzed change in outcomes using nested hierarchical linear models (HLM)² with random intercepts and slopes to model change over time and compare Pre vs. Post and FU (see Supplement).

Results

Intervention Feasibility and Acceptability

Of 51 study-referred patients (by providers, flyers), 35 (69%) enrolled in the study, representing 95% of study-eligible patients. Of these 35 enrollees, 26 began the intervention and 24 (69%) completed the assessments, including 1 who dropped out of the intervention (Supplemental Figure 1). Participants who began the intervention ($n=26$) completed an average of 3.25 ($SD=.68$) of 4 group sessions, 2.92 ($SD=.28$) of 3 online sessions, and overall 6.17 ($SD=.76$) of the 7 group and online sessions together, indicating good feasibility. They also completed an average of 3.02 ($SD=1.81$) of online check-ins per week. For acceptability, the Client Satisfaction Questionnaire $M=3.29$ ($SD=.39$) and ‘how valuable was this session’ question $M=4.57$ ($SD=.49$) met or exceeded aims.

We analyzed outcomes for all 24 participants with data beyond baseline, see Supplemental Figure 1.

Outcomes

As Table 2 presents, anxiety, depression, and sense of life meaning improved significantly over time and from Pre to Post/FU (see Supplemental Table 2 for the full models, including intercepts). ACP and fear of dying improved significantly over time and from Pre to FU (ACP was discussed toward the end of M-ACT; thus, change did not emerge until FU). By FU, 65% completed the three ACP tasks, compared to 29% at baseline. Pain interference showed no change.

Mechanisms

Among the mechanisms/processes, both measures of acceptance/defusion increased over time

²We report 2-level HLMs as 3-level HLMs showed similar outcomes but did not improve fit, showed little clustering, and had few *dfs* for random intercepts.

(decentering marginally, Table 2). We thus focused analyses on these two mechanisms and on outcomes that improved significantly from Pre to Post. In mixed models, change in each general defusion/decentering (EQ) and cancer-specific acceptance/defusion (AAQc) from Pre to Mid predicted change in anxiety, depression, and life meaning from Pre to Post ($ps < .001$) and change in these outcomes, plus fear of dying, from Pre to FU ($ps < .001$, though Pre to FU life meaning was predicted by decentering only), see Supplement.

Discussion

This study developed and preliminarily evaluated the first known blended online and in-person group intervention for anxious and depressed adults with metastatic cancer. Aims included developing the M-ACT intervention (for online sessions) or adapting it from previous work (for group sessions), refining intervention content in response to participant and provider feedback, and conducting a single-arm pilot trial to assess intervention feasibility, acceptability, and potential to impact outcomes and theorized mechanisms.

Feasibility and Acceptability

Based on *a priori* quantitative and behavioral indices, we met or exceeded the study's feasibility and acceptability goals, establishing a foundation for future studies. Nearly all (92%) who began M-ACT finished the assessments, showing strong retention relative to previous studies in metastatic cancer;^{7, 10} by comparison, one recent major study comparatively retained 59% by 2-month follow-up of patients who began the intervention⁷ (the same endpoint as the current study). However, one quarter of enrolled participants did not begin our intervention, due largely to health declines. In addition to sample size considerations for a larger trial, future directions may include telehealth or videoconferencing to better accommodate health declines and a briefer enrollment-to-intervention period to minimize illness-related attrition. Finally, participants completed online daily check-ins an average of three days/week, suggesting a need to bolster reminders or adjust expectations.

Potential Benefit to Participants

Although the study was not fully powered to assess efficacy, the findings suggest M-ACT's promise for improving anxiety, depression, ACP, sense of meaning, and fear of dying, with medium to medium-large effects by follow-up. These findings suggest the promise of the M-ACT approach for improving psychological symptoms, ACP completion, and existential well-being among anxious and depressed adults with advanced cancer. Pain-related interference did not show improvement, perhaps due to limited power, not sufficiently assessing or addressing interference, or many reporting that pain worsened along with their cancer during the study. Future studies should be fully powered to examine group differences and develop content that robustly addresses pain, or focus on other outcomes.

