**Protocol Title:** Exploring the Feasibility of a Mindfulness-Music Intervention to Reduce Anxiety and Stress in Adolescents and Young Adults Receiving Cancer Treatment

**DF/HCC Principal Research Investigator / Institution:** Robert Knoerl PhD, RN, Dana-Farber Cancer Institute

**DF/HCC Site-Responsible Research Investigator(s) / Institution(s):** Robert Knoerl PhD, RN, Dana-Farber Cancer Institute

**Main Consent**

If you are a parent or guardian of a child under 18 years old, the word "you" refers to your child. You, the parent, will be asked to read and sign this document to give permission for your child to participate.

## A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." This study is evaluating how well a music therapy program works to improve anxiety and stress in adolescents and young adults with cancer.

It is expected that about 48 people will take part in this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

If you decide to participate in this research study, certain questions will be asked of you or certain tests will be taken to see if you are eligible to be in the research study. These tests are called screening tests. The research study has certain requirements that must be met. If the screening tests show that you can be in the research study, you will be able to start on the study intervention.

If the tests show that you cannot be in the research study, you will not be able to participate in this research study. We encourage you to take some time to think this over and to discuss it with other people and to ask questions now and at any time in the future.

## B. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study will test how well a music program works to improve anxiety and stress in adolescents and young adults during cancer treatment. The program is designed to incorporate music-based meditation practices and music making activities (e.g., guitar, drums) to help promote relaxation during cancer treatment.

## C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following options:

- Decide not to participate in this research study
- Participate in another research study

If you decide not to participate in this study, we will ask you to share why you are not interested in participating.

## D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

**Before the research starts:** After signing this consent form, you will be asked to answer some questions or undergo some screening tests or procedures to find out if you can be in the research study.

- Report that you are unable to hold music instruments
- Have a significant hearing impairment such as deafness

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

**After the screening procedures confirm that you are eligible to participate in the research study:**

Table 1 describes the surveys that will be completed by you at every visit associated with the study and the approximate amount of time that it will take you to complete the surveys. If you do not want to answer specific questions for whatever reason, you are able to do so.

**Table 1: Study Calendar**

| Data Collection Tool | Time to Complete | Baseline | End of Study |
|---|---|---|---|
| *Patient* | | | |
| PROMIS - 29 | 10 minutes | X | X |
| Post Traumatic Growth Inventory Short Form | 5 minutes | X | X |
| Perceived Stress Scale | 5 minutes | X | X |
| Adapted Acceptability E – Scale | 5 minutes | | X |
| Demographics Questionnaire | 5 minutes | X | |
| Content Validity Index | 10 minutes | | X |
| Semi-Structured Interview | 45 minutes | | X |
| Participant Music Meditation Use Log | < 5 minutes | To be completed at each music therapy session | |

**Study Visit:** Baseline
After you sign the consent, we will have you complete several surveys.

**This visit will involve the following:**

- **Questionnaires or Surveys:** PROMIS - 29, Post Traumatic Growth Inventory Short Form, Perceived Stress Scale, Demographics Questionnaire. It is estimated that the surveys will take 25 minutes to complete (paper/pencil or email).

**Study Visit:** End of Study
Approximately twelve weeks after beginning the study or after completing all four music sessions (whatever comes first), we will have you complete several surveys.

**This visit will involve the following:**

- **Questionnaires or Surveys:** PROMIS – 29, Post Traumatic Growth Inventory Short Form, Perceived Stress Scale, Adapted Acceptability E – Scale, and Content Validity Index. It is estimated that the surveys will take 35 minutes to complete (paper/pencil or email).

**Intervention:** Music Program Intervention
Table 2 outlines an example of the overall schedule of the music program and how much time each session will take to complete. You will attend four sessions with the music therapist. If you drop out of the study at any time, we will ask you if you are willing to share why you stopped the study early.

**Table 2: Music Program Schedule**

| Week | Activities | Duration |
|---|---|---|
| 1 | *In-person or Zoom, individual session*<br>• Introduction to music therapy and mindfulness:<br>• Music-based meditation<br>• Debrief<br>• Closure | 45 min |
| 2 | *In-person or Zoom, individual session*<br>• Check in<br>• Music-based meditation<br>• Using personal music to shift energy, mood, and support relaxation<br>• Closure | 45 min |
| 3 | *In-person or Zoom, individual session*<br>• Check In<br>• Mindfulness through active music making<br>• Debrief<br>• Discuss bringing mindfulness to daily activities<br>• Closure | 45 min |

| | | |
|---|---|---|
| 4 | *In-person or Zoom, individual session*<br>• Check In<br>• Mindfulness through active music making<br>• Debrief of experience<br>• Debrief of program<br>• Closure | 45 min |
| | Note: The content or order of the music therapy sessions may change based on your symptoms, the location of the music therapy session, instrument available or your preferences. | |

The music program intervention consists of four individual sessions (45 minutes) over twelve weeks. The purpose of the initial session is to introduce you to the goals of music-based meditation and how the use of music may promote relaxation during your cancer treatment. After the initial session, you will attend up to three more individual music sessions over the remainder of the twelve-week study period. A study team member will call you to schedule all sessions. If another participant is available at the same time and both participants are willing, you may be scheduled in a "group" session. During sessions 2, 3, and 4, the instructor will review the goals of music-based meditation and lead you in a hands-on music making activity (e.g., hand chimes, drumming). The instructor will close sessions 2, 3, and 4 by discussing ways to use music meditation principles in your daily life and cancer treatment (will receive educational materials). The instructor will encourage you to practice the music-based meditation strategies in between sessions. You will record your daily use of music-based meditation strategies using the Participant Music Meditation Use Log.

