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Biofeedback Enabled CALM (BeCALM)—the feasibility of biofeedback on procedural anxiety during radiation therapy: study protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction Patients undergoing treatment for cancer who require radiation therapy (RT) report anxiety specifically relating to the RT procedure. Procedural anxiety can be detrimental to treatment delivery, causing disruptions to treatment sessions, or treatment avoidance. Acute procedural anxiety is most commonly managed with anxiolytic medication. There is a need for effective, non-pharmacological interventions for patients not suitable for, or who prefer to avoid, anxiolytic medication. The primary objectives of this pilot trial are to evaluate the: (1) feasibility of conducting the Biofeedback Enabled CALM (BeCALM) intervention during RT treatment sessions; (2) acceptability of the BeCALM intervention among patients; and (3) acceptability of the BeCALM intervention among radiation therapists. The secondary objective of this pilot trial is to examine the potential effectiveness of the BeCALM intervention delivered by radiation therapists to reduce procedural anxiety during RT.

Methods and analysis This is a pilot randomised controlled trial. A researcher will recruit adult patients with cancer (3-month recruitment period) scheduled to undergo RT and meeting eligibility criteria for procedural anxiety at the Calvary Mater Hospital, Newcastle (NSW), Australia. Participants will be randomly assigned to receive treatment as usual or the BeCALM intervention (biofeedback plus brief breathing techniques). The primary outcomes are feasibility (measured by recruitment, retention rates and percentage of treatment sessions in which the intervention was successfully delivered); radiation therapists perceived feasibility and acceptability (survey responses); and patient perceived acceptability (survey responses). Secondary outcome is potential effectiveness of the intervention (as measured by the State Trait Anxiety Inventory—State subscale; the Distress Thermometer; and an analysis of treatment duration).

Ethics and dissemination The study protocol has received approval from Hunter New England Health Human Research Ethics Committee (2021/ETH11356). The results will be disseminated via peer-reviewed publications, as well as presentation at relevant conferences.

Trial registration number ACTRN12621001742864.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The randomised controlled trial design is a major strength of this pilot study.
⇒ This study is being conducted in a real-world setting with few exclusion criteria, and therefore should have excellent external validity.
⇒ There is no specific measure validated for measuring anxiety during radiation therapy delivery. However, the State Trait Anxiety Inventory State (STAI-S) is intended to capture transient states of anxiety and has been used in this context previously.
⇒ Anxiety may have multiple causes and it is not possible to determine whether anxiety is due to the radiation therapy procedure itself or how much impact other factors may have. However, participants were directed to report how they felt in relation to the procedure on introducing the STAI-S.

INTRODUCTION

Cancer is a major cause of morbidity and mortality worldwide, with the prevalence increasing every year.[1 2] In Australia, 139 413 new cases were diagnosed in 2017[3] and it is estimated that this will increase by more than 10 000 in 2021.[3] Approximately half of those diagnosed with cancer are expected to receive radiation therapy (RT) as part of their treatment plan,[4 5] with 74 200 courses of RT delivered in Australia in 2018–2019.[6] Although RT is a safe and effective treatment option,[4] many people experience significant distress and anxiety during their treatment journey.[7]

Patients who experience significant anxiety during treatment report poorer quality of life throughout the treatment journey,[8–10] and are more likely to experience impacts on treatment delivery such as disruptions to treatment sessions and avoiding or terminating medical procedures.[11–14] In RT, treatment

avoidance (or termination) is detrimental to treatment efficacy, with prolonged total treatment duration leading to reduced tumour control, ultimately increasing morbidity and mortality.[15 16] As well as the treatment efficacy implications for the patients, disruptions to treatment sessions can be problematic for the healthcare providers and the health service, with anxiety during RT delivery consuming greater staff resources, often causing delays for subsequent patients.[17]

