



CLINICAL RESEARCH PROTOCOL

INVESTIGATIONAL PRODUCT(S):	Virtual Reality program developed by Novobeing (formerly Rocket VR). To be administered on HTC Vive Flow, HTC Vive Focus or Pico Neo Pro headsets
STUDY NUMBER(S):	IRB Number 854756
	Other Protocol Identifiers UPCC# 14523
PROTOCOL(S) TITLE:	Virtual Reality to Promote Mindfulness and Relaxation prior to Radiation Simulation: A Prospective Pilot Feasibility Study
REGULATORY SPONSOR:	N/A
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PRINCIPAL INVESTIGATOR SIGNATURE

STUDY
SPONSOR:

N/A



STUDY TITLE: Virtual Reality to Promote Relaxation Prior to Radiation Simulation: A
Prospective Pilot Feasibility Study

STUDY ID IRB# 854756 / UPCC# 14523

PROTOCOL V3
VERSION

I have read the referenced protocol. I agree to conduct the study in accordance to this protocol, in compliance with the Declaration of Helsinki, Good Clinical Practices (GCP), and all applicable regulatory requirements and guidelines.

Principal
Investigator Name

Signature

Affiliation:

Date



Abbreviations

RT: Radiation Treatment

3D: Three dimensional

VR: Virtual Reality

CRC: Clinical research coordinator

1 STUDY SUMMARY

1.1 Synopsis

Title:	Virtual Reality to Promote Relaxation Prior to Radiation Simulation: A Prospective Pilot Feasibility Study
Short Title:	Virtual Reality to Promote Relaxation Prior to Simulation
Study Description:	The purpose of this study is to assess the feasibility of a pre-simulation virtual reality (VR) platform designed to promote relaxation for cancer patients planned for radiation therapy (RT). We hypothesize that at least 75% of enrolled patients will successfully complete the VR program.
Objectives:	<p>Primary Objective:</p> <ol style="list-style-type: none">1. To evaluate the feasibility of a pre-simulation VR platform prior to radiation. <p>Secondary Objectives:</p> <ol style="list-style-type: none">1. To evaluate patient feedback on pre-simulation VR program2. To evaluate patient situational anxiety prior to and after use of VR program
Primary Endpoint:	Feasibility based on the ability of at least 75% patient VR completion rate. Based on the expected accrual of 25 patients, futility and early termination will be triggered if six participants fail to meet the conditions described above.
Secondary Endpoints:	<ol style="list-style-type: none">1. To evaluate patient-reported situational anxiety levels prior to and after use of the VR headset.2. To collect patient feedback on the usability of and overall satisfaction with the VR program prior to simulation.
Study Population:	Adult radiation oncology patients at least 18 years of age who are undergoing radiation treatment at the Perelman Center for Advanced Medicine.
Phase:	Pilot Study



Description of Sites/Facilities	Department of Radiation Oncology at Perelman Center for Advanced Medicine
Enrolling Sites:	Department of Radiation Oncology at Perelman Center for Advanced Medicine
Description of Study Intervention:	The program is designed to be used as a relaxation tool prior to RT using a HTC or Pico VR headset. It is a three-dimensional (3D) auditory and visual immersive experience using scenery, sounds and narration to help patients relax and reduce anxiety prior to RT planning simulation.
Study Duration:	12 months
Participant Duration:	One day

