



**STUDY TITLE: Retuning the Nervous System in Youth with Chronic Pain
*Patient Consent Form***

**FUNDING ORGANIZATION: Cincinnati Children's Hospital Medical Center
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Phone number: 513.636.9384**

INTRODUCTION

We are asking you to be in a research study so that we can learn new information that may help others. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

The purpose of this research study is to learn more about how attention can change the way that the brain processes pain. We are interested in chronic pain, which means pain that has been there for a long time. Many people with chronic pain feel that the pain can spread away from the injury, or they can have pain in many different body areas. We want to find out if we can train attention. We want to know if focusing attention on the body can shrink the spread of pain and make pain less intense/strong. The results of this study may help us develop new ways of treating chronic pain in the future.

We are asking you and other people to be in this study because you have chronic pain. We are looking for up to 50 youth with chronic pain and 30 youth who do not have chronic pain.

WHO IS IN CHARGE OF THIS RESEARCH?

Robert Coghill, Ph.D. is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study. This study is paid for by Cincinnati Children's Hospital Medical Center.

WHO SHOULD BE IN THIS STUDY

You can be in this part of the study if you have chronic pain and are between the ages of 10 and 17.

WHO SHOULD NOT BE IN THIS STUDY

You should not be in this study if you have mostly pain in your belly, have developmental delays, or other conditions that will make it hard for you to tell us about sensations from your body.

WHAT WILL HAPPEN IN THIS STUDY?

You will first be randomly (like the flip of a coin) assigned to one of two different attention training groups. Both groups will receive training in focusing their attention on parts of their body. However, one group will receive two-point discrimination training (described below) while the other group will receive training to tell the difference between different objects placed on the skin. Both types of attention training have the potential to make chronic pain better. However, we do not know yet if one type of attention training will be better than the other.

This study may have up to 10 visits. It will start with a baseline visit, then there are up to 8 training visits, and then a completion visit. Each visit will be on separate days. Your parent/guardian will need to be with you for the baseline visit to fill out some of the forms before the study tests begin. During all visits, you will be required to turn your cell phone off and to not have any family/friends in the room

during testing. Also, your parent/guardian will be shown the areas where study tests will occur before the tests are started.

Baseline Visit

After you sign the consent form, you will fill out a series of forms that ask about you, your chronic pain, your personality and your feelings. We may also take a photo, so that you can use this photo to mark out where your pain is in your own body. You may also use a diagram to mark out your pain.

We will see how well your nervous system processes touch by testing tactile discrimination. Firstly, two-point discrimination lets us measure how well you can tell the difference between being touched in two places on your skin from being touched in one place. To do this, we use a caliper, a special tool that makes it easy for us to measure how far apart the two points on your body need to be before you can feel them as two separate points instead of one point. We will have you close your eyes, and then we touch the skin gently with the caliper. You will then tell us if you felt two points or one point. Secondly, one-point discrimination involves you identifying different objects placed on your skin. We will test several body sites including places far away from where you have pain, places near to where you have pain, and on the area where you have pain. At any time, if you find this uncomfortable, we can stop the testing.

After you finish these initial tests, you will start attention training. This will consist of up to 1 hour of practice learning how to focus your attention on different parts of your body to more accurately feel touch sensations.

Training Visits

Each training visit will last no more than 1 hour. There will be up to 8 training visits. Again, if the training is making your pain worse we can stop testing in the painful area, or we can stop the training if you choose.

Completion Visit

You will have up to 1 hour of training as before. You will then do a final set of tactile discrimination testing, and complete forms about your chronic pain, personality and feelings again. We will use the photo/diagram again at this point, to see if the location of your pain is any different. This visit will last no more than 2 hours.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for up to 10 visits between 2 to 5 weeks. You can stop participating at any time. If you decide to stop participating in the study, there are no potential health or safety consequences.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Although you are not expected to receive any direct benefit from taking part in this research study, there is a potential that one or both forms of attention training can make your pain get better. We hope the information learned from this study will help other people in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures and information we are studying include:

Questionnaires

You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You do not need to answer any questions that you do not wish to answer and you can stop the testing at any time. If you become very upset during the testing at any time, we will end the testing. We will also offer to have you speak to someone about what you are feeling. Rarely, these questionnaires can reveal psychological problems that would put you at risk for hurting yourself. If this is the case, we will refer you to a clinical psychologist for a full clinical evaluation and/or treatment.

Sensory Testing and Attention Training

The touch stimuli are gentle and do not cause pain on healthy parts of your body. However, when they are put onto body regions where you have chronic pain, they may hurt or make your chronic pain worse for a short period of time, much like when your clothes touch that part of your body. You can tell us to stop the testing at any time, and we can skip the body regions where you have chronic pain until you feel ready.

The attention training may make you tired because you have to work hard to focus on your body.

Confidentiality

Taking part in this research study may involve providing information that you consider confidential or private. However, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. We will code research records, keep research records secure, and allow only authorized people to have access to research records. If we use a photo, we will not use it for any other purpose than for this study, so only study personnel will be able to see the image.

Other Risks

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

WHAT OTHER CHOICES ARE THERE?

At any time, instead of being in this study, you can choose not to be in it. At any time, if the study team thinks it is not good for you to be in this study we will end your participation.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. Any records with your name or other identifying information will be securely stored in locked file cabinets or on password protected, encrypted computers.

Once we start to analyze the data, we will remove your name and other identifiers from all data and replace it with a code. The link between this code and your name will be kept in a locked file only accessible to study personnel and, if requested, regulatory personnel from CCHMC or other regulatory agencies.

Anytime that we talk about the data in presentations or scientific papers, we will not present any information that could identify you. You can choose to opt-out at any time if you would not like your de-identified data to be used in future.



WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be paid for your time, effort and travel while you are in this research study. You will be paid \$30 for the baseline visit, \$20 for each of the training visits, and \$30 for the completion visit.

You will receive payment for this study in the form of a reloadable debit card. We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay you. You will need to complete a Federal W-9 form for income tax reporting. This form requires your Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address. Information collected for this research may result in the development of a product that could be patented/licensed and sold. You will not be paid if this happens.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you have been injured as a result of this research you should contact Dr. **Robert Coghill** as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form. CCHMC follows a policy of making all decisions about compensation on an individual basis regarding the medical treatment of physical injuries that happened during or were caused by research.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the principal investigator listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your “protected health information” (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records



The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging studies (like CT scans, MRI scans, x-rays, etc.) and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Since this study involves the creation or maintenance of a research database repository, this permission will not expire.

Will your other medical care be impacted?

By signing this document you agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.



SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below. You will receive a copy of this signed document for your records.

Printed Name of Research Participant

Signature of Research Participant
Indicating Consent or Assent

Date, Time

Signature of Parent or Legally Authorized
Representative*

Date, Time

* If signed by a legally authorized representative, a description of such representative's authority must be provided

Signature of Individual Obtaining Consent

Date, Time