INSTITUTE: National Cancer Institute

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

STUDY TITLE: Acceptance and 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

Screening

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary**.**

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, 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). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

If you are signing for a minor child, "you" refers to "your child" throughout the consent document.

Why is this study being done?

The primary purpose of this study is to test whether a newer type of therapy, called Acceptance and Commitment Therapy (ACT), can help people with neurofibromatosis 1 (also called NF1) cope better with the pain associated with NF1. This study will see whether participating in an intervention based on a variety of ACT techniques improves pain and coping in patients with

NF1 pain 8 weeks after the ACT intervention. We will also be looking at its effects on the parents of children with NF1.

In order to be eligible for this study, you must meet specific criteria, including:

- Be 16 through 59 years of age
- Have been diagnosed with NF1 and have one or more plexiform neurofibromas (PN)
- Have regular, private access to a computer and be able to read and understand English
- Be able to travel to the NIH for the pre-study and 2 follow-up evaluations
- Have a level of pain that interferes with your daily functioning, as determined by your responses to questions we will ask you from the 6-item Pain Interference Index
- Have pain that interferes with functioning for at least the past 3 months.

If it appears from the information you have provided us that you may be eligible for this study, you will need to come to the NIH to complete following screening procedures so we can confirm your eligibility. When you come to NIH you will have the following procedures to confirm you are eligible for this study.

1. Physical exam with height and weight, and a medical history done by an NIH doctor or nurse practitioner (if you are enrolled on Dr. Widemann's study 08-C-0079 [Natural History Study and Longitudinal Assessment of Children, Adolescents, and Adults with Neurofibromatosis Type 1] and had a physical exam in the past 4 weeks, this does not need to be repeated).
2. Answer questions about your pain, which will take about 5 minutes.

If these tests and questions show that you meet the criteria to participate in this study, you will be asked to read the consent for study participation. If you agree to participate in the study, you will be randomly assigned to the Acceptance and Commitment Therapy (ACT) group OR to a 'wait-list' group. You will come to the NIH for 1-2 days of study tests and procedures. The ACT group will receive the ACT intervention immediately while the 'wait-list' group will receive the usual methods of treating pain for 8 weeks. After 8 weeks, everyone will return to NIH for evaluations. At that time the 'wait-list' group will receive the ACT intervention.

In this study, we will use a series of questionnaires and a heart test, called electrocardiogram (ECG) to assess pain and coping before starting the ACT intervention and then 8 weeks after starting the program to see if there is a change in coping with the chronic pain of NF1. We also will look at any recent MRI scans of your plexiform neurofibroma, if available, so that we can see how the location of the tumor may impact the effectiveness of the intervention; this is an optional part of the study. Everyone will complete a series of final questionnaires from their home computer 6 months after the formal ACT intervention is completed.

Why are you being asked to take part in this study?

You have been diagnosed with NF1 and have had chronic pain that may be interfering with your day to day activities.

How many people will take part in this study?

We expect 82-90 people with NF1 will participate in this intervention study.

Risks or Discomforts of Participation

There are no risks, other than the time and inconvenience it takes to come to answer the phone questions and if you are thought to be eligible, the time and inconvenience it takes to come to NIH for a day to do the physical exam and screening questions to complete the screening process.

Potential Benefits of Participation

Are there benefits to taking part in this study?

There are no benefits to you for doing this screening. If you choose not to have the screening done, we will not be able to enroll you in the ACT program for chronic pain.

Compensation

We will be providing you with $30, via direct deposit or check, each time you complete a set of questionnaires (baseline or follow-up) to thank you for your time.

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 support therapies offered by NIH. If you choose not to participate, it will not affect your medical care or participation in any other research study at NIH.

Research Subject's Rights

What are the costs of taking part in this study?

If you choose to take part in the screening, the following will apply, in keeping with the NIH policy:

You will receive screening exams and tests at no charge to you. We will also cover the costs of travel and some meals during your visits. Further, the study will provide the standard government reimbursement for travel costs, and external grant funding will cover additional travel and meal costs not covered by the government.

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 National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), which are involved in overseeing research.
- National Institutes of Health Intramural Institutional Review Board

A description of this clinical trial will be available on http://www.Clinicaltrials.gov, as required by U.S. Law. 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.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by the NIH; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to this disclosure;
- is for other research.

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

OTHER PERTINENT INFORMATION

1. Confidentiality. 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.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The 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 National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. 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 Peron Ph.D., Building 82, Room 107, Telephone: 240-760-6025; or Pam Wolters, Ph.D. at 240-760-6035; or Brigitte Widemann, MD at 240-760-6203. You may also call the Clinical Center Patient Representative at 301-496-2626.

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

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/ Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.

(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/ Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM MARCH 13, 2019 THROUGH MARCH 28, 2020.

Signature of Investigator _____ Date _____ Signature of Witness _____ Date _____

Print Name _____ Print Name _____