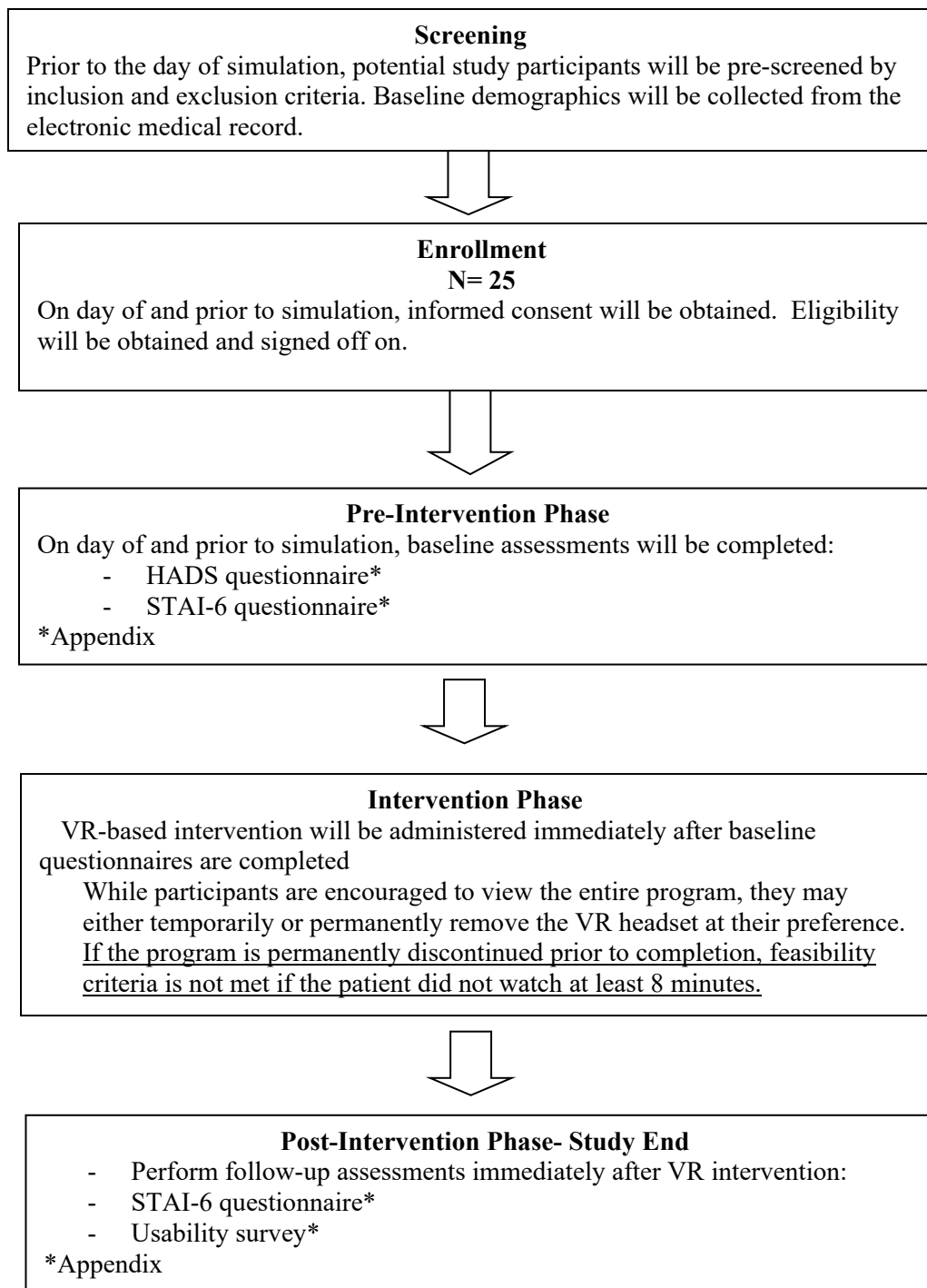


1.2 Key Roles and Study Governance

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1.3 Schema

Please note that after patients are screened for eligibility, study intervention will take place on one day, prior to scheduled simulation for radiation treatment planning.



2 INTRODUCTION AND RATIONALE

2.1 Study Rationale

It is well documented in the literature that cancer patients experience disproportionate rates of psychologic distress and anxiety compared to the general population [1-3]. The National Cancer Comprehensive Network (NCCN) defines distress as a “multifactorial, unpleasant experience of a psychological (i.e. cognitive, behavioral, emotional), social, spiritual, and/or physical nature that may interfere with one’s ability to cope effectively with cancer, its physical symptoms and its treatment” [4]. In turn, cancer-related distress is associated with decreased adherence to treatment, satisfaction with care, quality of life and overall survival [5-8]. Interventions to mitigate psychologic distress in this patient population are critical to the delivery of high quality, patient-centered care. VR provides a non-invasive, low cost, immersive experience that may help mitigate distress and anxiety associated with starting active cancer treatment. The purpose of this pilot feasibility study is to assess the role of a VR-based platform that utilizes mindfulness-based practices to distract and relax patients prior to the start of RT.

2.2 Background

Mindfulness meditation is a well-established technique for stress reduction across multiple patient populations [9]. It emphasizes attention to the present moment and acceptance of one’s thoughts, feelings and bodily sensations without judgment. In cancer patients, mindfulness-based interventions have been found to decrease psychologic distress, improve quality of life and reduce fear of cancer recurrence [10-12]. A meta-analysis of 28 randomized control trials of over 3,000 adult cancer patients found that mindfulness-based interventions reduced anxiety and depression severity up to six months after the initial intervention [13]. These interventions were, however largely delivered in person which may prove to be a barrier for patients with limited resources.

Virtual reality (VR) has recently become a widely available and affordable non-invasive technology that may be implemented in the clinical setting. VR provides viewers a visual and auditory experience via a head mounted display. Its potential as an evidence-based, therapeutic device is an area of active research in cancer patients. In one study, when VR was used as a distraction device, patients report reduced cancer-related anxiety, depression and pain [14-15]. When utilized during chemotherapy infusions, patients felt treatment time was shortened and found the program enjoyable [16]. While these studies use VR as a distraction device, little is known in regards to efficacy of VR-based mindfulness meditation. The incorporation of mindfulness meditation principles with VR is currently being investigated in patients with chronic pain [17]. To our knowledge, the use of a VR based platform to promote relaxation has never been implemented in the oncologic setting.

