PRINCIPAL INVESTIGATOR: Staci Martin, Ph.D.

STUDY TITLE: Feasibility and Preliminary Efficacy of an Enhanced Mindfulness Intervention for Children and Young Adults with High Grade or High-Risk Cancer and Their Caregivers: A Pilot Randomized Controlled Trial

STUDY SITE: National Institutes of Health Clinical Center

Cohort: Caregiver

Consent Version: 12/13/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

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This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The primary purpose of this study is to learn whether a type of coping tool called mindfulness is feasible and acceptable for pediatric patients with high-grade or high-risk cancer and their caregivers.

Mindfulness is a practice that teaches people to focus on the present moment with an open mind. This study will see whether caregivers of children, adolescents and young adults with high-grade or high-risk cancer are able to carry out mindfulness practices during their child's cancer treatment and aims to learn more about what aspects of this intervention were helpful. This study will also assess whether mindfulness can help emotional and physical wellbeing of patients and their caregivers.

People cope with cancer in different ways. Some people may talk to family or friends, seek counseling with a mental health professional, or try to stay focused on things that feel good. There is no standard tool for coping however, and very little is known about what helps caregivers of children, adolescents and young adults with high-grade or high-risk cancer and their caregivers. In addition to evaluating whether mindfulness is feasible, we want to learn whether it helps people cope more than typical methods. As a result, in this study we will randomly assign participants to the mindfulness group or to a standard care coping group, which will be provided with information about coping in the context of cancer. You will have equal chance of being in the mindfulness group or standard care group.

Participants and their caregivers assigned to the mindfulness group will work with trainers who will teach them more about mindfulness and give them exercises to practice over an 8 week period.

The standard care group will receive an information sheet that includes tips and resources about coping in the context of cancer. After 8 weeks and up to a year, participants in the standard care group can opt to participate in the mindfulness intervention (this is optional).

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

Your child has been diagnosed with a high-grade or high-risk cancer and you indicated to a treatment team member that this study would be of interest to you.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We expect that about 40 participants will complete this study, including 20 caregivers and 20 patients.

DESCRIPTION OF RESEARCH STUDY

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS RESEARCH STUDY?

Before you begin the study

A member of your child's treatment team referred you to this study. To make sure you meet the requirements for taking part in this study we will talk to your child's medical doctor. We will also make sure you have access to the internet and equipment that will allow you to do the protocol activities.

During the study

Once you sign the consent document you will be asked to complete 10 questionnaires, which will take about 30-35 minutes to complete.

The questionnaires will collect information about the following areas:

1. Demographic questionnaires (basic information such as age, gender, profession, education, marital status, support network, etc.)
2. Emotional wellbeing (including mood, stress, anxiety, and self-compassion)
3. Physical wellbeing (including sleep, pain, and fatigue)
4. Quality of life (including things like friendships, school, activities, health)

5. Mindfulness (including how much you pay attention to the present moment, acceptance of difficult circumstances)

Also, we will ask you for permission to collect data from your child's medical record if you receive treatment at an outside institution. We will have them send us your child's records for review, so we can gather additional information about your child's medical condition.

Once you complete these questionnaires for the first time, we will have our Registration Office "randomize" your child to one of two groups:

1. Mindfulness Group or
2. Standard Care group

"Randomize" means to assign you to one of these two groups by chance, similar to flipping a coin. We cannot predict which group you will be assigned to. People who are randomize to the Standard of Care group will have the opportunity to later participate in the mindfulness program.

Once your child's group is known you will be placed in the same group.

Standard Care Group

Participants in the standard care group will receive information with general recommendations for coping with cancer. The information is designed to benefit both youth and caregivers and will be briefly reviewed with you by the research team following completion of the baseline questionnaires. Supportive check-in sessions lasting about 10 minutes each will be scheduled one-week and three-weeks after starting the protocol, during which any questions or concerns about coping or emotional wellbeing can be addressed.

