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Study protocol for a pilot randomised controlled trial of a virtually delivered behavioural intervention (ACTION) for adults with cancer at risk for opioid use disorder

Miryam Yusufov ,[1,2] William F Pirl,[1,2] Joseph A Greer,[2,3] Emanuele Mazzola,[2,4] Kristy L. Dalrymple,[5,6] James A Tulsky,[1,2] Ilana M Braun,[1,2] R. Kathryn McHugh[2,7]

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For numbered affiliations see end of article.

Correspondence to
Dr Miryam Yusufov; miryam_yusufov@dfci.harvard.edu

ABSTRACT

Introduction Opioid therapy is often central to pain management during cancer care. However, opioid exposure and unaddressed psychological suffering jointly amplify opioid use disorder risk. Therefore, we iteratively developed a behavioural, individually delivered intervention to mitigate the risk of opioid use disorder during cancer care (Acceptance and Commitment Therapy Intervention when Opioids are Necessary (ACTION)).

Methods and analysis This is a single-site, non-blinded, randomised, controlled pilot trial of ACTION compared with a waitlist control group. The aims of this study are to examine the feasibility (defined as an overall enrolment rate of ≥60% and a retention rate of >75%) and acceptability (assessed via patient-reported feedback in exit interviews and Client Satisfaction Questionnaire-8 ratings) of ACTION (primary outcomes) and to assess changes in participant-reported depression, anxiety and opioid misuse (secondary outcomes). Patients will be recruited from Dana-Farber Cancer Institute (Boston, Massachusetts, USA). The total number of patients completing the study will be 40. All patients will complete baseline and follow-up measures after 6 weeks. Patients randomly assigned to ACTION (n=20) will receive six weekly 30-min sessions delivered by a mental health provider either via telehealth or in-person. Patients assigned to the waitlist control group (n=20) will be offered the intervention on completion of their follow-up assessments, approximately 6 weeks (±2 weeks), following baseline.

Ethics and dissemination This study is approved by the Dana-Farber/Harvard Cancer Center Institutional Review Board (Protocol #21-587). Participants provide either written or electronic informed consent on study approach and once enrolled, they can withdraw from the study at any time. Results will be published in peer-reviewed journals and presented at scientific meetings.

Trial registration number NCT05643027.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Given the lack of behavioural interventions for opioid misuse risk during cancer care, the study design and intervention were informed by an extensive literature review, patient feedback and iterative intervention development to maximise patient-centeredness, feasibility and acceptability.
⇒ To maximise scalability and to offer clinician training, this intervention is currently being delivered by three mental health professionals (social work, psychology, psychiatry) under the supervision of the principal investigator; treatment integrity and fidelity monitoring development is ongoing.
⇒ Patients receive a workbook in which they complete exercises and readings in between study visits to reinforce intervention content.
⇒ Patients participate virtually for all study procedures (and have the option for in-person completion) to maximise scalability and dissemination, while minimising patient burden.
⇒ Given sociodemographic homogeneity, findings will be limited with regard to generalisability.

INTRODUCTION

Patients with cancer often rely on opioids to target cancer-related pain.[1] An American Society of Clinical Oncology expert panel suggested that opioids should be offered to patients experiencing moderate to severe cancer-related pain on active cancer treatment.[2] However, opioid therapy exists within a broader context of the ongoing opioid epidemic in the USA.[3] Therefore, despite the need for opioids, individuals with cancer on opioid therapy are at risk for developing opioid use disorder, which can negatively impact cancer treatment and quality of life, as well as result in opioid-related hospitalisations.[4 5]

Multiple factors contribute to opioid misuse (ie, use without a prescription or taken differently than prescribed) or opioid use disorder (ie, pattern of opioid use that results in functional impairment) risk during

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cancer care.[6] Opioid accessibility, long-term exposure to opioids and cancer-related psychological suffering jointly amplify opioid use disorder risk. For example, a study of 751 patients with cancer suggested that those with an anxiety disorder had an increased risk for aberrant medication behaviours.[7] This is consistent with studies of non-cancer pain that have identified psychiatric symptoms and coping skills deficits as risks for medication misuse and opioid use disorder.[8–10] In sum, behavioural interventions can mitigate opioid use disorder risk during cancer care by addressing known treatment targets, such as untreated depression, anxiety and coping skills deficits, while supporting patients in taking their opioids safely.[11]