In this study, we will utilize a VR-based, immersive scene designed for relaxation and promotion of mindfulness-based principles for patients who are planned for radiation simulation.

The primary objective of this study is to assess the feasibility of a VR platform prior to simulation into patient workflows. Secondary objectives include patient-reported situational anxiety pre- and post- VR and qualitative and quantitative patient feedback on usability and satisfaction with the VR device.

2.2.1 *Clinical Adverse Event Profile*

We anticipate minimal discomfort from study participation. Subjects may experience discomfort from using VR including headache, dizziness, lightheadedness, vision problems, nausea, vomiting, ect. which is expected, temporary, and should resolve within 24 hours. This kind of discomfort is not considered an adverse event. Patients with active nausea, vomiting, dizziness, lightheadedness, monocular vision or hearing loss that is not treated at time of enrollment, a history of motion sickness, car sickness, migraines, light sensitivity or vertigo within the last 6 months, or a history of epilepsy and seizures will be excluded from the study via screening procedures as these may place patients at higher risk.

2.3 Risk/Benefit Assessment

2.3.1 *Known Potential Risks*

Individuals will be identifiable during the data collection phase, but not when the data is disseminated. Subjects may experience discomfort while wearing the VR headset. They will be notified that they can stop anytime and participation is completely voluntary. Participation, lack of participation, withdrawal or any other factor related to involvement in this study will have no impact on the subjects' care.

2.3.2 *Known Potential Benefits*

This study may have benefits for both the study participants and for society in general. Participation will provide patients with a method for relaxation based in mindfulness meditation principles prior to initiation of RT.

We will collect patient feedback in regards to the VR experience which can inform development of new virtual reality-based programs designed to improve the experience of patients undergoing active cancer treatment.

This study is grounded in patient-centered care with the goal of improving the overall experience during active cancer care which is in line with the strategic goals of the Department.

Society in general may benefit from the knowledge generated by this trial, particularly with respect to improving the patient-experience, reducing patient distress and anxiety and informed consent.

2.3.3 *Assessment of Potential Risks and Benefits*

This study is expected to introduce minimal risk to study participants with potential benefit of promoting a patient-centered experience.

3 STUDY OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Demonstrate feasibility of VR prior to radiation simulation for treatment planning.	This is a feasibility study. Feasibility is based on the ability of at least 75% of study participants to complete a VR program prior to simulation. Based on the expected accrual of 25 patients, futility and early termination will be triggered if six participants fail to meet the conditions described above.	To assess patient participation in an immersive VR experience prior to radiation simulation.
Secondary		
Assess degree of baseline anxiety prior to study intervention	Measure baseline score on Hospital Anxiety and Depression Scale (HADS)	Assess degree of patient-reported anxiety prior to use of VR-based intervention.
Assess efficacy of VR program to reduce situational anxiety.	Measure change in STAI-6 score at baseline and after VR intervention.	Assess degree to which use of VR program changes scores on STAI-6 from baseline. This questionnaire is designed to measure situational anxiety.
Collect feedback on VR ease of use and patient satisfaction with the experience.	Post-intervention survey designed to collect qualitative and quantitative patient feedback.	Questionnaire will be administered after intervention to assess degree of patient satisfaction, ease of use and perceived quality of the VR program.

4 STUDY PLAN

4.1 Study Design

The purpose of this prospective feasibility study is to assess the implementation of a VR-based intervention in patients who are pending initiation of RT. We hypothesize that this intervention will be safe and feasible. If 75% of enrolled patients complete the VR intervention (defined as at least 8 min before permanent discontinuation), then feasibility will be met. Ten minutes' length is likely to be tolerated by most patients and likely to provide benefit. The maximum length of the VR video is 11 minutes. Patients will still be evaluable after 8 minutes of the video as this provides ample time to practice mindfulness based breathing exercises.

As this is a feasibility study, investigators and participants will not be blinded to study procedures. Potential study participants will be adult patients who are undergoing simulation for radiation treatment planning at the Perelman Center for Advanced Medicine at Penn Medicine. This is a single site study. No interim analyses or sub-studies are planned. Based on the expected accrual of 25 patients, futility and early termination will be triggered if 6 participants fail to meet the conditions described above.

4.2 Scientific Rationale for Study Design

The purpose of this study is to ensure feasibility and ease of implementation of a VR device into established clinic patient workflows. All enrolled participants will receive the study intervention. There is no control arm.

4.3 End of Study Definition

A participant is considered to have completed the study if he or she has completed all phases of the study including completion of the follow up assessments [Appendix].

5 STUDY POPULATION

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Able to understand, read or speak English sufficient for signing of informed consent and completion of study assessments
2. Patients scheduled for simulation for radiation treatment planning at Perelman Center for Advanced Medicine (PCAM)
3. Adults, at least 18 years of age
4. Performance Status (ECOG) 0-2

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Prior radiotherapy
2. History of motion sickness, car sickness, vertigo, migraines, or light sensitivity within the last 6 months
3. History of epilepsy and seizures
4. Current nausea, vomiting, dizziness, lightheadedness, monocular vision or hearing loss that is not treated

5.3 Screen Failures

Screen failures are defined as participants who consent to participate in the clinical trial but are not subsequently entered in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any serious adverse event (SAE).