Intervention Mechanisms

Opening toward internal experience through acceptance and cognitive defusion/decentering predicted all significant outcomes apart from the ACP checklist, suggesting that this mechanism exerted therapeutic effects. This finding is consistent with previous studies of ACT in cancer populations.^{18, 21} Future studies should examine whether improvement in ACP is predicted instead by improved anxiety and depression outcomes, which could be linked to patients' ability and motivation to engage in ACP.

The finding that values-aligned behavior did not improve significantly over time was unexpected and suggests one of three possibilities: (1) M-ACT functioned primarily via other mechanisms such as acceptance/defusion, (2) M-ACT allowed participants to maintain their baseline valued behavior over time, despite health declines, and such behavior would have otherwise declined, or (3) valued behavior did improve but the study was underpowered to detect improvement or employed an insufficient measure. To evaluate among these possibilities, future studies should compare M-ACT to another condition within a randomized trial and include alternative measures of valued behavior.³⁸

Conclusions

The current study supports M-ACT's feasibility, acceptability, and potential for improving psychosocial

outcomes and ACP for anxious and depressed adults with advanced cancer. A randomized trial to conclusively evaluate M-ACT's effects appears warranted.

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Disclosure Statement

The authors declare no potential conflicts of interest with respect to the research, authorship, or publication of this article.

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Table 1. Participant characteristics (n=35)

Medical Characteristics	
Cancer type	
Gastrointestinal	25.71% (9/35)
Breast	22.86% (8/35)
Gynecologic	17.14% (6/35)
Prostate	8.57% (3/35)
Multiple Myeloma	5.71% (2/35)
Lung	5.71% (2/35)
Other ^a	14.29% (5/35)
ECOG Performance Status	
Score of 0	11.43% (4/35)
Score of 1	60.00% (21/35)
Score of 2	28.57% (10/35)
Sociodemographic characteristics	
Age (mean)	61.81 (<i>SD</i> =11.94)
Female	62.86% (22/35)
White, non-Hispanic	90.00% (27/30)
Married or partnered	68.18% (15/22) ^b
Have children	81.82% (18/22) ^b
Education (median)	2 year college
Household income (median)	\$31,000 - \$40,000

ECOG=Eastern Cooperative Performance Group

^a“Other” signifies rare cancers that we did not wish to identify in a small sample

^bSociodemographic data are unavailable for up to $n=13$ due to attrition before baseline data collection ($n=3$) or error of omitting these sociodemographic questions for Cohort 1 ($n=10$)

Table 2. Outcome and Process Measure Model Findings

	Linear Slope	Pre vs. Post		Pre vs. Follow-up	
	β (SE)	β (SE)	Effect Size (<i>d</i>)	β (SE)	Effect Size (<i>d</i>)
Outcomes					
Depression (HADS-D)	-.54** (.18)	-1.75** (.64)	.41	-2.20** (.74)	.51
Anxiety (HADS-A)	-.62** (.17)	-2.02* (.80)	.56	-2.36** (.68)	.66
Advance Care Planning checklist	.40* (.20)	.28 (.20)	.48	.40* (.20)	.72
Sense of Meaning (FACIT-Sp)	.86*** (.22)	2.67** (.92)	.34	3.09*** (.88)	.39
Fear of Dying (DADDS)	-1.59* (.66)	-3.87 (2.60)	.26	-6.10* (2.61)	.41
Pain Interference (SF-36)	-.02 (.07)	.05 (.25)	.04	-.09 (.28)	.08
Mechanisms/Processes					
Decentering (EQ)	.65 ^a (.35)	3.39 ^a (1.75)	.42	2.47 ^a (1.35)	.31
Psychological Flexibility (AAQc)	-1.31* (.54)	-3.61 (2.48)	.22	-4.42 ^a (2.29)	.27
Values (BEVS)	.10 (.08)	.37 (.26)	.25	.39 (.29)	.27

Notes: ^a $p < .09$; * $p < .05$; ** $p < .01$; *** $p < .001$; see Supplement for *d* approaches. HADS=Hospital Anxiety and Depression Scale; EQ=Experiences Questionnaire; FACIT-Sp=Functional Assessment of Chronic Illness Therapy-Spirituality Meaning/Peace Subscale; AAQc=Cancer Acceptance and Action Questionnaire (lower scores=higher flexibility); DADDS=Death and Dying Distress Scale; SF-36=Rand Short Form Health Survey-36; BEVS=Bulls Eye Values Survey