THOMAS JEFFERSON UNIVERSITY
Sidney Kimmel Cancer Center

Improving the Patient Experience During Bone Marrow Biopsy/Aspiration (BMBA): Do interventions decrease distress and pain.

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator:

Signed: _____ Date: _____

Name: Anne Delengowski

Title: Director Oncology Nursing Education, Oncology Clinical Nurse Specialist

Statement of Compliance

This study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and Thomas Jefferson University research policies

List of Abbreviations

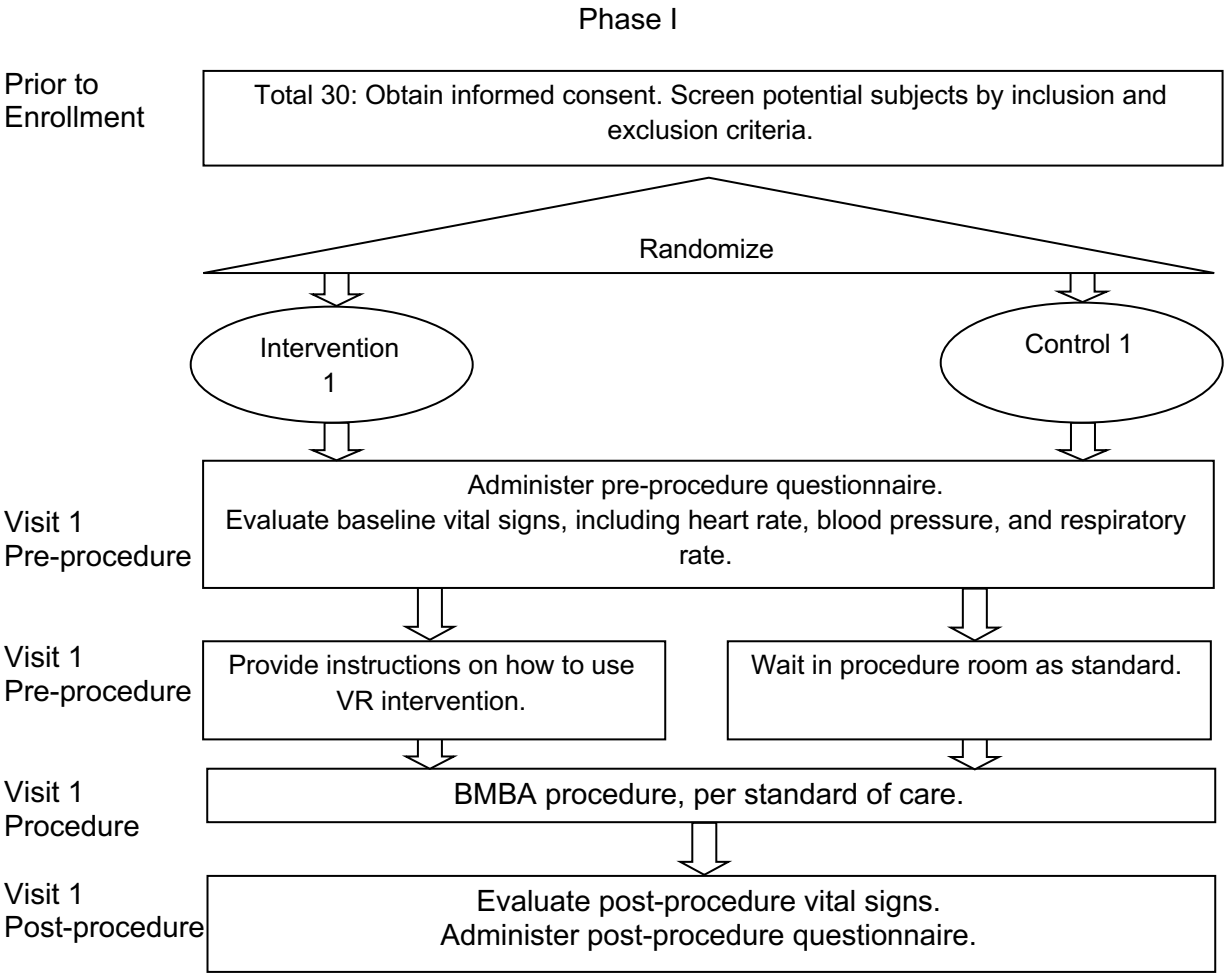
AE	Adverse Event/Adverse Experience
BMBA	Bone marrow biopsy aspiration
CFR	Code of Federal Regulations
Co-I	Co-Investigator
CTCAE	Common Terminology Criteria for Adverse Events
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
N	Number (typically refers to participants)
PHI	Protected Health Information
PI	Principal Investigator
PRC	Protocol Review Committee
SAE	Serious Adverse Event/Serious Adverse Experience
SKCC	Sidney Kimmel Cancer Center
TJU	Thomas Jefferson University
UAP	Unanticipated Problem
VR	Virtual reality