Research staff will explain the nature of the study protocol and risks associated with the protocol in detail to the subject. The subject must sign and date the written informed consent prior to study participation. Informed consent process must be obtained before protocol procedures are performed. If a procedure required for screening was performed prior to signing the informed consent and the procedure meets the time limits of the protocol, this procedure may be used for the screening evaluation.

Screening will be completed prior to administration of the baseline questionnaires or VR intervention. Patients who enroll but do not use the VR headset will not factor into determination of study feasibility.

Screening includes:

- Consulting investigator confirms that (s)he plans to recommend radiotherapy simulation at Perelman Center for Advanced Medicine.
- Complete the pre-screening questionnaire.
- Complete medical history.
- Informed consent.
- Confirmation that inclusion and exclusion criteria are met.

Prior to informed consent, study procedures will be explained in detail to assess interest in the study. If the patient expresses interest in the study, the patient will be asked the pre-screening questionnaire designed to assess for those who may be at increased risk of side-effects from VR. Patients who indicate a history of motion sickness, car sickness, migraines, light sensitivity or vertigo within the last 6 months will be excluded from the study. Patients who indicate a history of epilepsy or seizures will be excluded from the study. Patients with active nausea, vomiting, headaches, dizziness, lightheadedness will also be excluded. The pre-screening questionnaire is listed in the Appendix.

5.4 Strategies for Recruitment and Retention

- Target study sample expected to be drawn primarily from the thoracic radiation oncology patient population in the Department of Radiation Oncology at Penn Medicine.
- Patients may undergo head imaging per National Comprehensive Cancer Network (NCCN) guidelines version 3.2023
- Anticipated accrual rate of 2-4 patients per week.
- After patients are screened, study intervention will take place on the day of simulation for radiation planning.
- Subjects will be recruited at the Perelman Center for Advanced Medicine.
- Patients will be approached prior to their radiation simulation. Simulation schedules will be prescreened prior to patient visits and potential study participants will be identified. The research staff will approach and inform the patient about the study and explain study procedures. If the patient expresses interest in the study, the patient will be asked the pre-screening questionnaire. If the patient passes the pre-screening questionnaire, the research staff will plan to meet with the patient prior to their radiation simulation to conduct

informed consent and the study visit. Basic demographic data will be collected from the medical record.

- On day of and prior to simulation, the person obtaining consent will explain the requirements of the study, state the volunteer nature of research, and advise the patient to take sufficient time to discuss the study if necessary before making their decision to sign the informed consent document. Patients will be informed that participation in this study will not affect their medical care. If a decision to participate is made, the informed consent form will be signed. A copy of the Informed Consent Form will be provided to the patient. Eligibility will be confirmed with the study investigator or delegate.
- Information of this study's availability will be made known to treating professionals throughout our practice and referring physicians.

6 STUDY INTERVENTION

6.1 Study Intervention(s) Administration

Study intervention will take place in one day. Prior to simulation, the research staff will seat participants in a semi-private area. A head mounted, HTC Vive Flow, HTC Vive Focus, or Pico Neo Pro device will be provided. The VR headsets will not collect any patient data. The headset will be adjusted accordingly for comfort prior to turning on the device. Patients will be reminded that they can take a break or stop at any time. They will also be instructed to alert staff if they are feeling unwell at any point during the VR experience.

6.1.1 *Study Intervention Description*

Prior to using the VR headset, patients will be asked to complete electronic-based, multiple choice, pre-intervention surveys [Appendix]. Questionnaires are designed to assess baseline anxiety and situational anxiety. Study participants will be provided a HTC or Pico VR head-mounted device (HTC Flow, HTC Focus or Pico Neo Pro) which will be fitted for comfort. Patients will remain seated for the entirety of the VR program. The program generally takes about ten minutes to complete but may last up to 11 minutes. Participants will be reminded they may stop at any time. They may also temporarily or permanently take off the headset at any time for any reason. The patient must voluntarily express interest in proceeding prior to the headset being replaced.

The program is designed to last for ten minutes in order to ensure subjects have adequate time to watch a short orientation video where the purpose of the VR exercise is explained and to practice breathing exercises. Ten minutes' length is likely to be tolerated by most patients and likely to provide benefit. Patients will provide feedback on the length of the video which can be incorporated into future studies. The program displays a relaxing environmental setting with narration based in mindfulness meditation principles. Subjects will be prompted to practice breathing exercises designed to relax and reduce anxiety.

After the VR immersion is complete, patients will be verbally assessed by staff to ensure they have no side effects from the program. Patient will then complete the post-intervention questionnaires via electronic survey. Questionnaires will be administered to assess situational anxiety and elicit feedback on participant experience and satisfaction with VR. Once the questionnaires are complete, all study tasks are complete.