Understandably, there are several reasons a patient may be anxious ahead of treatment for cancer, including cancer-related concerns (fear about disease progression, symptoms, treatment side effects, ability to undergo, or complete treatment and possible death[18]) and non-cancer related factors such as pre-existing anxiety and other mental health disorders. In addition, patients report anxiety about impending medical procedures, such as chemotherapy, MRI, as well as RT.[18] Specific to RT, patients report concerns about feeling isolated during treatment, claustrophobia, discomfort from the treatment positioning, worry over the technical equipment and incorrect radiation dose.[19 20] The affective state of anxiety or fear in relation to a medical procedure is referred to as 'procedural anxiety'.[21] Procedural anxiety can occur during or in anticipation of a procedure, and is generally transient.[11]

Currently, standard practice for managing acute patient anxiety, such as procedural anxiety, involves administration of benzodiazepines, or other non-benzodiazepine anxiolytic medication.[18] However, the use of anxiolytic medication is not suitable for all patients, and many patients report a strong preference to avoid medication where possible.[22] As such, there is a need to find non-pharmacological solutions to patient anxiety.

Literature pertaining to the management of procedural anxiety in the RT setting is emerging (eg, music listening, music therapy, information, aromatherapy, mindfulness-based stress reduction).[23–35] However, there is a more substantial literature to draw from regarding the management of procedure related anxiety in other clinical settings such as dental anxiety and MRI. An innovative randomised controlled single-centre study conducted by Morarend *et al* (2011)[36] investigated the use of biofeedback as a strategy to reduce dental anxiety and pain among 81 individuals. Biofeedback is a technique where individuals learn to modify certain autonomic nervous system functions (such as cardiac activity or blood pressure) that innately respond to stressors in the environment.[37 38] Using biofeedback, an individual can learn to alter their emotions by manipulating the symptoms of physiological arousal, such as respiration patterns.[39 40] Biofeedback has been shown to be effective in improving a broad spectrum of physical[41] and psychological conditions such as depression and anxiety.[38 42–46] Promisingly, the results of the Morarend trial[36] indicated that the use of a biofeedback device (a belt-type respiration sensor) had a significant positive impact on the overall dental experience,[36] and anecdotal reports from participants indicated a positive view of the device. A similar device has recently been trialled in the paediatric population for children undergoing medical procedures.[32] While results of the study are yet to be published, feasibility and acceptability data indicate the device was well accepted among both patients and clinicians.[47] As far as the authors are aware, the present study is the first to trial the novel use of biofeedback in the RT setting for procedural anxiety.

There are many different modalities of biofeedback, using a variety of forms of physiological information such as muscle tension, body temperature, heart rate and brain activity (neurofeedback).[48] In the present study, we propose to use a fingertip pulse oximeter device to monitor and feedback pulse rate. Pulse oximeters are a ubiquitous device within healthcare settings, and are minimally resource intensive to use, presenting a unique opportunity for a likely seamless transition into practice.

As well as accessibility, biofeedback provides a potential anxiety reduction tool requiring minimal training for patients or staff, and thus could conceivably be delivered by any healthcare provider. While many healthcare providers are involved in patient care during the course of RT treatment, radiation therapists are the healthcare providers who are in daily contact with patients from commencement of simulation and treatment, and often a strong rapport is formed between the patient and the radiation therapist.[22 49] Given the frequency and nature of contact, and consequent rapport with patients, radiation therapists are ideally placed to deliver interventions to reduce procedural anxiety. As such, we will conduct a pilot randomised controlled trial to assess the feasibility, acceptability and potential effectiveness of biofeedback delivered by radiation therapists to reduce procedural anxiety in adult patients undergoing RT for cancer.

OBJECTIVES

The primary objectives of this pilot study are to evaluate the (1) feasibility of conducting the Biofeedback Enabled CALM (BeCALM) intervention during RT treatment sessions; (2) acceptability of the BeCALM intervention among patients; and (3) acceptability of the BeCALM intervention among radiation therapists. The secondary objective of this pilot trial is to examine the potential effectiveness of the BeCALM intervention delivered by radiation therapists to reduce procedural anxiety during RT.