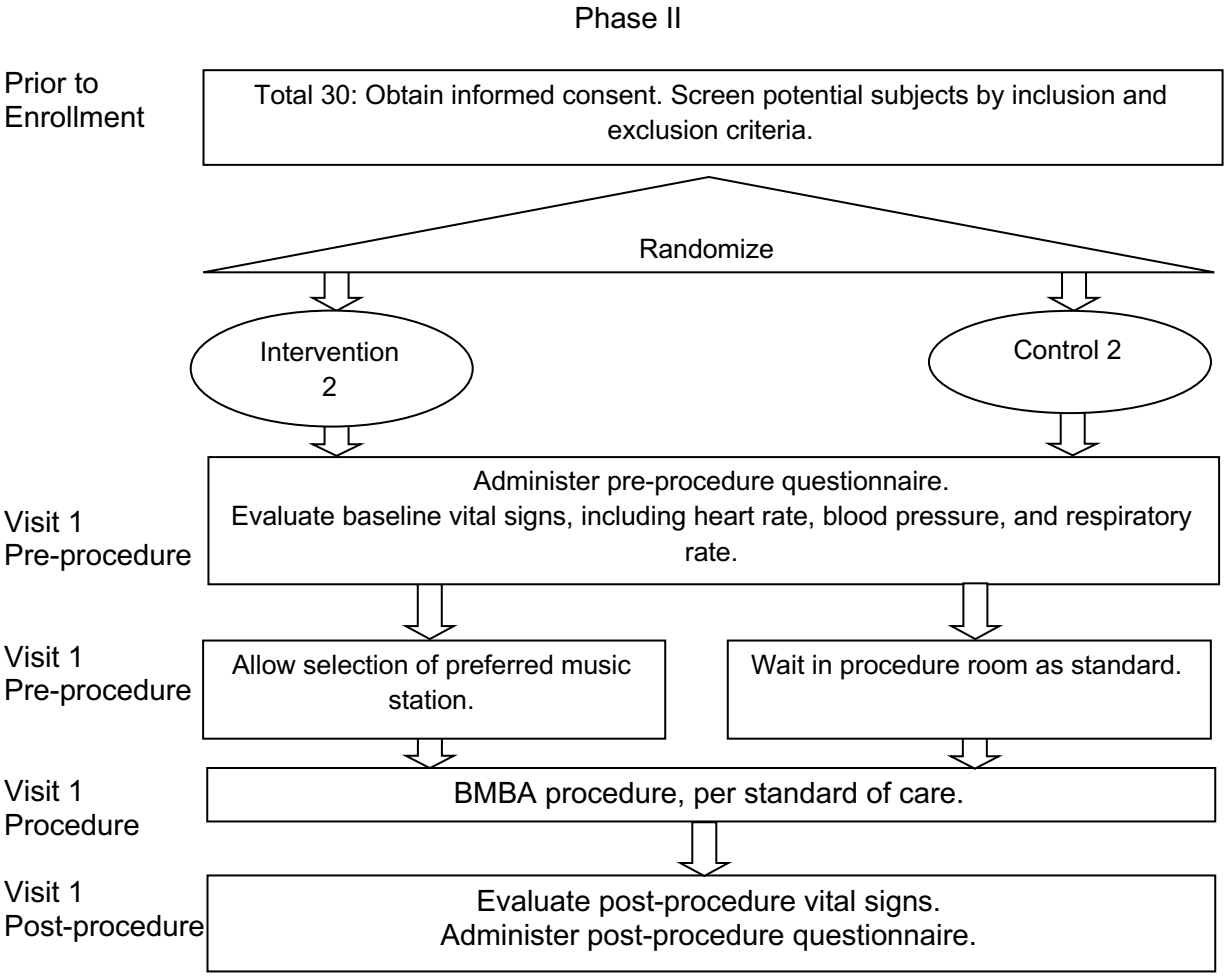
Study Summary

Title:	*Improving the Patient Experience During Bone Marrow Biopsy/Aspiration (BMBA): Do interventions decrease distress and pain.*
Précis:	Patients undergoing a **bone marrow biopsy aspiration** (BMBA) will trial possible interventions to decrease their **distress and pain**, as suggested by a previous patient survey conducted with this population. The study will assess both pre-intervention and post-intervention distress scores and a post-intervention pain score. Patient **satisfaction** will also be assessed to determine overall patient experience. Each intervention will be compared to a control group to validate if one or both interventions are valuable to offer to patients in the future.
Objectives:	Primary: Trial VR and environmental interventions to determine if either result in a reduction in patient **distress** during BMBA. Secondary: Determine if either intervention results in decreased **pain** or improved **satisfaction** scores.
Population:	Young adult to geriatric patients with hematologic malignancies of varying health statuses and demographic groups Most patients have hematological cancers, including leukemia, lymphoma, and multiple myeloma.
Phase:	N/A
Number of Sites:	TJU
Description of Intervention:	Two interventions will be trialed. The first intervention is **virtual reality (VR) guided mediation**. Patients will be provided with wireless VR headsets that contain a guided meditation application. The application allows users to select their preferred music, visual setting, and a topic for meditation. The second intervention is **environmental changes**. A nature themed wall mural decal will be installed in the BMBA room and the in-room computer will play music from Pandora. A selection of suggested stations will be provided, with the option for outside selections.
Study Duration:	10 months

Participant Participation Duration:	Approximately 45 minutes, the duration of a normal BMBA visit, including procedure
Estimated Time to Complete Enrollment:	6 months

Schematic of Study Design:





1 Introduction

1.1 Background Information

Bone marrow biopsies are frequent occurrences for hematological cancer patients. These procedures are a source of anxiety for many patients. Current literature suggests a wide variety of changes that can be employed to reduce stress and improve patient experience, including: room décor changes[1, 2, 3, 4] some including nature inspired imagery,[3, 5, 6] music for relaxation during procedure,[7, 8, 9, 10] guided meditation,[11, 12] virtual reality (VR) distraction therapy,[13, 14, 15, 16, 17, 18] etc. These changes have the potential to decrease patient stress both prior to procedures[9, 19] and during them.[16]

In a human-centered design survey conducted by this team in December 2019, patients were asked about their pain and anxiety relating to BMBA procedures, as well as their thoughts on possible interventions. A large majority (72%, n=16) of patients believed that the addition of music to their treatment would improve their experience. Other options were also considered including virtual reality (26%, n=5) and guided meditation

(30%, n=6). Though fewer patients expressed interest in these interventions, only 8% (n=2) had previously experienced guided meditation and none of the patients surveyed had any experience with VR. For this reason investigators will trial two interventions with patients to determine if one or both are effective at improving the patient experience. The overall goal of the study is to identify an intervention–or both interventions–as a potential offering for patients during BMBA procedures to improve their overall experience.