To address the substantial need to target opioid use disorder risk during cancer care,[11] we iteratively developed an individual behavioural intervention to be delivered virtually (with an in-person option to maximise patient access): Acceptance and Commitment Therapy Intervention when Opioids are Necessary (ACTION). This is presently the only manualised psychotherapeutic intervention that targets opioid use disorder risk during cancer care. Intervention development was informed by a comprehensive literature review,[12] prior efficacious treatments[13 14] and expert feedback from palliative care clinicians and behavioural scientists. We then modified intervention content, logistics, mode of delivery (from in-person to virtual) and study procedures using qualitative feedback from exit interviews with 13 participants[15] prior to launching this pilot randomised controled trial (RCT). Participants were satisfied with the coping skills learnt and reported that the intervention fostered accountability and normalised internal experiences (eg, feelings, thoughts, memories), and they named ways that they would continue to use the skills beyond the completion of the research study.[15] Participants also preferred virtual delivery, particularly because it was convenient and lowered barriers to research participation.[15]

In this paper, we outline the details of the pilot RCT that is currently ongoing, comparing the refined intervention (ACTION) to a waitlist control group. The primary goal is to establish the feasibility and acceptability of ACTION compared with the control group. The secondary aims are to quantify the effects of the intervention on participant-reported depression,[16] anxiety[17] and opioid misuse.[18] This pilot RCT will inform a future, larger efficacy trial fully powered to quantify intervention efficacy relative to control.

METHODS AND ANALYSIS

Study design and setting

This is a single-site, randomised, controlled, pilot feasibility study comparing a behavioural intervention (ACTION) to a waitlist control group in 40 patients at risk for opioid use disorder during cancer care. Recruitment will occur at Dana-Farber Cancer Institute (DFCI). The Consolidated Standards of Reporting Trials diagram is illustrated in figure 1.

Participant selection

To be eligible, patients must be age 18 years or older, have any cancer diagnosis, be on opioid therapy, be at risk for opioid use disorder (as defined by an Opioid Risk Tool score of ≥4, reflecting moderate to high risk of opioid use disorder),[19 20] be able to read and comprehend English sufficiently enough to participate in a psychotherapy study and have an estimated survival time of ≥6 months, as determined by their respective palliative care clinicians. To ensure patient engagement and adherence to study procedures, patients with cognitive impairment, untreated psychosis, bipolar disorder or borderline personality disorder will not be eligible. To further promote participant retention and complete follow-up, we will only randomise participants who complete baseline questionnaires (ie, to minimise post-randomisation dropouts). We will also contact patients a maximum of three times to follow-up on completion of any of the study procedures. If patients remain unresponsive after three attempts, we will consider them withdrawn from the study. 13 patients participated in a trial run-in phase (previously published),[15] and 40 will participate in the RCT.

Patient and public involvement

Patient feedback is being integrated at all phases of this intervention development. In the feasibility phase (previously published),[15] patients provided feedback that fostered intervention refinement. In this pilot RCT phase, all patients who complete the intervention will be interviewed using a semistructured interview guide to gather additional feedback. Findings from this intervention will be presented and discussed at scientific meetings.

Recruitment

Trained study staff will review the clinic schedules and electronic health record of outpatient palliative care encounters to identify potentially eligible patients at DFCI. For identified patients who appear to meet study criteria, study staff will request permission from the respective palliative care clinicians to approach patients about study participation. After receiving approval, study staff will approach patients via phone call or during an upcoming palliative care appointment to explain study procedures and to determine interest in participation. Consistent with the treatment manual content, patients are informed that the goal of this study is to deliver and practice skills to address common issues during cancer care that may elevate opioid misuse risk (eg, coping skills deficit, worry, mood disorders, etc). Clinicians can also directly refer patients to the study, after which study staff will screen for eligibility criteria. Patients may participate in other research during their enrolment in this trial, as long as they do not participate in other behavioural interventions.

Enrolment and randomisation

Eligible patients will complete electronic informed consent via REDCap[21] with trained study staff (see online