6.2 Preparation/Handling/Storage/Accountability

6.2.1 Acquisition and accountability

HTC or Pico VR headsets and software will be provided by Novobeing (formerly Rocket VR) or the University of Pennsylvania Department of Radiation Oncology. Headsets will be checked for quality control by research staff prior to use.

6.2.2 Formulation, Appearance, Packaging, and Labeling

Clinical supplies will be affixed with a clinical label in accordance with regulatory requirements. This trial is open-label; therefore, the subject, the trial site personnel, and/or designee are not blinded to treatment. Random code/disclosure envelopes or lists are not provided.

Each headset will undergo specialized cleaning procedures after patient use.

6.2.3 Product Storage and Stability

Clinical supplies must be stored in a secure, limited-access location.

6.2.4 Preparation

Headset Cleaning Procedures:

- Interior and exterior aspects of VR headsets and controllers will be cleaned between each use.
- A germicidal, alcohol-based cleaning wipe will be used on the interior and exterior aspects of the headset and controllers. A microfiber cloth or non-alcohol-based pad will be used to clean the headset lenses.
- Study staff will wash hands prior to cleaning and use nitrile gloves while cleaning study equipment. The gloves will be disposed of after use.
- All equipment will completely air dry (for approximately 2 minutes) after cleaning prior to next use.

6.3 Measures to Minimize Bias: Randomization and Blinding

Given this is a pilot feasibility study, patients will not be randomized. All enrolled participants will receive the intervention. As such, research staff will not be blinded.

6.4 Study Intervention Compliance

Compliance with the study procedures will be monitored by the research staff and includes participation in all required study visits and completion of all baseline and end-of-study surveys by participants.

6.5 Concomitant Therapy

N/A

6.5.1 *Rescue Medicine*

N/A

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention

Discontinuation of the VR headset does not mean discontinuation from the study. A patient may ask to temporarily remove the VR headset or may himself/herself temporarily remove the VR headset. However, the patient must voluntarily express interest in proceeding, replace the VR headset, and subsequently complete 8 minutes of the VR program in order to meet feasibility criteria.

Subjects who permanently remove the VR headset early will be asked to complete the follow up surveys, and verbal and written subjective feedback will be solicited from the patient.

7.2 Participant Discontinuation/Withdrawal from the Study

Subjects may withdraw consent at any time for any reason or be dropped from the trial at the discretion of the investigator should any untoward event occur. In addition, a subject may be withdrawn by the investigator if enrollment into the trial is inappropriate, the trial plan is violated, or for administrative and/or other safety reasons. A subject must be discontinued from the trial for any of the following reasons:

- The subject or legal representative (such as a parent or legal guardian) withdraws consent
- Unacceptable adverse experiences
- Intercurrent illness that prevents further administration of intervention
- Investigator's decision to withdraw the subject
- Noncompliance with trial treatment or procedure requirements
- Administrative reasons

Subjects who sign the informed consent form but withdraw or are dropped from the trial at the discretion of the investigator prior to use of the VR headset may be replaced. Subjects who sign the informed consent form, use the VR intervention and then subsequently withdraw, or are withdrawn/discontinued from the study, prior to completing 8 minutes of the program will not be replaced and will count towards feasibility.

7.3 Lost to Follow-Up

Study intervention will take place on the day of the subject's radiation simulation appointment. There are no follow up procedures.

8 STUDY ASSESSMENT AND PROCEDURES

8.1 Efficacy Assessments

During pre-screening, basic demographic data including gender, age, race/ethnicity, primary cancer diagnosis, performance status and radiation treatment plan will be collected from the medical record.

Secondary endpoints will be collected via electronic surveys. A baseline assessment of anxiety will be obtained using the Hospital Anxiety and Depression scale (HADS) validated tool. This tool has been used extensively in the oncologic setting and in patients receiving radiation therapy [20-21]. The HADS is a 14-item scale with seven items for each anxiety and depression. Subscale scores greater than 8 denotes anxiety or depression. It was designed to detect anxiety and depression in the general population [22]. Given high rates of baseline anxiety in cancer patients, the HADS will be administered to document the prevalence of generalized anxiety. This instrument will take approximately three minutes to complete. If the HADS score is noted to be 8 or higher for any study participant, the PI or other clinical staff will assess patient to determine if a referral to mental health services is warranted. If deemed appropriate, the primary clinical team will also be notified.

Situational anxiety will be assessed with the state-trait anxiety inventory (STAI-6). The STAI-6 is adapted from the original 20-item STAI [23-24]. The original STAI scores range from 20-80. A score of 40 or higher is correlated with high anxiety [23]. The STAI-6 consists of six questions rated on a 1-4 Likert scale creating a score range from 6 to 24 [24]. In order to generate scores compatible with the original STAI, STAI-6 scores will be multiplied by 20 and divided by 6 to give a range between 20-80. This instrument has previously been used to assess situational anxiety in patients receiving radiation treatment [25]. This instrument will take appropriately two minutes to complete.