1.2 Rationale for the Proposed Study

Human-centered design puts "the user at the core of the design process" and allows spaces to be adapted to actual desired needs rather than perceived needs.[20,21] The interventions being trialed were selected with the target patient population as part of the conversation.

Intervention 1 provides patients with a guided meditation experience through a VR headset. Existing literature shows that guided imagery increases patient comfort and that meditation can substantially improve "psychological function, mental health, and [quality of life]" for cancer patients.[22] VR has also been shown to be an "effective distraction intervention for managing pain and anxiety among breast cancer patients,"[23] during lumbar punctures[13] and for patients with chronic pain.[15, 18] Participants will be introduced to the Oculus Go VR headset while waiting in the procedure room prior to their procedure. They will use the headset for approximately 10 minutes, or until their provider arrives for their procedure. The provider will prepare the patient for their BMBA procedure, and then allow them to continue using their VR headset and chosen guided meditation during the procedure, for approximately 20 minutes. Oculus guidelines suggest new users take breaks every 30 minutes or as needed while adjusting to the technology.[24] Participant usage should fit within this suggested timeframe.

Intervention 2 provides patients with changes to their procedure room environment. Natural environments have a positive influence on human perceptions of stress[25] and allow for greater recovery from mental fatigue.[26] Furthermore, natural interior design, including soundscape,[2] can have restorative properties for patients.[1, 4] In particular, music therapy improves "anxiety and depression symptoms presented by patients with cancer,"[27] has been associated with lower pain scores for palliative care patients,[28] and been used for anti-anxiety interventions for outpatient procedures,[10] including BMBA.[8] For this intervention, participants will be able to select their preferred type of music for the duration of their time in the procedure room, including while waiting before their procedure. They will be provided with a list of suggested music types, based on the previous patient survey's results, but will also have the option to select outside the list based on their preference.

Our hypothesis is that patients undergoing bone marrow biopsy and aspiration (BMBA) who receive distraction techniques (room décor, music, and virtual reality) will have lower levels of distress and pain than patients who receive only the standard of practice care. Additionally, these patients will have higher levels of satisfaction with their overall experience. This study aims to evaluate pre-procedure and post-procedure distress and

pain scores, and post-procedure satisfaction ratings to determine if one or both of the selected interventions are valuable to employ in-clinic for the entire patient population.

1.3 Potential Risks and Benefits

1.3.1 Potential Risks

Potential risks vary based on intervention arm.

Intervention 1: Virtual reality may cause symptoms associated with motion sickness, including nausea, dizziness, disorientation, and vertigo.[29] Mild eyestrain or headaches may also occur.

Intervention 2: There are no known risks associated with music therapy or décor changes.

Participants in all study arms will undergo a BMBA procedure as part of their standard care. Potential risks of bone marrow biopsies are bruising and pain at the biopsy site, discomfort at the site during or post-procedure, prolonged bleeding, and infection.

1.3.2 Benefits

Potential benefits include improved patient satisfaction, reduction of acute pain perception, decreased distress around BMBA, and overall improvement in patient experience.

2 Study Objectives

2.1 Objectives

2.1.1 Primary

To assess patient distress scores related to BMBA procedures.

The primary outcome will be reported on a scale of 0-10, based on the National Comprehensive Cancer Network (NCCN) Distress Thermometer. This scale is standardly used with oncology patients to determine their distress levels—distress refers to “an unpleasant experience of a mental, physical, social, or spiritual nature. It can affect the way you think, feel, or act. Distress may make it harder to cope with having cancer, its symptoms, or its treatment.”[30]

2.1.2 Secondary

To assess patient pain scores related to their BMBA procedure. This will be measured through the 0-10 Numeric Pain Intensity Scale

To assess patient satisfaction with their procedure. This will be assessed through a patient satisfaction survey including Likert-type questions.

2.2 Endpoints/Outcome Measures

Primary outcomes will be assessed via the patient questionnaires. All endpoints are measured pre- and post-procedure at Visit 1.

2.2.1 Primary

The primary endpoint of patients' distress levels towards BMBA procedures are the responses to Question 13 and 16 of the survey (Appendix B).

2.2.2 Secondary

The secondary endpoint of patients' pain scores during BMBA procedures are the responses to Question 12 and 17 of the post-procedure survey.

The secondary endpoint of patients' satisfaction levels towards their BMBA procedures is the response to Questions 18 of the post-procedure survey.

3 Study Design

3.1 Characteristics

Trial of interventions to improve patient experience during BMBA procedures at outpatient oncology office.

3.2 Number of Participants

60 total patients will be enrolled in the study. For Phase I, 15 patients will enroll in Intervention 1 and 15 patients will enroll in the control arm. For Phase II, 15 patients will enroll in Intervention 2 and 15 patients will enroll in the control arm.