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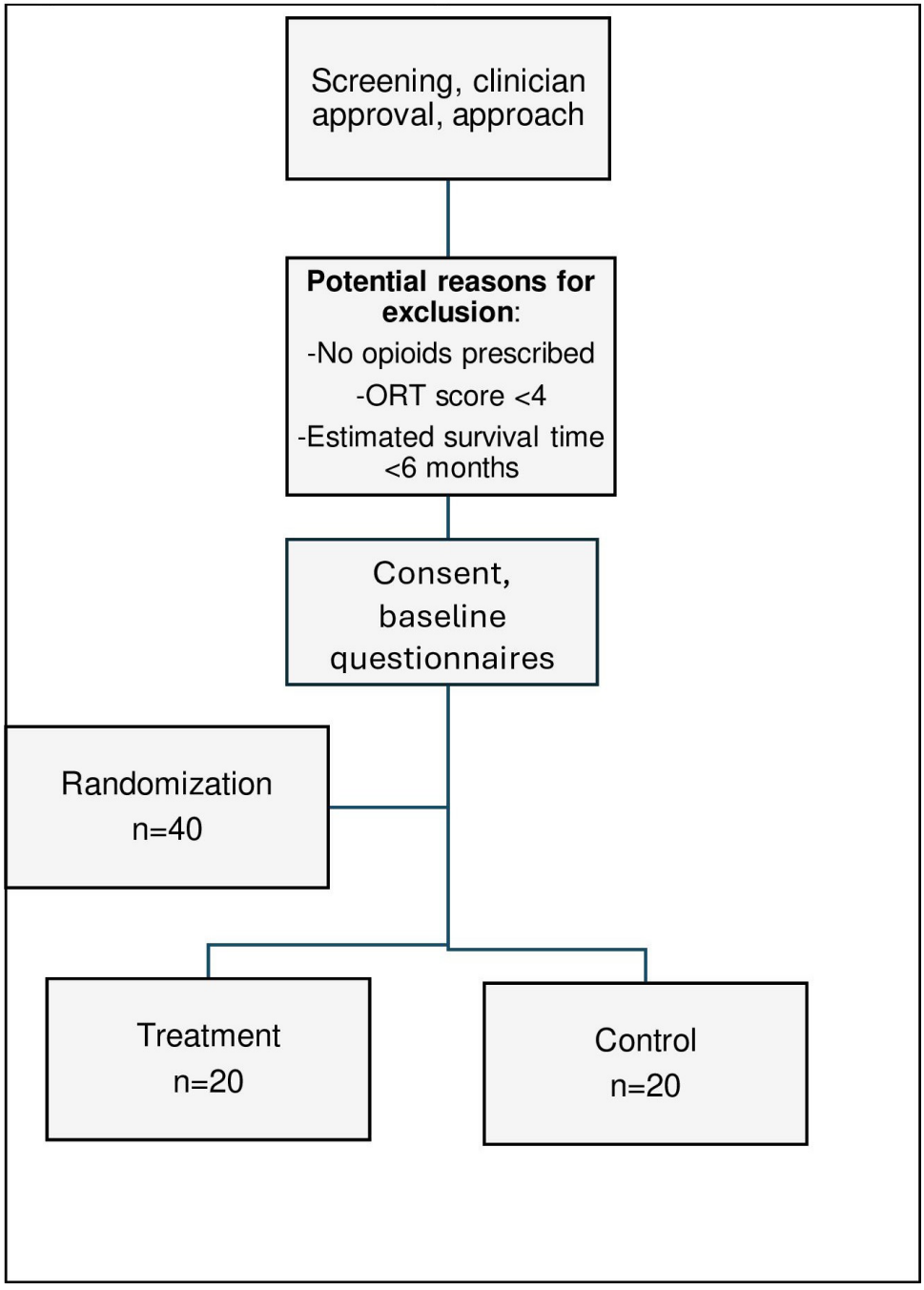


Figure 1 CONSORT flow diagram. CONSORT, Consolidated Standards of Reporting Trials; ORT, Opioid Risk Tool.

supplemental file 1). Enrolled patients will complete baseline self-report assessments via REDCap. Following informed consent and completion of self-report baseline assessments, study staff will randomly allocate patients 1:1 to either ACTION or the wait list control group via a computer-generated randomisation schema created by the study biostatistician. Group allocation will be concealed for each patient until randomisation occurs.

Assessments and intervention

Patients will complete the same self-report measures at baseline and follow-up; see table 1. Follow-up measures will be administered 6 weeks (±2 weeks) after baseline measures are completed. Assessments will be conducted electronically via REDCap, a Health Insurance Portability and Accountability Act (HIPAA) compliant, web-based survey tool,[21] or via mailed paper questionnaires, if the patient prefers. If randomised to the treatment arm (ACTION), participants will begin the behavioural intervention following the completion of baseline measures.