Mindfulness Group

Within one week of completing baseline questionnaires, participants assigned to participate in the mindfulness intervention will attend an in-person training session with members of the research team ("mindfulness coaches"). The participant will meet with one member of the research team for an initial training session, while the parent participant will have a training session at the same time with the second member of the research team. The initial in-person session will last approximately 90 minutes, and we will teach you about mindfulness, practice mindfulness exercises, and discuss options for at-home practice. The parent and participant will come together for the final 20 to 30 minutes of the training session.

If you or your child does not have access to a device with audio and internet capability, an iPod can be loaned to you or your child for the duration of the intervention. The research team will provide you with a self-addressed pre-paid envelope in which to return the iPod at the end of the study, or it can be returned in-person if convenient.

After completing the in-person session, participants will be asked to practice mindfulness exercises four out of seven days per week, though daily practice is encouraged, for an 8-week period. Weekly text messages (or emails) will be sent to ask you how many days you practiced. One week and three weeks after the in-person session, participants will check in with their coach (either in-person or via video chat) to troubleshoot any difficulties and make adjustments to the practice routine. Check-ins will last approximately 30 minutes.

8-Week Follow-up

Everyone will be asked to complete follow-up questionnaires about 8 weeks after starting the study. This will include the same questionnaires completed at baseline, and for participants in the mindfulness group, it will include an additional survey assessing your impression of the program. Questionnaires should take about 35 minutes to complete.

If you are in the mindfulness group, you will be encouraged to continue using the mindfulness practices at home.

Participants in the "Standard Care" group will be offered the opportunity to enroll in the mindfulness intervention at this time point or at their next in-person visit to the NIH (as long as it falls within one year of starting the study). If participants elect to enroll in the intervention, they will follow the same procedures as described above.

16-Week Follow-up

Everyone will complete a final set of questionnaires from their home computer, tablet, or smartphone approximately sixteen weeks after baseline. This will be the end of your participation in this study. At this time, the study staff will be able to answer questions or can refer you to an appropriate provider in your community if you need further assistance coping or have concerns regarding your emotional wellbeing.

RISKS OR DISCOMFORTS OF PARTICIPATION

What side effects or risks can I expect from being in this study?

The time commitment for the in-person session and completion of the questionnaires is the primary burden of participation. In addition, some individuals experience stress related to talking about difficult things, such as their child's cancer diagnosis and treatment.

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The primary aim of this study is to see if mindfulness has potential as a coping tool for patients with similar health conditions. In addition, this study will examine whether there are any benefits to this type of intervention for patients with high-grade or high-risk cancer. We do not know if you will receive personal benefit from taking part in this study. The potential benefits could include reductions in stress, improved coping, and emotional wellbeing. We also hope that the knowledge gained from this study may help others in the future who have cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You have the option to not participate in this study. You may still participate in any other supportive therapies offered by NIH or elsewhere. If you choose not to participate, it will not affect your medical care or participation in any other research study at NIH.

STOPPING PARTICIPATION

The study doctor may decide to stop your therapy for the following reasons:

- you have completed the study follow-up period
- you are in in need of additional support due to a mental health condition
- if he/she believes that it is in your best interest

In this case, you will be informed of the reason therapy is being stopped.

You can stop taking part in this study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study investigator first.

PAYMENT

Will you receive any type of payment for taking part in this study?

- You and your child could be paid up to $60 for your time and effort. You will also receive a Mindfulness toolkit.

If you and your child are unable to finish the study, you and your parent/caregiver will receive $20 for each part you completed.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information .

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

COST

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

There are no costs associated with taking part in this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The St. Baldrick's Foundation who have provided us support through a grant.

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act

protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

USE OF DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from their data. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your data will be used for research purposes only and will not benefit you. It is also possible that the stored data may never be used. Results of research done on your data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored data used for future research, please contact us in writing and let us know that you do not want us to use your data. Then any data that have not already been used or shared will be destroyed and will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Staci Martin, Ph.D. martins@mail.nih.gov, 240-760-6025. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date