3.3 Duration of Therapy

Approximately 20-30 minutes of a 45-minute visit. No follow-up visit will occur.

3.4 Treatment Assignment Procedures

3.4.1 Randomization Procedures

We will adopt a permuted block randomization schedule for both Phase I and II. Study staff will utilize a sealed envelope system provided by the Biostatistics department.

3.5 Study Timeline

Patients will be enrolled on a rolling basis as they are scheduled for their BMBA procedures. We anticipate enrolling 2-3 patients per week, resulting in a 6-month timeline to achieve 60 participants. Both primary and study completion dates will conclude at the end of the enrollment period.

4 Study Enrollment and Withdrawal

Pregnant women are not commonly a part of the BMBA patient population, but there is no reason to exclude their participation so pregnancy will not be included in the exclusion criteria.

4.1 Eligibility Criteria

4.1.1 Inclusion Criteria

Individuals must meet all of the following inclusion criteria in order to be eligible to participate in the study:

- Provide signed and dated informed consent form
- Willing to comply with all study procedures
- Over 18 years of age
- Prior history of at least 1 (one) BMBA at Jefferson outpatient oncology office within the past 2 (two) years
- Visiting the Jefferson outpatient oncology office for a BMBA procedure during the study duration

4.1.2 Exclusion Criteria

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

- Inability to read questions in English
- Inability to answer questions autonomously
- History of vertigo
- Legal blindness in both eyes
- Severe or profound hearing loss, or deafness

4.2 Gender/Minority/Pediatric Inclusion for Research

Pediatric patients are not included in this study as they are not treated at the outpatient medical oncology office at 925 Chestnut St where it is being conducted. All adult patients, regardless of gender or minority will be included.

4.3 Strategies for Recruitment and Retention

Participants will be recruited from patients already attending the outpatient medical oncology office at 925 Chestnut for BMBA procedures. Study staff will review the BMBA schedule a week prior to procedures and call patients who fit the inclusion criteria to

inform them about the study. This will include a discussion of the goals of the study, expectations for participation, and a general overview of the consent process.

Participation is for a one-time session and retention will not be necessary.

4.4 Participant Withdrawal

4.4.1 Reasons for Withdrawal

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may terminate a study participant's participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

4.4.2 Handling of Participant Withdrawals and Participant Discontinuation of Study Intervention

Any participant who experiences an AE and discontinues participation will be asked to provide details about their experience. They may also be asked to complete the post-procedure survey, if deemed appropriate by study staff.

4.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the investigators, funding agency and regulatory authorities. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

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

- Determination of unexpected, significant, or unacceptable risk to participants.
- Insufficient adherence to protocol requirements.
- Data that is not sufficiently complete and/or evaluable.
- Determination of futility.

5 Study Intervention

5.1 Study Product

The Phase I intervention is virtual reality (VR) guided mediation. Patients will be provided with a wireless VR headset that contains a guided meditation application. The application allows users to select their preferred music, visual setting, and a topic for meditation. Patients who are enrolled to this study group will receive instructions on how to use the VR device prior to the procedure.

The Phase II intervention involves environmental changes. A nature-themed wall mural decal will be installed in the BMBA procedure room, and the in-room computer will play music from Pandora. A selection of suggested stations will be provided, with the option for outside selections if desired.

6 Study Schedule

6.1 Pretreatment Period/Screening

Screening (Day -7 to -1)

- During the week prior to a patient's scheduled procedure, study staff will call patients to remind them of their appointment and determine their interest in participating in the study.
- Based on the scheduling, staff will know if participants meet the eligibility criteria "Prior history of at least 1 (one) BMBA at Jefferson outpatient oncology office within the past 2 (two) years." No other eligibility criteria will be evaluated at this time.
- Information about the consent process will be provided to the patient if desired, but the formal informed consent form will be completely reviewed and signed on the day of the procedure in a private room prior to entering the procedure room.

6.2 Enrollment/Baseline

Enrollment/Baseline (Visit 1, Day 1)

- Obtain and document consent from participant on study consent form. Consent interview will be conducted in a private room separate from the procedure room.
- Verify inclusion/exclusion criteria.
- Randomize patient to Control or Intervention arm via sealed envelope.
- Administer pre-procedure survey which includes:
    - Demographic information and focused medical history.
    - Assessment of current distress level (0-10 scale).

- Escort patient to procedure room.
- Obtain baseline vital signs: heart rate, blood pressure, respiratory rate.
- If randomized to an intervention group, provide intervention-specific instructions.
    - For Intervention 1, patients will be instructed on how to put on and use the VR headset and how to select their preferred guided meditation.
    - For Intervention 2, patients will be provided with Pandora music station options or allowed to select their own option.

6.3 Treatment Period

Visit 1, Day 1

- Confirm patient is comfortable proceeding with assigned intervention during BMBA procedure.
- Standard of care BMBA procedure.
- Assess post-procedure vital signs: heart rate, blood pressure, respiratory rate.
- Administer post-procedure questionnaire, which includes:
    - Assessment of current distress level (0-10 scale).
    - 0-10 Numeric Pain Intensity scale.
    - Patient satisfaction questions.

6.4 Withdrawal Visit/Discontinuation of Therapy

If a participant withdraws early or terminates participation, they will be requested to complete the post-procedure questionnaire, if deemed appropriate by study staff.

