

**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: Assent 12 – 17 years old

Assent Version: 12/13/2021

**What is a research study?**

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about a research study that we are doing and the choice that you have to take part in it. You are being asked to join this research study because you have a high-grade or high-risk cancer.

**Important things to know...**

- You get to decide if you want to take part.
- You can say ‘No’, or you can say ‘Yes’.
- No one will be mad at you if you say ‘No’.
- If you say ‘Yes’, you can always change your mind and say ‘No’ later.
- You can say ‘No’ at any time.
- You will still be able to get good care from a doctor no matter what you decide.

**Why are we doing this research?**

We are doing this research to find out whether children, teenagers, and young adults with cancer can use a coping tool called “mindfulness” to help them handle stress during treatment. Mindfulness is a practice that teaches people to notice what is happening around them with an open mind. Children, teenagers, and young adults cope with cancer in different ways. Some people may talk to someone they trust (family, friends, or a counselor), or they try to stay focused on things that feel good. There is no standard tool for coping with a cancer diagnosis. We want to learn if young people can practice mindfulness while they are being treated for cancer, and if it helps.

**PATIENT IDENTIFICATION****Assent to Participate in a Clinical Research Study**

NIH-2977-1 (7-19)

File in Section 4: Protocol Consent (3)

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### What would happen if I join this research?

If you decide to be in this research, we would ask you to do the following:

- Questionnaires: We would ask you to read questions and then mark your answer. The questions will be about how you are feeling and your overall ability to participate in and enjoy life. You will complete answer these questions 3 times during the study (baseline, in about 8 weeks, and then about 4 months from now).

In this study, we will randomly assign you to one of two groups (kind of like flipping a coin):

- A mindfulness group *or*
- A 'Standard Care' group

You will have equal chance of being in the mindfulness group or standard care group and we do not know which group you will be in before you agree to be in the study.

### Mindfulness Group

If you are assigned to the mindfulness group, you and your parent/caregiver will each meet with a member of the research team to learn more about mindfulness. During this meeting, we will also ask you questions to learn more about how you are feeling and how you cope when you are worried or stressed. At the end of the first meeting, we will come back together with your parent/caregiver and do some mindfulness practices together.

If you do not have a device with audio and internet capability, you can borrow an iPod while you are in this study. The research team will provide you with an envelope in which to return the iPod at the end of the study, or it can be returned in-person.

As part of this study, we will give you some different mindfulness exercises – this includes things that you can listen to and art activities – that you can practice at home. We will ask you to practice a little bit each day for the next 8 weeks. We will check in with you about 1 week after starting the study to see how you are doing, either in person or by video chat on the computer. A couple weeks later, we will check in with you again.

### Standard Care Group

If you are put in the standard care group, you and your parent/caregiver will each meet with a member of the research team to talk about how you are feeling and how you handle difficult feelings like worry or sadness. Also, we will give you and your parent/caregiver a paper with general information about coping with cancer. About a week later, we will check in with you and your parent/caregiver to see how you are doing. We will check in a second time about two weeks after that.

**8-Week Follow-up**

Everyone will be asked to complete more questionnaires about 8 weeks after starting the study. This will include the same questionnaires you completed at the start of the study. If you are in the mindfulness group, we will also ask you to fill out a survey about the study in order to understand what parts you liked or did not like.

After 8 weeks in the Standard Care group, participants and their parent/caregiver will be asked if they would like to participate in the mindfulness program. If you and your parent/caregiver decide to do this, we would do things the same way as described above. We will set-up a time to do the mindfulness training within one year of your first appointment for this study.

**16-Week Follow-up**

Everyone will complete a last set of questionnaires from their home computer, tablet, or smartphone about 16 weeks after baseline.

**Could bad things happen if I join this research?**

You might find it difficult or boring to fill out the questionnaires. In addition, some people find it difficult to talk about their feelings or cancer. Other people do not find these things difficult.

**Could the research help me?**

People may have good things happen to them when they are in research studies. The good things may be that doing mindfulness helps you cope during this time.

**What else should I know about this research?**

If you don't want to be in the study, you don't have to be.

It is also OK to say 'yes' and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.

To thank you for being in the study, we will give you \$20 (up to \$60 total) for each set of questionnaires. You should talk with your parents about how you would like to use this.

**What if I have any questions?**

You can ask questions any time. You can talk to Staci Martin (240-760-6040). Ask us any questions you have. Take the time you need to make your choice.

**Is there anything else?**

If you want to be in the research study after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

**Assent of Participant:**

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Signature of Participant

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Print Name of Participant

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Date**Investigator:**

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Signature of Investigator

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Print Name of Investigator

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Date