METHODS AND ANALYSIS

This protocol is presented in accordance with the 2013 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement (see online supplemental appendix 1).

Trial design

The BeCALM pilot study will use a (pilot) randomised controlled trial design.

Setting

The trial will be conducted in the Department of Radiation Oncology at the Calvary Mater Hospital, Newcastle, New South Wales, Australia.

Participants

Patients eligible for participation will meet the following criteria:

Inclusion criteria

- Aged at least 18 years.
- Scheduled to undergo RT at the Calvary Mater Hospital, Newcastle, Department of Radiation Oncology.
- Undergoing 2 or more fractions of RT.
- Having sufficient comprehension of English to be able to understand and complete the study documents and the verbal instructions to use a biofeedback device.
- Score≥4 on a Distress Thermometer[50] (DT) post RT planning simulation (SIM) with confirmed procedural anxiety.

Exclusion criteria

- Patients with breast cancer receiving treatment that involves deep inspiration breath hold.
- Patients scheduled to undergo RT using optical surface monitoring.
- Inability to provide informed consent or complete the eligibility screening.

Patients were not excluded from the study based on pre-existing psychological disorders or anxiolytic medication use.

PROCEDURE

Recruitment

Patients will be approached by a researcher or a trained research assistant immediately following SIM. They will be asked to complete a brief (single item) anxiety screener (DT,[50] modified to specify RT procedural anxiety) and those scoring≥4will be invited to participate in the study. Clarification to confirm procedural anxiety will be given as needed.

The cut-off score of≥4 on the DT will be used, as it is well accepted that ≥4 on the DT indicates clinically significant distress.[50 51]

The researcher/research assistant will introduce the study and provide interested patients with the participant information statement and consent form. Patients will be phoned several days later (prior to treatment commencing) to ascertain interest in participation. Eligible patients who express interest in participating in the study at the phone call following screening, will then complete verbal consent, the baseline assessment and randomisation over the phone.

Limited disclosure

A 'limited disclosure' approach will be used to minimise study bias. Potential participants will be informed that they will be asked to complete assessments and what they will include. They will also be informed that they may receive a form of anxiety monitoring or support. They will not be told that some participants will be randomised to receive biofeedback. All participants will receive treatment as usual (TAU) and have access to usual care for psychological support. After data collection has ended, all participants will be provided with information about the aims of the research and an explanation of why limited disclosure was necessary. Participants will also be offered the opportunity to withdraw any data provided by them.

Randomisation

Individual randomisation will occur immediately following completion of baseline assessment, using block randomisation,[52 53] with equal probability of allocation to either TAU or the BeCALM intervention. Block size will be predetermined by an independent statistician and programmed within an electronic data collection system. The researcher/research assistants will remain blinded to the block size.

INTERVENTION PROCEDURES

Treatment as usual

RT treatment session 1: the participant will receive pretreatment education with the radiation therapist to discuss what to expect during RT. Immediately following pretreatment education, the participant will be taken to the treatment bunker to commence RT. The participant will be asked to wear the pulse oximeter (for data collection purposes only), with sound disabled on the device.

RT treatment session 2: the procedure will remain the same as treatment 1, without the pretreatment education.

BeCALM (treatment as usual + intervention)

Participants in the intervention group will receive TAU, as well as the intervention.

RT treatment session 1: during the pretreatment education, the radiation therapist will provide a brief explanation of the biofeedback device (pulse oximeter) and how to use it. The radiation therapist will allow the participant to test the device and will briefly coach the participant on breathing techniques (see treatment guide for radiation therapists, online supplemental appendix 2). The participant will be taken to the treatment bunker to commence RT. The participant will be provided with the pulse oximeter in the treatment bunker which they will wear for the duration of the treatment session. Sound will be enabled on the device, and it will be adjusted to a volume that is comfortable for the participant. Radiation therapists will provide breathing prompts during the treatment session at their discretion (via the speaker).

RT treatment session 2: the procedure will remain the same as treatment 1, without the pretreatment education.