7 Study Procedures and Evaluations

7.1 Study Procedures/Evaluations

- Medical History:
    - Pre-procedure questionnaire will obtain diagnosis requiring BMBA, general reasons for receiving medical care, and history of previous BMBA procedures.
- Physical examination:
    - Vital signs, including heart rate, blood pressure, and respiratory rate.

8 Evaluation of Safety

8.1 Specification of Safety Parameters

8.1.1 Unanticipated Problems

Unanticipated problems (UAPs) include, in general, any incident, experience, or outcome that meets the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;

UAPs are considered to pose risk to participants or others when they suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.1.2 Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

Potential adverse events include fainting or lightheadedness during or post-procedure, bruising resulting from needle insertion, prolonged bleeding at biopsy site, discomfort at the site during or post-procedure, infection, dizziness, nausea, disorientation, and vertigo.

8.1.3 Serious Adverse Events

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the participant at immediate risk of death from the event as it occurred)
- Is disabling or incapacitating
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate

medical judgment, the event may jeopardize the participant or may require intervention to prevent one of the outcomes listed in this definition.

Potential SAEs include anaphylactic reaction after lidocaine or analgesic administration, post-biopsy bleeding, and severe infection.

8.2 Safety Assessment and Follow-Up

The PI will follow adverse events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed for outcome information until resolution or stabilization.

8.3 Recording Adverse Events

The following subsections detail what information must be documented for each adverse event occurring during the time period specified in Section 8.2 Safety Assessment and Follow-Up.

8.3.1 Relationship to Study Intervention

The relationship to study intervention or study participation must be assessed and documented for all adverse events. Evaluation of relatedness must consider etiologies such as natural history of the underlying disease, concurrent illness, concomitant therapy, study-related procedures, accidents, and other external factors.

The following guidelines are used to assess relationship of an event to study intervention:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

8.3.2 Expectedness

The PI is responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not

consistent with the risk information previously described for the intervention. Risk information to assess expectedness can be obtained from published medical literature, the protocol, or the informed consent document.

8.3.3 Severity of Event

Adverse events will be graded for severity according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

8.3.4 Intervention

Any intervention implemented to treat the adverse event must be documented for all adverse events.

8.4 Safety Reporting

8.4.1 Reporting to IRB

8.4.1.1 *Unanticipated Problems*

All incidents or events that meet criteria for unanticipated problems (UAPs) as defined in Section 8.1.1 Unanticipated Problems require the creation and completion of an unanticipated problem report form (OHR-20).

UAPs that pose risk to participants or others, and that are not AEs, will be submitted to the IRB on an OHR-20 form via the eazUP system within 10 working days of the investigator becoming aware of the event.

UAPs that do not pose risk to participants or others will be submitted to the IRB at the next continuing review.

8.4.1.2 *Adverse Events*

Grade 1 AEs will be reported to the IRB at continuing review.

Grade 2 AEs will be reported to the IRB at the time of continuing review.

8.4.1.3 *Serious Adverse Events*

SAEs will be reported to the IRB on OHR-10 forms via the electronic reporting system (eSAEy) according to the required time frames described below.

Grade 3-4 AEs that are unexpected and deemed to be at least possibly related to the study will be reported to the IRB within 2 working days of knowledge of the event.

Grade 3-4 AEs that are deemed unrelated to the study will be reported to the IRB within 5 working days.

Grade 5 AEs will be reported to the IRB within one working day of knowledge of the event.

All SAEs will be submitted to the IRB at continuing review, including those that were reported previously.

8.4.2 Reporting to SKCC DSMC

All AEs and SAEs, safety and toxicity data, and any corrective actions will be submitted to the DSMC per the frequency described in the SKCC DSMP. The report to the SKCC DSMC will also include any unanticipated problems that in the opinion of the PI should be reported to the DSMC.

For expedited reporting requirements, see table below:
DSMC AE/SAE Reporting Requirements

	Grade 1	Grade 2		Grade 3				Grades 4 and 5
				Unexpected		Expected		
	Unexpected and Expected	Unexpected	Expected	With Hospitalization	Without Hospitalization	With Hospitalization	Without Hospitalization	Unexpected and Expected
Unrelated Unlikely	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	5 Working Days	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	5 Working Days	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Phase I - 48 Hours (Death: 24 Hours) Phase II - 5 working days
Possible Probably Definite	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	48 Hours (Death: 24 Hours)	Phase I - 48 Hours Phase II - 5 working days	48 Hours (Death: 24 Hours)	Reviewed at Quarterly DSMC Meeting and IRB Annual Review	Phase I and Phase II - 48 Hours (Death: 24 Hours)

8.4.3 Reporting to Funding Sponsor

Funding provided by the DAISY Foundation requires an interim report after patient enrollment is complete, anticipated as 6 months after start date. A final report of findings is due after data analysis is complete, no later than 1 year after the study start date.

8.4.4 Reporting of Pregnancy

Pregnant women are not commonly a part of the BMBA patient population, and no participants will undergo pregnancy tests. As the study takes place for a single day, no ongoing reporting for pregnancy will be required.

8.5 Halting Rules

Six or more patients experiencing Grade 4 and 5 AEs, as well as three or more patients experiencing SAEs, will prompt a temporary suspension of enrollment until a safety review can be convened.

9 Study Oversight

In addition to the PI's responsibility for oversight, study oversight will be under the direction of the SKCC's Data and Safety Monitoring Committee (DSMC). The SKCC DSMC operates in compliance with a Data and Safety Monitoring Plan (DSMP) that is approved by the NCI.