The VR immersion will last approximately ten minutes to allow patients ample time to view the brief orientation video and practice mindfulness principles. The primary endpoint of this study is feasibility. In order to be counted towards feasibility, at least 75% of enrolled patients must participate in the VR immersion for a minimum of 8 minutes. If a patient withdraws from the study prior to the VR immersion, they will not be counted towards feasibility. Patients may ask to temporarily remove the VR headset or remove the VR headset themselves at any time. They must express a desire to complete the program before the head-mounted device is replaced. Patients may also permanently discontinue the VR immersion at any time for any reason. Post-intervention STAI-6 will assess for change in situational anxiety. We will also obtain patient feedback on his or her VR experience with both multiple choice and free response questions. This usability survey will take between 7-10 minutes to complete.

8.2 Safety and Other Assessments

Patients will be asked to provide feedback on their comfort level during the VR experience verbally. If the patient indicates discomfort, the VR experience will be terminated. Patients will also be verbally assessed at the end of the VR immersion to ensure no untoward side effects.

The virtual reality technology device is not expected to have any impact on safety as it involves the use of a headset in the up-right seated position. Patients will be provided contact information of the investigators should any concerns arise regarding device safety or overheating. Patients with significant pre-existing medical history that may predispose to higher risk of side effects will be excluded from the trial as described in section 5.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

Patients will be asked to provide feedback on their comfort level during the VR experience verbally as well as in the Usability survey. If the patient indicates discomfort, the VR experience will be terminated. The study team will track how many patients were unable to complete the VR program and the reason they were unable to complete the VR program.

Subjects may experience discomfort during the VR immersion, such as temporary headache, dizziness, lightheadedness, vision problems, nausea, vomiting, etc. which is expected, temporary, and should resolve within 24 hours. This kind of discomfort is not considered an adverse event.

9 STATISTICAL CONSIDERATIONS

9.1 Statistical Hypotheses

- The primary endpoint is feasibility based on participants to successfully complete the VR immersion. For VR to be deemed feasible, these conditions must be met for at least 75% of participants. Based on the expected accrual of 25 patients, futility and early termination will be triggered if 6 participants fail to meet the conditions described above.
- Secondary Efficacy Endpoint(s):

1. Patient survey results defined as a change in post- and pre- VR immersion survey values as assessed by the STAI-6.
2. Patient-reported feedback on VR immersive experience as collected in a Usability survey. This will be assessed with multiple choice and open-ended questions.

9.2 Sample Size Determination

For this feasibility study, we aim to recruit 25 patients. Using the primary outcome of completion of a minimum of 8 minutes of VR immersion, 25 patients will allow us to identify the feasibility

target of 75% of patient completion rate with an 80% confidence interval 60%-86% (Clopper-Pearson exact) [18-19].

9.3 Populations for Analyses

Data collected from all enrolled participants will be analyzed. Additional data will be collected by medical record review when needed for analysis.

9.4 Statistical Analyses

9.4.1 Analysis of the Primary Efficacy Endpoint(s)

For the primary endpoint of feasibility:

The overall feasibility will be calculated, dividing the number of patients who successfully completed 8 minutes of the VR immersion, over the total number of enrolled patients. Following an intent to treat analysis, all patients who enrolled and participated in the VR immersion, represent the denominator. The primary endpoint will be met if 75% of these patients meet feasibility criteria.

9.4.2 Analysis of the Secondary Endpoint(s)

- The STAI-6 is adapted from the original 20-item STAI [21-22]. The original STAI scores range from 20-80. A score of 40 or higher is correlated with high anxiety [21]. The STAI-6 consists of six questions rated on a 1-4 Likert scale creating a score range from 6 to 24 [22]. In order to generate scores compatible with the original STAI, STAI-6 scores will be multiplied by 20 and divided by 6 to give a range between 20-80. Changes in situational anxiety scores (when comparing post-VR to pre-VR immersion) will be tested using a paired t-test, assuming the differences between the scores are normally distributed. If they are normally distributed, a nonparametric test will be used (Wilcoxon signed-rank test).

9.4.3 Baseline Descriptive Statistics

Baseline and demographic characteristics will be summarized by standard descriptive statistics (including mean and standard deviation for continuous variables such as age and frequency and percentage for categorical variables such as gender).

9.4.4 Tabulation of Individual Participant Data

Individual participant data may be listed by measure. There is only one-time point in this study.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 Regulatory, Ethical, and Study Oversight Considerations

10.1.1 *Informed Consent Process*

Consent forms will be provided describing study procedures in detail. Written documentation of informed consent is required prior to starting the study intervention.

10.1.1.1 *Consent Procedures and Documentation*

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The investigator or designee will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

10.1.2 *Study Discontinuation and Closure*

This study may be temporarily suspended or prematurely terminated by the PI if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform the Institutional Review Board (IRB) and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements

- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed.