**After the final intervention:**
Research staff will collect data related to your cancer diagnosis and treatment.

Participants will have an opportunity to participate in a 45-minute semi-structured interview to tell us about their experience with the mindfulness-music therapy program. All interviews will be audio recorded and take place using Zoom or phone. Interview participation is optional.

## E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?
You will be in this research study for up to twelve weeks.

You may be taken off the research study for reasons such as:

- It is considered to be in your best interest
- The study procedures are found to be unsafe or ineffective
- There is any problem with following study procedures
- There are any problems with research funding
- Or for any other reason

If you are removed from the research study, the research Investigator will explain to you why you were removed.

In addition, you can stop participating in the research study at any time.

## F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. You may experience distress when answering the surveys or by participating in the music program. If you do, you can talk to your health care providers in the clinic, and they may refer you for special support, such as counseling. You can also contact the study principal investigator whose contact information is listed below.

You may also be concerned about the privacy of the information you report in this study. All information you provide to the study team will be stored in a locked file cabinet at Dana-Farber Cancer Institute. Only the doctor or nurse practitioner who provides care to you at Dana-Farber and the research team, will be able to see the information you report. All audio recordings will be stored in a secure online data-base and destroyed after three years when all the research is completed.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

## G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you. You may experience an improvement in anxiety or stress by participating in this study. We hope the information learned from this research study will provide more

information about how well music therapy works to improve anxiety and stress in adolescents and young adults receiving cancer treatment. If you indicate at the start of the study that you do not already have a subscription to a music streaming service (e.g., Apple Music, Google Play Music, Amazon Music, Spotify, etc.), you will receive a $10 iTunes gift card to purchase music to practice the meditation strategies if you attend the initial music therapy session.

## H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or Investigator.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are entitled.

## I. WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

However, you or your insurance company will be charged for other portions of your care during this research study that are considered standard care. You may be responsible for co-payments and deductibles that are standard for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Dana-Farber Cancer Institute: (617) 632-3455

You will be responsible for the following additional costs:

- Parking

## J. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments will be billed to your insurance company. You will be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

## K. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS.

The study team plans to publish the results of this research study and when we do, we may be asked to the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do research.

This trial may be registered on https://www.clinicaltrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify

you. At most, the website will include a summary of the results. You can search this website at any time.

## L. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

**Dana-Farber Cancer Institute**

- Robert Knoerl, PhD, RN, 617-632-6386

**24-hour contact:**
**Dana-Farber Cancer Institute:** Robert Knoerl, PhD, RN, 617-632-6386

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

## M. FUTURE USE OF DATA AND SPECIMENS

Your personal information collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information cannot be linked back to you. As a result, we will no longer be able to identify and destroy them.

Investigators, including investigators from collaborating institutions, can request this data for new research. Data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

## N. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

### 1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

### 2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug and its use in cancer; and,
- To better understand the diseases being studies and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

**3. Who will use or share protected health information about me?**

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

**4. With whom outside of DF/HCC may my protected health information be shared?**

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

**5. For how long will protected health information about me be used or shared with others?**

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

**6. Statement of privacy rights:**

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

## P. DOCUMENTATION OF ASSENT

**Signature of participant under age 18:** The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study. I can decide not to take part in this research study if I don't want to and nothing at all will happen if I decide I do not want to participate.

_____ _____
Signature of Participant Date

**To be completed by person obtaining assent:**

The assent discussion was initiated on _____ (date).

☐ The information was presented in age-appropriate terms. The minor:

- ☐ Agreed to take part in the study
- ☐ Did not agree to take part in the study

☐ An assent discussion was not initiated with the minor for the following reason(s):

- ☐ Minor is incapacitated
- ☐ Minor is under 10 years of age
- ☐ Other_____

_____

Signature of Individual obtaining assent: _____

Printed name of above: _____

Date: _____

## Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary, and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant



| | |
|---|---|
| DFCI Protocol Number: 18-341 | Approved Date (DFCI IRB Approval): 01/06/2021 |
| Date Posted for Use: 01/07/2021 | |

**To be completed by person obtaining consent:**

## Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

*The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.*

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

**To be completed by person obtaining consent:**

## Minor Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

☐ 1) The parent or legally authorized representative gave permission for the minor to participate.

☐ 1a) Parent or legally authorized representative is a non-English speaker and signed the translated Short Form in lieu of English consent document

*As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed name of Interpreter/Witness: _____

Date: _____

☐ 1b) Parent or legally authorized representative is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

*The consent form was presented to the parent or legally authorized representative who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.*

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 1c) The parent or legally authorized representative did not give permission for the minor to participate



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|---|---|
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