Title: Home-Based Intervention for Chronic Pain in Adults with Sickle Cell Disease

NCT# NCT04906707

Date: 12/06/2023

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 40 people who are being studied at Emory.

Why is this study being done?

This study is being done to learn about your chronic pain experience and evaluate a pain management program. You are being asked to be in this research study because you are an adult who has sickle cell and chronic pain.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for approximately 12 weeks in total (8-week program at home and follow-up at 12 weeks) with 3 possible in person or remote study visits. The researchers will ask you to do the following: complete questionnaires throughout the 12-week period, use a pain management program at home for 8 weeks along with completing an electronic pain diary daily, and participate in an interview (in person or remotely). All of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. This study may or may not help you directly.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The pain management program that is being evaluated may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include a risk of experiencing symptoms of cybersickness or digital motion sickness (which may include dizziness, lightheadedness, issues with balance, nausea, and/or vomiting) that are sometimes associated with virtual reality, loss of privacy, and breach of

confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you are at risk of experiencing symptoms of cybersickness or digital motion sickness, then you may be selected to use another pain management program. In addition, you can choose not to participate in the study.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Home-Based Intervention for Chronic Pain in Adults with Sickle Cell Disease

IRB #: STUDY00002004

Principal Investigator: Nadine Matthie, PhD, RN, CNL
Emory University, Nell Hodgson Woodruff School of Nursing

Study-Supporter: Federal/National Institutes of Health

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to learn about your chronic pain experience and evaluate a home-based, pain self-management program for chronic pain in Black adults with sickle cell.

What will I be asked to do?

Your participation in the study will involve completing questionnaires, using a pain management program at home for 8 weeks along with completing an electronic pain diary daily, and participating in an interview (in person or remotely). You will participate for approximately 12 weeks in total (8-week program at home and follow-up at 12 weeks) with 3 possible in person or remote study visits. We estimate that it may take approximately 45 minutes or less at each time point for the questionnaires, 2 hours weekly for 8 weeks to use one of the two pain management programs to which you will be randomly assigned (by drawing numbers), and 1 hour for the interview. To evaluate your eligibility for the pain management program, you will be asked some screening questions about any issues you've had or may have related to cybersickness or digital motion sickness. In the interview, you will be asked about your experience while using the pain management program, your chronic pain experience, and your preferences for future strategies to help you cope with

your pain. The interview will be conducted in person or remotely. All of the information will be collected during these sessions, by reviewing your medical records, and there may be a follow-up telephone call if we have any additional questions.

Who owns my study information?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may still be used for this study as we try to understand pain in individuals with sickle cell and develop interventions. If you would like us to discontinue use of your data after you withdraw from the study, then please contact the principal investigator, at the mailing address provided, with your written request. Once we receive your written request, your data will be destroyed.

What are the possible risks and discomforts?

This study will focus on your pain experiences. The study involves a low probability of risk, if any.

The most common risks and discomforts expected in this study are:
Exposure to virtual reality may result in an infrequent physical risk of cybersickness or digital motion sickness. We will ask you screening questions to find out if you have had or may have any of these issues. If so, then you will not be considered eligible for exposure to virtual reality only. If you are considered eligible for exposure to virtual reality, then you will complete a questionnaire just before the experience to make sure that you are feeling well. Each week, we will also contact you with a telephone call or text message to monitor for any symptoms while you are using the program at home and will stop the experience as needed. If you experience symptoms, then you can also stop using the program at any time. All participants will have the ability to withdraw from the study at any time.

Rare but possible risks include:
Additional rare but possible risks include that you may be uncomfortable answering some of the study questions. You can choose not to answer any questions at any time. There may also be potential social risks if there is a breach of confidentiality. A breach may result in being perceived negatively by healthcare providers, family members, or employers. Economic consequences may also arise if there is a breach because you may feel the need to choose an alternate healthcare provider and this provider may be in another county or state. In that case, you may incur costs for transportation to and/or care provided by the alternate healthcare provider. We will take steps to ensure your safety and that there is no breach of confidentiality. You should also report any problems to the principal investigator.

There may be side effects from the study program or procedures that are not known at this time. It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

If you are a woman: to protect against possible side effects, women who are pregnant or nursing a child will not participate in exposure to virtual reality. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will not be exposed to virtual reality.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your pain may improve while you are in this study, but it may not, and it may even get worse. This study is designed to learn more about the chronic pain experience of adults with sickle cell and identify strategies that can be used to help adults with sickle cell better cope with their pain. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

To compensate you for your time and effort, you will get a $_50 gift card after completing the initial study questionnaires, a $_50 gift card after each 4-week study period and completing the electronic pain diary daily ($150 in total), and a $_50 gift card after completing the interview. If you do not finish any portion of the study, then we will compensate you for the portion(s) you have completed. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, your medical care will not be affected. You do not have to be in this study to be treated for sickle cell.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before

your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial pain management program) that could be sold by a company. You will not receive money from the sale of any such product.

No results returned to participants

In general, we will not give you any individual results from the study of the data you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include data from the questionnaires, the interviews, and the use of the pain management program at home.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this research, you should contact Dr. Nadine Matthie at (404) 712-8449 or nadine.matthie@emory.edu. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Neither Emory, Grady Health System nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There are no costs, research or standard of care related, associated with the study.
There will be no costs to you for participating in this study, other than basic expenses like transportation, if necessary. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- If you experience any symptoms of cybersickness or digital motion sickness (such as dizziness, lightheadedness, issues with balance, nausea, and/or vomiting) during or after exposure to virtual reality.
- If you experience severe mentaldistress.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/pastmedications.
- Results of exams, procedures, and tests you have before and during thestudy.
- Laboratory test results.

Purposes for Which Your PHI will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study-related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory and Grady Health System may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- ___The National Institutes of Health____is the Supporter of the study. The Supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Supporter may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research, including the Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:
Nadine Matthie, PhD, RN, CNL
Emory University, Nell Hodgson Woodruff School of Nursing
[redacted]
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy

Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Nadine Matthie at [redacted]

- If you have any questions about this study or your part in it,
- If you feel you have had a research-related injury or an adverse reaction to study procedures,or
- If you have questions, or concerns about the research

Contact the Emory Institutional Review Board at [redacted]

- If you have questions about your rights as a research participant.
- If you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration [redacted]

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and ableto consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent(IC) Discussion

Date/Time when IC discussion tookplace

Signature of Person Conducting Informed Consent Discussion

Date/Time when IC was signed

Name of Person Conducting Verbal InformedConsent (VIC) Discussion

Date/Time when VIC discussion took place

Signature of Person Conducting Verbal InformedConsent (VIC) Discussion

Date/Time when VIC was provided