INSTITUTE: National Cancer Institute

STUDY NUMBER: 15-C-0142 PRINCIPAL INVESTIGATOR: Staci Martin Peron, PhD

STUDY TITLE: Acceptance Commitment Training for Adolescents and Adults with Neurofibromatosis Type 1, Plexiform Neurofibromas, and Chronic Pain: A Phase III Clinical Trial

Continuing Review Approved by the IRB on 03/13/19
Amendment Approved by the IRB on 03/05/19 (F) Date posted to web: 03/19/19
Assent

We would like to invite you to take part in a research study at the National Institutes of Health (NIH). Before you decide about taking part in the study, we want you to know why we are doing the study and if it will help you. We also want you to know about any risks (what might go wrong) and what you will have to do. You can only be in the study if you and your parent(s) agree.

This form gives you information about the study. Your doctor will talk to you about the study and answer questions you have. If you would like to take part in this study, we will ask you to sign this form to show that you understand this study. We will give you a copy of this form to keep. It is important that you know:

- You do not have to join the study.
- You may change your mind and drop out of the study at any time.

If we make important changes to the study we will tell you about it and make sure you still want to be in the study.

Why is this study being done?

You are eligible for this study because you have neurofibromatosis type I (also called NF1) and at least one plexiform neurofibroma (PN) tumor. NF1 can cause pain that is very hard to control and may last for a long time (chronic pain). The purpose of this study is to test a strategy for helping people cope with chronic pain. That strategy is called Acceptance and Commitment Training (ACT). ACT is a type of therapy that focuses on things like values (who and what is important to you) and living in the present moment. One common way people now use to control chronic pain include medications, but sometimes these do not work very well and might cause side effects. Because we want to see if ACT is a better way to deal with pain, we will divide people in this study into two groups: 1. People who get the ACT training immediately, OR 2. People who get the ACT training after 8 weeks of doing what they usually do to treat their pain. We will 'randomly' put people into one of the two groups using a computer. We can't predict which group you will be in before you agree to be in the study.

What will I be asked to do? What are the requirements?

When you start this study, we will ask you to fill out several questionnaires about your pain and your feelings, and we will check your heart rate. You will do these things again after 8 weeks, and finally everyone will complete a final set of questionnaires from their home computer 6 months after the ACT training intervention is completed.

Everyone will continue their current pain medications if they take any. The questionnaires will collect information about the following areas:

1. Demographic questionnaire (basic information about demographic and educational history).
2. Pain interference, or how much pain interferes with your daily activities;
3. Quality of life (including energy level, appetite, mood, school attendance and how you get along with friends);
4. Functional abilities (including how the pain affects your everyday activities);
5. Chronic pain acceptance (including how you cope with your pain);
6. Mood (including your enjoyment of life, problems sleeping, feelings of depression, anxiety);
7. Pain severity (how much pain you feel); and
8. Pain Management (what things you do now to cope with your pain)

We will ask you to read some words as a quick task of reading ability. Also, everyone will have an electrocardiogram (ECG) to check heart rate, since heart rate is related to how we react to pain and stress. This test is not painful. You will be asked to lay down and remain still for a few minutes and small sticky pads will be put on your chest and arms and legs. This test takes about 5 minutes.

If you are in the immediate ACT intervention group, you will have two sessions with an ACT trainer after the first set of questionnaires. We will teach you techniques for setting goals based on your personal values, and work to change your relationship with your pain. In other words, instead of fighting against your pain, we will talk about how to do the things that matter most to you, even while you have pain. You will do practice exercises between the sessions. At the end of the training you will get a workbook with more exercises so you can continue to practice them at home. For the "at-home" part of the training, you will receive weekly e-mails on different topics with a practice exercise each week and will be asked to join a biweekly Skype session from your home computer with your trainer for about 30 minutes each session. You will be encouraged to spend at least 10 minutes per day on these practice exercises.

If you are in the 'Wait-List' group, you will not attend the ACT Training right away. You will return home for two months and keep doing what you usually do to deal with your pain.

Everyone will be asked to return to NIH at about 8 weeks after starting the study. At this study visit, you will be asked to complete the questionnaires again and have a second ECG. These questionnaires should take you less than 45 minutes to complete.

At this second NIH visit, people in the 'Wait-List' group will attend the ACT Training, and then will return home for the "at-home" part of the training, which includes the email exercise and Skype sessions as described for the first group. After 8 weeks of practicing the ACT exercises, participants in the 'Wait-List' group will return to NIH to complete the questionnaires and ECG again.

Everyone will complete a final set of questionnaires from their home computer six months after the formal intervention ends. We will be providing you with $30, via direct deposit or check, each time you complete a set of questionnaires to thank you for your time. That will be the end of your participation in this study. At this time, the study staff will be available to answer questions or can help you if you need further assistance in managing the symptoms of NF1. Sometimes things that aren't good happen in research studies.

The time you spend completing the questionnaires and attending the workshop is the primary burden in this study.

What benefit can I expect?

People may also have good things happen to them when they are in research studies. We do not know if this study will help you but you may be experience an improvement in your ability to cope with your pain and in your overall quality of life. We hope the information that we learn from this study will help us learn more about ways to help other people with NF1 cope with their chronic pain.

Can I refuse to be in the study?

Please talk to your parents about this before you decide whether or not to be in this research study. We will also ask your parents to give their permission for you to be in this study. But even if your parents say "yes," you can still decide not to be in this research study.

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

You may stop being in this any time

Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop.

Consenting

Once you have turned 18, we will contact you to find out if you would still like to participate in the study.

You can ask any questions that you have about the study.

If you have a question later that you didn't think of now, you can call me 240-760-6025 or ask me next time

Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient:_____ Date:_____

Print Name:_____

Signature of Investigator:_____ Date:_____

Print Name:_____