NO_FIGURE_FOUND **Figure 1** Schedule of enrolment, interventions, and assessment for participants. BeCALM, Biofeedback Enabled CALM; PISCF, participant information statement and consent form; RT, radiation therapy; STAI-S, State Trait Anxiety Inventory State; TAU, treatment as usual.

Discontinuation

While we do not consider the breathing intervention high risk for exacerbating distress, patients and radiation therapists will have the option to cease the intervention at any time should they feel that it is provoking an adverse response.

The schedule of enrolment, interventions and assessment for participants is described in figure 1.

Outcome measures

Outcome measures will be administered immediately following treatment 1 (T1 Post-RT) and treatment 2 (T2 Post-RT). The assessments will be completed independently by the participant using an iPad, assisted by the researcher/research assistant if required.

Primary outcomes

Feasibility of the intervention will be measured by:

- Percentage of treatment sessions in which the intervention (pulse oximeter and breathing techniques) was successfully delivered.
- Radiation therapist perceived feasibility (author created feasibility items included in the radiation therapist feasibility and acceptability survey).
- Recruitment and retention rates (project records).

Acceptability of the intervention as measured by:

- Participant perceived acceptability (author created acceptability items included in the post RT participant assessments).
- Radiation therapist perceived acceptability (item 4 included in the radiation therapist feasibility and acceptability survey).

Secondary outcomes

- Differences in procedural anxiety scores (State subscale of the State-Trait Anxiety Inventory[54] and on the DT[50]).
- Comparison of BeCALM and TAU treatment duration (recorded at time participant enters treatment bunker to time participant exits treatment bunker).

Patient and public involvement

The design of this trial was guided by a small qualitative study conducted by EF, with input from a consumer representative on study resources.

MEASURES

Sociodemographic and health characteristics

Participant sociodemographic and health information will be obtained using purpose-designed self-report items within the baseline assessment, including age and date of birth, gender, ethnicity, marital status, highest level of education, employment status, history of an anxiety disorder, and current psychotropic medication. Diagnostic and treatment information will be extracted from medical records including cancer type, site, stage, RT technique, stereotactic (yes/no) number of RT fractions (total number of treatment sessions), radiation dose (duration of radiation per fraction), treatment intent (curative or palliative) and whether anxiolytic medication is required for each treatment session.

Feasibility and radiation therapist acceptability

Following each participant treatment session, a radiation therapist will complete a checklist of feasibility questions, including: pulse oximeter worn (yes/no); If no, why?; sound on or off?; breathing techniques delivered (yes/no); If no, why?; breathing prompts provided during treatment? and treatment time (x minutes, x seconds).

Following completion of recruitment and data collection (final participant follow-up), radiation therapists involved in the intervention will be provided with a brief survey to ask about their experience of delivering the intervention. Specifically, radiation therapists will be asked about: (1) ease/difficulty of using the pulse oximeter (5-point Likert scale); (2) ease/difficulty of providing breathing techniques to participants (5-point Likert scale); (3) suggestions for making the intervention easier to deliver (open response); (4) receptiveness to using the BeCALM intervention as an ongoing strategy to support patients with procedural anxiety (yes/no); and (5) any additional comments (open response).

Participant acceptability

Six acceptability items included in the post-RT assessments will ask participants about their experience of the intervention. Participants will be asked (1) *Was there anything you found helpful in managing your anxiety during treatment today?* (yes/no); (2) *If so, what were these things?* Intervention participants will also be asked (1) *During your treatment session today, did you try to pay attention to the sound of your pulse?* (yes/no); (2) *If no, why?* (3) *During your treatment session today, how easy/difficult did you find it to focus on the sound of your pulse?* (5-point Likert scale); (4) *Did you use the breathing techniques during your treatment session?* (yes/no); (5) *If no, why?* (6) *Did you feel that the breathing techniques you were given were useful?* 5-point scale); (7) *During your treatment session today, how easy/difficult did you find it to remember the breathing techniques the radiation therapist gave you?* (5-point Likert scale); (8) *Do you have any other comments or suggestions?* (open response).