10 Clinical Site Monitoring and Auditing

Clinical site monitoring and auditing is conducted to ensure that the rights of human participants are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring and auditing for this study will be performed in accordance with the SKCC's Data and Safety Monitoring Plan (DSMP) developed by the SKCC Data and Safety Monitoring Committee (DSMC). The DSMP specifies the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of participant data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Appropriate staff will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the SKCC DSMP.

11 Statistical Considerations

11.1 Study Hypotheses

Alternate hypothesis: Patients undergoing BMBA who receive distraction techniques (room décor, music, and virtual reality) will have lower levels of distress and pain than

patients who receive only the standard of practice care. Additionally, these patients will have higher levels of satisfaction with their overall experience.

Null hypothesis: Patients undergoing BMBA who receive distraction techniques will have no change in their level of distress and pain when compared to patients receiving the standard of practice care. Additionally, the satisfaction of these patients will be comparable to the satisfaction of patients receiving the standard of care.

11.2 **Analysis Plans**

Endpoints: All endpoints are measured pre- and post-procedure.

The primary endpoints are

1. Q13: a scale from 0-10, measuring pre-procedure patient distress, which will be treated as a numeric value in statistical analysis.

2. Q16: a scale from 0-10, measuring post-procedure patient distress, which will be treated as a numeric value in statistical analysis

The secondary endpoints are

1. Q12: a scale from 0-10, measuring patient pain scores, which will be treated as a numeric value in statistical analysis

2. Q17: a scale from 0-10, measuring post-procedure patient pain scores, which will be treated as a numeric value in statistical analysis

3. Q18, which is on a 5-level Likert scale, measuring satisfaction. This endpoint focuses on the post-procedure response and does not have a pre-procedure comparison.

Statistical Analysis: Responses to the questionnaire before and after the procedure will be reported using summary statistics such as means, standard deviations and proportions. The numeric difference between post vs. pre responses of Q13, Q16, Q12 and Q17 will be compared between Intervention 1 and Control in Phase I, and between Intervention 2 and Control in Phase II, using two-sample t-test. The post-responses of Q18 will be compared between the procedures in Phase I and Phase II using two-sided test for ordinal categorical variables.

11.3 **Sample Size Considerations**

We expect to enroll 15 patients for Intervention 1 and 15 patients for Control for Phase I, and 15 patients for Intervention 2 and 15 patients for Control for Phase II. For the primary endpoint of Q13 and Q16 in each of the two phases, the numeric difference of post- vs. pre- responses will be compared between Intervention and Control arms. This sample size will achieve 82.8% power to detect an effect size of 1.1 at 5% significance level using a two-sided two-sample equal-variance t-test.

11.3.1 Accrual Estimates

30 patients will be accrued into each phase of the trial, resulting in 60 total patients enrolled.

11.4 Evaluation of Safety

Safety will be assessed on a per participant basis as each patient will only be tracked for one visit. There is no statistical analysis of safety planned.

12 Source Documents and Access to Source Data/Documents

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, and regulatory and institutional requirements for the protection of confidentiality of participant information. Study staff will permit authorized representatives of SKCC and regulatory agencies to examine (and when required by applicable law), to copy research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

Source data will be maintained via the electronic medical record (EMR) and the Qualtrics survey platform. The EMR will maintain recorded vital signs and Qualtrics will maintain all survey data, including demographics. Qualtrics is a HIPAA compliant platform. Survey responses will be accessible to the PI and one Co-I for review and analysis.

Physical copies of the randomization envelopes, provided by the Biostatistics department, will also be retained for reference.

13 Quality Control and Quality Assurance

The PI, in conjunction with the research coordinator, Victoria Gulick, will provide training for all study staff on appropriate language for communicating with patients, proper implementation of interventions, and usage of Qualtrics survey software. This will include an introduction to the VR hardware and guided meditation software. All study staff will follow the same plan for onboarding patients to interventions to assure consistency in care.

Source materials will be evaluated weekly, or as problems arise, to ensure data entry is maintained and information remains organized. The research coordinator will be responsible for addressing Qualtrics quality assurance issues. All other compliance will be assessed by the PI.

14 Ethics/Protection of Human Participants

14.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

14.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

14.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to participants and their families, if applicable. An e-consent form describing in detail the study procedures and risks will be given to the participant via the REDCap HIPAA-compliant platform. Consent forms will be IRB-approved, and the participant is required to read and review the e-document or have the e-document read to him, her, or them. Paper consent will be available at patient request. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will electronically sign the informed consent document prior to any study-related assessments or procedures.

Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be emailed to participants for their records. If a participant does not have an email or does not wish to provide one, they will instead receive a paper copy of their consent form.

The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. The consent process will be documented in the research record.

14.4 Exclusion of Women, Minorities, and Children (Special Populations)

Individuals of any gender, race, or ethnic background are eligible to participate. Individuals must be over 18 years of age as pediatric patients are not treated at the

outpatient medical oncology office, at 925 Chestnut, where BMBA procedures are performed.

14.5 Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators and study staff. This confidentiality is extended to cover all study information relating to participants. To ensure this protection, participants will be assigned a study ID number. This number will be linked to their study arm enrollment and associated questionnaires.

The study protocol, documentation, data, and all other information generated will be held in strict confidence.

15 Data Handling and Record Keeping

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents must be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain source documentation, including survey records on the Qualtrics platform.

15.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the PI. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the PI.

15.2 Data Capture Methods

Survey data will be captured through a Qualtrics survey and analyzed through the Qualtrics software. This is password/login protected and recognized as a Jefferson preferred, HIPAA-compliant survey system.