The intervention will be delivered virtually (using a secure, HIPAA-compliant platform) by a therapist, who is a member of the study team, under the supervision of the principal investigator (PI), who is a clinical psychologist (MY). Each of the six study visits is dedicated to one of the

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Table 1 Study measures and timepoints

Measure	Screening	Baseline	Follow-up 6 weeks post-baseline (±2 week window)
Electronic health record review	x		
Patient Health Questionnaire-9 (PHQ-9)[16]		x	x
Generalised Anxiety Disorder-7 (GAD-7)[17]		x	x
Brief COPE[27]		x	x
Brief Pain Inventory-Short Form (BPI-SF)[31]		x	x
Acceptance & Action Questionnaire-II (AAQ-II)[32]		x	x
Anxiety Sensitivity Index (ASI-3)[26]		x	x
Current Opioid Misuse Measure (COMM)[18]		x	x
Client Satisfaction Questionnaire (CSQ-8)[23]*			x

*CSQ-8 will be administered to intervention participants only.

core processes of Acceptance and Commitment Therapy (ie, mindfulness, values, defusion, acceptance, self-as-context and committed action).[22] Participants receive a workbook that accompanies the study visit content. The overarching goal of this approach is for participants to acquire and practice 1–2 skills, metaphors or frameworks after each visit. An overview of this treatment approach was previously published.[15] All sessions will be audio-recorded and a random 20% of the sessions will be selected for external fidelity ratings. Interventionists will meet with the PI weekly for supervision and to review study visits. Interventionists will be re-trained if fidelity is inadequate for the randomly selected 20% of sessions.

Safety and adverse events

Study staff will review self-report measures on completion for missing data and to monitor safety. If a patient endorses 'yes' on the suicidality question on the Patient Health Questionnaire-9 (PHQ-9),[16] the PI will be notified and either the PI or one of the trained study therapists will contact the patient via telephone to conduct a risk/safety assessment. If the patient requires further outpatient services (eg, psychiatry evaluation) or is at risk for self-harm, study staff will make the necessary referrals for treatment and/or urgent psychiatric care. If suicidality or risk of harm to others is otherwise determined at any study visit, the patient will be referred to appropriate services.

At weekly meetings, the research team will discuss summaries of adverse events, and all serious adverse events will be reported to the PI, the Dana-Farber/Harvard Cancer Center (DF/HCC) Institutional Review Board (IRB) and the appropriate federal agencies (eg, National Cancer Institute). The research team will also discuss retention and reasons for dropout or withdrawal by treatment group. The project will be stopped immediately if, at any point, the DF/HCC IRB or the study investigators judge that the risks of study procedures outweigh the benefits. Further, the DF/HCC IRB will conduct trial auditing if deemed necessary throughout the study. Important protocol modifications will be communicated to the IRB, trial participants, clinicaltrials.gov and the National Cancer Institute.

Data collection and management

The study PI will oversee all aspects of data collection and management. All data management activities will use REDCap[21] for electronic collection and management of data. Study documents, such as signed consent forms, completed eligibility checklists and any paper-based self-reported questionnaires, will be scanned and stored digitally on a secure drive within the encrypted DFCI network accessible only to the study team. DFCI investigators will have access to the final trial dataset. The DFCI IRB and our funding agency did not deem a Data Safety Monitoring Board necessary.

Statistical analysis

The primary objective of this pilot RCT is to demonstrate feasibility and acceptability, defined as an overall enrolment of ≥60% and a retention rate of ≥75% (for feasibility); as well as semistructured exit interviews and Client Satisfaction Questionnaire (CSQ-8) ratings for acceptability. We justified our sample size on the feasibility rate of 60%: testing with an exact binomial test at a one-sided significance level of 0.1, for which we will have 90% power to detect a difference in feasibility (vs non-feasibility) of 22% (ie, 60% vs 38%), using at least n=36 patients across both arms (treatment vs wait list control). See table 2.

Table 2 Power calculations

Power	Detected difference (in units of common SD)	N
80%	0.535	25
80%	0.482	30
85%	0.520	30

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Acceptability will be assessed using ratings on the CSQ-8[23] and exit interview content.

While the main goal of this pilot RCT is to determine feasibility and acceptability, we will assess psychological (anxiety; Generalised Anxiety Disorder-7 (GAD-7), depression; PHQ-9) and behavioural (opioid misuse; Current Opioid Misuse Measure (COMM)) outcomes to estimate effect sizes for a future, larger RCT (Stage II of the NIH Stage Model of Intervention Development).[24 25] We will estimate effect sizes by examining changes from baseline to follow-up (ie, at the completion of intervention) in secondary outcomes. We hypothesise that participants who complete the intervention will report lower anxiety (GAD-7),[17] depression (PHQ-9)[16] and opioid misuse (COMM).[18] We will collect data on anxiety sensitivity (Anxiety Sensitivity Index-3),[26] pain (Brief Pain Inventory-Short Form) and coping styles 'avoidant coping' (eg, substance use, self-blame) vs approach coping (positive reframing, seeking emotional support) (Brief COPE),[27] to obtain estimates of the effect size and variability of these measures to inform the examination of mechanisms in the Stage II efficacy trial. For this pilot study, we will focus on descriptive statistics and consideration of effect sizes, rather than inferential statistics to establish statistical significance, consistent with recommendations for pilot research.[24 25 28]