In terminating the study, the Principal Investigator will assure that adequate consideration is given to the protection of the subjects' interests.

10.1.3 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators and their staff. This confidentiality covers the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior approval by the Penn IRB.

All research activities will be conducted in as private a setting as possible.

The study monitor, representatives of the Institutional Review Board (IRB), and other regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the participants in this study. The study site will permit access to such records.

The study participant's contact information will be securely stored at the site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and institutional policies.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Department of Radiation Oncology at Penn Medicine. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by Department of Radiation Oncology research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Department of Radiation Oncology at Penn Medicine.

The VR system will not collect any patient data.

10.1.4 Future Use of Stored Data

Study data will be de-identified prior to storage for future use.

10.1.5 *Safety Oversight*

The study PI is responsible for ensuring the ongoing quality and integrity of the research study. In addition, this study will be monitored or audited in accordance with Abramson Cancer Center's NCI approved Institutional Data and Safety Monitoring Plan.

10.1.6 *Clinical Monitoring*

The study PI is responsible for ensuring the ongoing quality and integrity of the research study. In addition, this study will be monitored or audited in accordance with Abramson Cancer Center's NCI approved Institutional Data and Safety Monitoring Plan.

10.1.7 *Data Handling and Record Keeping*

10.1.7.1 *Data Collection and Management Responsibilities*

Source data is all information, original records of clinical findings, observations, or other activities in a research study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents and may be paper, electronic or a combination of both. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data and follow ALCOAC standards (attributable, legible, contemporaneous, original, accurate, and complete).

The Principal Investigator will manage and collect electronic survey result data, which will be aggregated and deidentified prior to dissemination. Data collected for this study will be analyzed and computer-based files containing identifiable information will be stored in the University of Pennsylvania RedCap database, a password-protected University of Pennsylvania-managed shared drive (\\RadOnc_CAP\), and/or Penn+Box.

10.1.7.2 *Study Records Retention*

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Precautions are in place to ensure

the data is secure by using passwords and encryption, because the research involves web-based surveys.

The DHHS regulation (45 CFR 46.115) states that records relating to research conducted or supported by any Federal department or agency shall be retained for at least 3 years after completion of the research.

Records for this study will be maintained in a secure location with access limited to the investigators and the study specific research team for 3 years from the date of full study terminations. If necessary, after the first year of termination, records may be moved to an off-site secure storage facility.

10.1.8 Protocol Deviations

The PI and the study team should document all scenarios where the protocol is not followed and provide, in particular:

- Who deviated from the protocol
- What was the deviation
- When did the deviation occur
- How did the deviation happen
- What is the impact of the deviation
- A root cause analysis of why the deviation occurred

If the assessment results in a determination that any of the following are potentially affected:

- having the potential to adversely affect subject safety; OR
- increases risks to participants; OR
- adversely affects the integrity of the data; OR
- violates the rights and welfare of participants, OR
- affects the subject's willingness to participate in research.
- there is a potential for an overall impact on the research that should be shared with the IRB for consideration and development of next best steps to address it.

the deviation should be reported to the University of Pennsylvania IRB and Abramson Cancer Center Data and Safety Monitoring Committee (DSMC) per their reporting requirements.

10.1.9 Publication and Data Sharing Policy

The results of this study will be published in the peer-reviewed literature

10.1.10 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

10.2 Protocol Amendment History

Version	Date	Description of Change	Brief Rationale
2	4/18/2024	<ul style="list-style-type: none">-Steven Feigenberg, MD and Jeffrey Bradley, MD were added to the protocol as sub-investigators.-Clarified the screening and informed consent process. Screening: clarified that patients will be pre-screened by inclusion and exclusion criteria prior to the day of simulation. Basic demographic data will be obtained during pre-screening instead of at the time of enrollment.-Corrected STAI-6 consists of six instead of four questions.-Adverse events definitions were removed.-Clarification of discomfort from using VR, which is not considered as adverse events.	<ul style="list-style-type: none">-Steven Feigenberg, MD and Jeffrey Bradley, MD were added to the study as sub-investigators.-Clarified that patients will be pre-screened by inclusion and exclusion criteria prior to the day of simulation. Changed when the baseline demographics will be collected from the electronic medical record.- Corrected STAI-6 consists of six instead of four questions.-Adverse events definitions were not relevant to the protocol as we are not collecting adverse events.-Discomfort needed to be clarified as this kind of discomfort will not be considered as adverse events.