15.3 Types of Data

Survey questions, including patient demographics, will be collected pre- and post-procedure during Visit 1. Participant vital signs will be recorded as part of each patient's EMR. All data to be used in analyses will be deidentified and maintained on internal secure data servers.

A preliminary report will be generated following primary completion of Phase I. An additional report will be generated following primary completion of Phase II. The final report will look at data from both phases.

An interim report is due to the funding sponsor, the DAISY Foundation, after enrollment is complete. A final report is due after all analysis is complete.

15.4 Study Records Retention

Study records will be maintained for two years following study completion to allow for analysis and implementation into current processes.

15.5 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the participant, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

All deviations from the protocol must be addressed in study participant source documents and promptly reported to the IRB and other regulatory bodies according to their requirements.

16 Study Finances

16.1 Funding Source

This study is financed through a grant from the DAISY Foundation.

16.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All Jefferson University Investigators will follow the TJU Conflicts of Interest Policy for Employees (107.03).

16.3 Participant Stipends or Payments

Participants will not receive payment for participation in the study.

17 Publication and Data Sharing Policy

Publications of results will be the shared responsibility of all Co-Investigators and the Principal Investigator. Primary results will be published as a group effort with the approval of all investigators. Secondary publications and presentations may be released by individual investigators with the approval of the other investigators. All secondary/tertiary publications and presentations must reference the original publication and cite other investigators' work as applicable.

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Appendices

The following documents are officially affiliated with the protocol and will be submitted to the IRB as a part of the protocol. As such, changes to these items require a protocol amendment.

Appendix A: Schedule of Events

Appendix B: Patient Survey

APPENDIX A: SCHEDULE OF EVENTS

Vital Signs – Heart rate, blood pressure, and respiratory rate.

Procedures		Screening (Day 1)	Study Visit 1 (Day 1)	Premature Discontinuation
Signed Consent Form		X		
Assessment of Eligibility Criteria		X		
Review of Medical History		X		
Study Intervention			X	
Physical Assessment	Pre-procedure Vital Signs		X	
	Post-procedure Vital Signs		X	
Assessment of Adverse Events			(X)	X
Survey	Distress Assessment		X	(X)
	Pain Assessment		X	(X)
	Satisfaction Questionnaire		X	(X)

APPENDIX B: PATIENT SURVEY

Notes: Items Q1 and Q2 are for staff use only. Study staff will enter the patient's ID number and randomized arm assignment before sharing the survey with patients. There will be no "back" button so patients will be unable to stumble upon this information accidentally. These items will be completed at the time of randomization.

Q16 includes meta text ("${Q13/ChoiceGroup/SelectedChoices}") that will show to participants as the choice they selected as part of Q13.

Questions Q19 through Q23 will only be shown to participants in the relevant enrollment groups.

BMBA Pre- and Post-procedure Survey

Start of Block: Study ID

Q1 **FOR STAFF:** Enter Study ID number

_____

Q2 Patient enrollment group

- ○ Control
- ○ Intervention 1
- ○ Intervention 2

End of Block: Study ID

Start of Block: Demographics

Thank you for participating in this research study.

The following questions help us understand your experience in comparison to other patients like you. Please complete them to the best of your ability.

Q3 What is your age?

- ○ 18-19 years old
- ○ 20-29 years old
- ○ 30-39 years old
- ○ 40-49 years old
- ○ 50-59 years old
- ○ 60-69 years old
- ○ 70-79 years old
- ○ 80 years or older
- ○ Prefer not to answer

Q4 What best describes your gender? *(Select all that apply.)*

- ☐ Female
- ☐ Male
- ☐ Transgender
- ☐ Non-binary / Gender variant
- ☐ Not listed *(please include if not listed)* _____
- ☐ Prefer not to answer

Q5 Are you of Hispanic, Latinx, or Spanish origin?

- ○ Yes
- ○ No
- ○ Prefer not to answer

Q6 Please specify your race. (*Select all that apply.)*

- ☐ Asian
- ☐ Black or African American
- ☐ Native American
- ☐ Pacific Islander
- ☐ White
- ☐ Other *(please include if not listed)*

_____

- ☐ Prefer not to answer

Q7 What is the highest degree or level of school you have completed?

- ○ Some high school
- ○ High school graduate, diploma or equivalent (GED)
- ○ Some college
- ○ Associate degree
- ○ Bachelor's degree
- ○ Master's degree
- ○ Doctorate degree
- ○ Other *(please include if not listed)* _____
- ○ Prefer not to answer

End of Block: Demographics

Start of Block: Background Health

Q8 What diagnosis/diagnoses have required you to undergo one or more bone marrow biopsy? *(Select all that apply.)*

- ☐ Aplastic Anemia
- ☐ Leukemia
- ☐ Lymphoma
- ☐ Multiple Myeloma
- ☐ Other *(please include if not listed)* _____
- ☐ Prefer not to answer

Q9 For what other medical conditions do you receive medical care? *(Select all categories that apply.)*

- ☐ Blood or Vascular conditions (for example blood clots)
- ☐ Bone or Muscle conditions (for example osteoporosis, arthritis)
- ☐ Heart or Cardiovascular conditions (for example heart attack, heart disease)
- ☐ Inflammation and immune conditions (for example Rheumatoid arthritis)
- ☐ Kidney or Renal conditions (for example kidney disease)
- ☐ Lung or Pulmonary conditions (for example asthma, COPD)
- ☐ Mental health (for example anxiety, depression)
- ☐ Nutrition, Exercise or Metabolic conditions (for example diabetes, obesity)
- ☐ Stomach or Gastrointestinal conditions (for example Crohn's disease)
- ☐ Other *(please include if not listed)*

_____

- ☐ Prefer not to answer

End of Block: Background Health

Start of Block: BMBA History

Please answer the following questions about your previous bone marrow biopsy visits.