Given continuous outcome measures, we will evaluate Cohen's d effect sizes (0.20=small; 0.50=medium; 0.80=large).[29] Of note, clinically meaningful differences do not always correspond to effect sizes, and most measures included in this pilot RCT (table 1) do not have established cutoffs for clinically meaningful differences. Count outcomes will be used to examine relative effect sizes. They will be analysed as binary (below or above the median), using a McNemar test for categorical paired observations.[30]

Current trial status

Recruitment of participants started on 21 August 2024, and as of 21 October 2024, five participants had enrolled; two were assigned to the treatment condition and three to the control condition. Assuming an enrolment rate of five patients per 2 months, we anticipate that this study will be completed within 16 months (ie, January 2026).

ETHICS AND DISSEMINATION

This trial is being conducted in compliance with this study protocol, which has been approved by the Dana-Farber/Harvard Cancer Center Institutional Review Board (#21-587). Informed consent is obtained from every participant, either in-person, or via REDCap (see online supplemental file 1). All documents and information pertaining to the participants are confidential. Participant data are deidentified and compliant with the Standards of Privacy of Individually Identifiable Health Information of the Health Insurance Portability and Accountability Act. Any modifications to the study protocol will be submitted to the DF/HCC IRB for approval as amendments. Because this is a low risk, social/behavioural intervention, it is not likely that participants would be at risk of physical harm. However, it is possible that they may experience emotional distress either from the assessments or the intervention content. Participants may withdraw from the study at any time. Study results will be published in peer-reviewed journals and presented at scientific meetings. A description of the trial and a summary of results will be available on ClinicalTrials.gov. Only the study team will have access to the dataset, and access will be permitted through a data use agreement through the IRB.

DISCUSSION

There are several limitations to the current trial. First, the study is limited to patients currently receiving care at a Boston area academic cancer centre, limiting the generalisability of the results. Second, patients who have access to devices (eg, smartphones, computers, tablets) with videoconferencing capability are more likely to participate, which may bias the sample to individuals with higher incomes and education. However, videoconference delivery does have the potential to increase accessibility for patients for whom in-person sessions may be prohibitive due to travel, associated costs and disease-related impediments (eg, pain, fatigue, etc). As observed in our feasibility trial, participants reported a preference for a virtual delivery option.[15] Third, although we are using a randomised, controlled design, both the participants and the study therapists are aware of each patient's study group assignment after randomisation, as it is not possible to conduct a blinded psychosocial intervention study. Finally, although the study is underpowered to examine group differences in secondary outcomes (as this is a universal limitation at this stage of treatment development), the purpose of including all study questionnaires is also to examine the feasibility of participants completing an assessment battery of this size. If participants do not complete the surveys, this may indicate an unacceptable length that would prohibit data collection and analysis in a future full-scale efficacy trial. Of note, survey length was directly assessed in the feasibility phase of this study.[15]

Despite these limitations, this is the first manualised behavioural intervention to target opioid use disorder during cancer care, using an existing, evidence-based therapeutic approach (Acceptance and Commitment Therapy). All enrolled participants can receive the intervention, as those randomised to the waitlist control group are offered the intervention following completion of follow-up measures. This intervention also has clinical training opportunities embedded within it, which may enhance its scalability in future iterations, including a larger efficacy trial.

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Author affiliations
[1]Department of Supportive Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts, USA
[2]Harvard Medical School, Boston, Massachusetts, USA
[3]Massachussetts General Hospital, Boston, MA, USA
[4]Department of Data Science, Dana-Farber Cancer Institute, Boston, Massachusetts, USA
[5]Brown University Warren Alpert Medical School, Providence, Rhode Island, USA
[6]Lifespan Physicians Group, Providence, Rhode Island, USA
[7]McLean Hospital, Belmont, MA, USA

Contributors MY is responsible for the overall content and is the guarantor. MY, WFP, KD, JAG and KM contributed to the study conception and design. The protocol was developed and written by MY. The analytic plan was reviewed by EM. The first draft of the manuscript was written by MY and edited by WFP, JAG, EM, KD, JAT, IMB and KM. MY, WFP, JAG, EM, KD, JAT, IMB and KM read and approved the final manuscript.

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Competing interests MY is a paid consultant for One Huddle. All other authors declare that they have no conflicts of interest.

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ORCID iD
Miryam Yusufov http://orcid.org/0000-0002-0254-3864

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