State Trait Anxiety Inventory (STAI)

Procedural anxiety will be measured using the 40-item STAI-State (STAI-S) subscale.[54] The STAI-S subscale (20 items) is designed to assess temporary anxiety in response to danger or stress. Respondents are asked to indicate the intensity of their current feelings on a 4-point Likert scale (*not at all, somewhat, moderately so, very much so*).[55 56] To

capture patients' feelings during the procedure, patients will be asked to indicate '*how you are feeling about the radiation therapy procedure*' prior to RT and '*how you felt during your radiation therapy today' following RT*. The STAI has been found to be a highly reliable measure (median alpha reliability coefficient 0.92)[56 57] and has previously been used to measure procedural anxiety during SIM[26] and RT treatment.[34] Trait anxiety will also be measured using the STAI-T,[54] consisting of 20 items and designed to assess general trait anxiety. Respondents will be asked to indicate the intensity of their general feelings on a 4-point Likert scale (*almost never, sometimes, often, almost always*)[55 56]

Distress thermometer

A modified version of the DT[50] will also be used to screen for and measure procedural anxiety. The DT is a brief screening tool used to assess psychological distress. It is widely used in cancer settings and has been validated for use in more than 30 countries.[51] Modified versions of the DT have previously been used to measure procedural anxiety in RT.[22 58] Similar to Nixon and colleagues,[22] the DT will be modified to question distress related to the RT procedure: '*Please circle the number (0–10) that best describes the level of distress you felt during the radiation therapy procedure today?*'

Sample size

A time convenience sample of adult patients with cancer scheduled to undergo RT will be recruited. Recruitment will continue for a period of approximately 3 months, depending on recruitment rate. We anticipate recruitment of approximately 57 participants, based on: 10 patients undergoing SIM per day, a minimum of 3 days of recruitment per week, 20% meeting eligibility criteria with an 80% consent rate.

Data management

Electronic data will be housed on REDCap. REDCap is a secure server-based electronic data collection system, designed for research. It has the capacity for individual permissions, so research staff access to data can be limited by the administrator to only the necessary information. Access to REDCap will be provided by Hunter Medical Research Institute and managed according to established data safety protocols. Data will be retained for a period of 15 years after which it will be securely destroyed.

Statistical analysis

Descriptive statistics on the number of eligible participants, recruitment and retention rate, and reasons for dropout will be provided. Descriptive statistics will also be provided on the sociodemographic and health characteristics of participants.

Primary outcomes

Descriptive statistics will be provided on the feasibility and acceptability assessment items.

Secondary outcomes

The secondary outcome measures (STAI-S, DT and treatment durations) will be analysed using a linear regression. The outcome in the models will be the individual's STAI or DT score at T2, with their baseline scores for each respective measure used as a covariate. CIs will be estimated as per Lee *et al*,[59] examining differences between groups and the minimal clinically important differences.

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol has received approval from Hunter New England Health Human Research Ethics Committee (HNEHREC) of Hunter New England Health (2021/ETH11356).

Protocol amendments

Any protocol amendments will be submitted to HNEHREC for approval and the trial coordinator will ensure all investigators/research assistants are aware of the submission, and approval when it is received (and any associated new documentation). All protocol amendments will also be updated in the ANZCTR trial registration when ethics approval is granted.

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Contributors EF, KC, ALB, KLM and BB were involved in the initial conception and design of the BeCALM trial. SO provided advice regarding the radiation therapist delivery of the trial and also advised the team regarding practicalities of trial delivery. SO also facilitated the training of the radiation therapists involved in the delivery of the trial. MK, CW and MTT provided valuable advice regarding the medical considerations of the patient groups included in the trial. JN is an expert in procedural anxiety and provided valuable advice from previous lessons learned. The first draft of this manuscript was written by EF and significant contributions were received from KC, ALB, KLM, SO, MK, CW, MTT, JN and BB to achieve the final manuscript.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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