Q10 When was your **most recent** bone marrow biopsy at Jefferson Health?

- ○ Less than one month ago
- ○ One to five months ago
- ○ Six months to one year ago
- ○ Greater than one year ago

Q11 How many bone marrow biopsies have you had in the past **two years**?

- ○ One
- ○ Two or three
- ○ Four or five
- ○ Six or more

Q12 During your last bone marrow biopsy procedure experience, how would you rate your **pain**, on a scale of 0 to 10, with 0 being *no pain* and 10 being *extreme pain?*

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

End of Block: BMBA History

Start of Block: Distress Assessment

The following questions are about the **distress** you may feel about today's procedure.

Distress is an unpleasant experience of a mental, physical, social, or spiritual nature. It can affect the way you think, feel, or act. Distress may make it harder to cope with having cancer, its symptoms, or its treatment.

Q13 On a scale of 0 to 10, with 0 being *no distress* and 10 being *extreme distress*, how much **distress** do you feel today?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q14 What part(s) of a bone marrow biopsy procedure make you feel **distressed?** *(Select all that apply).*

- ☐ Being in a medical setting
- ☐ Sitting and waiting before the provider comes in
- ☐ Thinking about the pain I might feel
- ☐ Worrying about the process of the procedure
- ☐ Worrying about the results of the procedure
- ☐ None of the above, I don't feel distress about bone marrow biopsies.
- ☐ Other: _____

Q15 How do you **deal with feeling distressed** about bone marrow biopsies? *(Select all that apply.)*

- ☐ I bring a friend or relative with me to my appointments
- ☐ I distract myself with my phone, a book, or a magazine
- ☐ I listen to music
- ☐ I practice breathing techniques or meditate
- ☐ None of the above, I don't know how to handle my distress
- ☐ None of the above, I don't feel distress about bone marrow biopsies.
- ☐ Other *(please elaborate)*

_____

End of Block: Distress Assessment

Start of Block: Divider

Thank you for completing this part of the survey. Please return the iPad to the study team member. You will complete the rest of the survey after your procedure.

End of Block: Divider

Start of Block: Post-procedure

Post-procedure Questions

Q16 At the start of your visit, you rated your distress as
a ${Q13/ChoiceGroup/SelectedChoices} out of 10.

On a scale of 0 to 10, with 0 being *no distress* and 10 being *extreme distress*, how much **distress** do you feel now?

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q17 During your bone marrow biopsy procedure experience, how would you rate your **pain**, on a scale of 0 to 10, with 0 being *no pain* and 10 being *extreme pain?*

- ○ 0
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10

Q18 Please rate your satisfaction with each of the following parts of your bone marrow biopsy experience.

	Extremely Dissatisfied	Dissatisfied	Neither Satisfied or Dissatisfied	Satisfied	Extremely Satisfied
Time spent in the procedure room **before** the biopsy	○	○	○	○	○
Interactions with staff	○	○	○	○	○
Room decor	○	○	○	○	○

End of Block: Post-procedure

Start of Block: Intervention Specific Questions

Display This Question:

If Patient enrollment group = Intervention 2

As part of this study, you were provided with a selection of music and changes to your procedure room decor. These will be referred to as an **"intervention"** in the following questions. Please answer the following questions about your experience as it relates to this intervention.

Display This Question:

If Patient enrollment group = Intervention 1

As part of this study, you were provided with a virtual reality (VR) headset and a selection of guided meditations. These will be referred to as an **"intervention"** in the following questions. Please answer the following questions about your experience as it relates to this intervention.

*Display These * Questions:*

If Patient enrollment group is NOT "Control"

*Q19 Because of this intervention, the **distress** I felt **while waiting** before the procedure was...

- Significantly decreased
- Slightly decreased
- Neither increased or decreased
- Slightly increased
- Significantly increased
- None of the above, I don't feel distress about this procedure.

*Q20 Because of this intervention, the **distress** I felt **after** the procedure was...

- Significantly decreased
- Slightly decreased
- Neither increased or decreased
- Slightly increased
- Significantly increased
- None of the above, I don't feel distress about this procedure.

*Q21 Because of this intervention, the **pain** I felt **during** the procedure was...

- ○ Significantly decreased
- ○ Slightly decreased
- ○ Neither increased or decreased
- ○ Slightly increased
- ○ Significantly increased
- ○ None of the above, this procedure is not painful.

*Q22 Please rate your overall satisfaction with your experience based on this intervention.

- ○ Extremely satisfied
- ○ Somewhat satisfied
- ○ Neither satisfied nor dissatisfied
- ○ Somewhat dissatisfied
- ○ Extremely dissatisfied

*Q23 If offered during a future bone marrow biopsy procedure, would you be interested in using this intervention again? Use this space to provide any additional feedback about your participation in this study or your bone marrow biopsy experience.

- ○ Yes, I am interested in using this intervention for future procedures.
- ○ No, I am not interested in using this intervention for future procedures.
- ○ I am undecided.

Q24 Use this space to provide any additional feedback you may have about your participation in this study or your experience today.

End of Block: Intervention Specific Questions