Version	Date	Description of Change	Brief Rationale
3	10/11/2024	<p>-Exclusion criteria was changed to include the addition of a 6-month timeframe for exclusion #2. History of epilepsy and seizures was removed from exclusion #2 and made as its own separate criteria. The clarification of exclusion #4, hearing loss “that is not treated”.</p> <p>- Pre-screening questionnaire was modified to reflect the modified exclusion criteria.</p>	<p>We are changing the exclusion criteria to give patients who have not experienced recent motion sickness, car sickness, vertigo, migraines, or light sensitivity in the last 6 months, an opportunity to participate in the study. We will continue to exclude patients who have history of seizure or epilepsy from participating. We clarified the exclusion of hearing loss “that is not treated”, to be able to include patients who wear hearing aids in the study.</p>
4	9/23/2025	Updated section 9.3	<p>We would like to allow for additional data to be collected by medical record review when needed for analysis. Additional variables including smoking history, smoking pack years, primary cancer histology, cancer staging, and radiation treatment intent (definitive vs palliative)</p>

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12 APPENDIX

12.1 Schedule of Activities (SoA)



Protocol IRB# 854756 – Virtual Reality to Promote Relaxation Prior to Radiation Simulation
Feasibility

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Procedures	Day -30 to 1	Enrollment/Baseline Visit 1, Day 1
Screening (including pre-screening questionnaire)	X	X
Informed consent		X
Demographics	X	
HADS Questionnaire		X
STAI-Short form		X
VR intervention		X
Usability Survey		X

12.2 Questionnaires

Pre-Screening Questionnaire

Have you experienced motion sickness, car sickness, migraines, vertigo or light sensitivity within the last 6 months?

‘Yes’ will screen patients out of the study.

☐ Yes

☐ No

Do you have a history of epilepsy or seizures?

‘Yes’ will screen patients out of the study.

☐ Yes

☐ No

Are you currently experiencing nausea, dizziness, lightheadedness or vomited in the last 24 hours?

‘Yes’ will screen patients out of the study.

☐ Yes

☐ No

Hospital Anxiety and Depression Scale (HADS)- pre-intervention only

Choose the answer that is closest to how you have been feeling in the past week. Don’t take too long over your replies: your immediate is best.

1. I feel tense or ‘wound up’:

☐ Most of the time

☐ A lot of the time

☐ From time to time

☐ Not at all

2. I still enjoy the things I used to enjoy:

☐ Definitely as much

☐ Not quite so much

☐ Only a little

☐ Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

4. I can laugh and see the funny side of things:

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much now
- ☐ Not at all

5. Worrying thoughts go through my mind:

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ From time to time, but not too often
- ☐ Only occasionally

6. I feel cheerful:

- ☐ Not at all
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

7. I can sit at ease and feel relaxed:

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

8. I feel as if I am slowed down:

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

9. I get a sort of frightened feeling like 'butterflies' in the stomach:

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often

☐ Very often

10. I have lost interest in my appearance:

- ☐ Definitely
☐ I don't take as much care as I should
☐ I may not take quite as much care
☐ I take just as much care as ever

11. I feel restless as I have to be on the move:

- ☐ Very much indeed
☐ Quite a lot
☐ Not very much
☐ Not at all

12. I look forward with enjoyment to things:

- ☐ As much as I ever did
☐ Rather less than I used to
☐ Definitely less than I used to
☐ Hardly at all

13. I get sudden feelings of panic:

- ☐ Very often indeed
☐ Quite often
☐ Not very often
☐ Not at all

14. I can enjoy a good book or radio or TV program:

- ☐ Often
☐ Sometimes
☐ Not often
☐ Very seldom

The State-Trait Anxiety Inventory (STAI) – Administered pre- and post-intervention

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel **right now**, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Usability – administered post-intervention only

Prior to your participation in this study, how much experience do you have using virtual reality?

- ☐ None at all
☐ Some experience
☐ A lot of experience

The virtual reality program kept my attention

- ☐ Agree
☐ Neutral
☐ Disagree

The virtual reality program was relaxing

- ☐ Agree
☐ Neutral
☐ Disagree

The virtual reality program was easy to use

- ☐ Agree
☐ Neutral
☐ Disagree

The headset was comfortable

- ☐ Agree

- ☐ Neutral
☐ Disagree

The virtual reality program helped me cope with my cancer treatment

- ☐ Agree
☐ Neutral
☐ Disagree

The virtual reality program lowered my stress level

- ☐ Agree
☐ Neutral
☐ Disagree

The virtual reality program distracted me from my cancer treatment

- ☐ Agree
☐ Neutral
☐ Disagree

How would you rate your overall experience using the virtual reality program?

- ☐ Satisfied
☐ Neither satisfied or dissatisfied
☐ Dissatisfied

Would you use this virtual reality program again?

- ☐ Yes
☐ Maybe
☐ No

Would you recommend this program to other patients?

- ☐ Yes
☐ Maybe
☐ No

Did you find the breathing techniques described in the virtual reality program helpful?

- ☐ Yes
☐ Maybe
☐ No

In terms of length, the virtual reality program was:

- ☐ Too long

☐ Just about right

☐ Too short

What did you like most about the virtual reality program?

What did you like least about the virtual reality program?

Did you find anything problematic in the virtual reality program?
