University of Illinois at Chicago (UIC) and/or
University of Illinois Hospital & Health Sciences System (UI Health)
Research Information and Consent, and Authorization for Participation in Biomedical Research

Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain (GRACE)

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Sponsor: National Institutes of Health (NIH)

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are an adult living with chronic pain associated with sickle cell disease.

366 subjects will be enrolled in this research study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to evaluate two different approaches to managing chronic pain, acupuncture and guided relaxation, in patients who have sickle cell disease. Your physician has considered treatment options for your chronic pain associated with your sickle cell disease. Participation in this study and receipt of this experimental intervention is one of your treatment options.
WHAT WILL I BE	You will be asked to complete a demographic questionnaire,

ASKED TO DO DURING THE STUDY?	followed by questionnaires regarding your levels of pain and quality of life. You will be randomly assigned (like flipping a coin) into a group that receives acupuncture treatment, guided relaxation, or neither of these. You will be asked to complete surveys online or over the phone about your level of pain and quality of life again at 6 weeks, 12 weeks and 24 weeks after you enroll in the study. For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The demographic questionnaire will take approximately 5 minutes, and the total time estimated to complete all online questionnaires will be 45 minutes. The online questionnaires will require approximately 30 minutes. Your responses to these questions will be included in your medical record, and these may or may not be reviewed by your treating physician. *Acupuncture group:* If you are randomized into the group that receives acupuncture treatment: • You will attend 2 treatments per week for 5 weeks, a total of 10 study sessions. • During each session, needles will be inserted at 15 points on the body and will be left in for 30 minutes. *Guided relaxation group:* If you are randomized to the guided relaxation group, • You will go through the process of guided relaxation every day for 6 weeks, which take between 2-20 minutes per day. We cannot promise any benefits to you or others from your taking part in this research. If you are in the group that gets study treatment, this may work better than the standard treatment for your condition.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Being in this research study may not benefit you directly, but it is possible that the use of acupuncture and/or guided relaxation may turn out to be more effective than your current pain regimen alone.

WHAT ARE THE MAIN RISKS OF THE STUDY?	The primary risks presented by this research study are breaches of privacy (others outside of the study may find out you are a subject) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you during the study). Additional risks are: *Acupuncture Group* • The likely risks and discomforts expected in this study are minimal and include slight bleeding or bruising after an acupuncture needle is withdrawn. • Rare but serious risks include passing out after needles are inserted. • There is the risk of loss of privacy or confidentiality, but we will avoid this risk and all risks as much as possible. *Guided Relaxation Group* • Participants may have an emotional response because of thoughts or emotions that arise during guided relaxation. You may be uncomfortable with some of the questions you may be asked. This research includes some items about mental health and pain. You can skip and/or not respond to any questions that may make you uncomfortable. For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study. This is not a treatment study. Your alternative is not to participate in this study**.**
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Ardith Doorenbos at 312-996-2817 or email at ardith@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects

	(OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

What procedures are involved?

This research will be performed at the UIC College of Nursing.

Once you enroll in this study, you will be randomized into a group that continues with your current care for pain associated with sickle cell disease, a group that will receive acupuncture in addition to current care, or a group that uses guided relaxation in addition to current care.

If you are in the Acupuncture group, you will be asked to go to the UIC College of Nursing twice a week for 5 weeks (10 sessions total). Each session takes about 1 hour.

If you are in the Guided Relaxation group, you will be asked to use guided relaxation every day for 6 weeks. Each session of guided relaxation takes between 2-20 minutes.

At 6 weeks, if your pain is not improving, you will be randomized again and either continue with the same therapy or switch to the other.

All participants will answer questionnaires at the first study visit and then 6 weeks, 12 weeks and 24 weeks after.

During this study, Dr. Ardith Doorenbos and her research team will collect information about you for the purposes of this research. This information includes:

- Demographic information
- Intensity of pain
- Sleep duration
- Quality of life
- Opioid usage
- Constipation
- Hospitalizations

What will happen with my information used in this study?

Your information collected for this study may be used for future research studies and/or shared with other researchers in the future. If this happens, information which could identify you will

be removed before any information is shared. Once the identifying information is removed, the information cannot be withdrawn from further use. You will not be asked for additional consent.

Will I receive the results (including any psychological, health, and/or biospecimen results) from the study?

We will not share results of the study with you.

What are the potential risks and discomforts of the study?

During the study participants will be asked to answer questions about sensitive topics that may be upsetting, such as your level of pain, substance use and quality of life. The research team will help in identifying additional care, if needed. You can refuse to answer any questions for any reason without negative consequences.

Acupuncture

The risks from acupuncture needle insertions include

- Soreness
- minor bleeding
- bruising after acupuncture needle removal
- fatigue after acupuncture
- rare but serious risks include passing out after needles are inserted.

Patients will be encouraged to rest if necessary and will be provided with a light snack or juice following the acupuncture session.

Guided relaxation

Participants may have an emotional response because of thoughts or emotions that arise during guided relaxation. In anticipation of this possibility, we will provide local referrals to mental health providers as needed.

There may be risks from the study that are not known at this time.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.

- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health.

A possible risk of the study is that your participation in the study or information about you might become known to individuals outside the study. Your personal information and survey responses will be stored on a password-protected, HIPAA-approved data-hosting site to prevent access by unauthorized personnel.

Your individual data that is not entered into your electronic medical record will be stripped of identifying after data analysis is complete.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

Please remember that there is an exception to protecting subject privacy and confidentiality if child, elder, and/or disabled adult abuse or neglect of an identifiable individual, or the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities.

The research data will be collected electronically using a laptop, tablet computers, and other smart devices. All the study surveys may be completed online using an application developed for this study. For subjects randomized to the Guided Relaxation arm, this data will also contain information from PAIN*Report*It, a computer program developed by Dr. Wilkie at the University of Florida to collect subjects' pain information, as well as the other surveys in electronic format. Subjects' data will be written directly to that server and will not reside, even temporarily, on the laptop, tablet computer, or smart devices. HTTPS will be used for data transfer to the College of Nursing server and the transfer from the tablet to the server is encrypted. The application for the data transfer will be located in a secure College of Nursing server with restricted access, with access only to the immediate study personnel.

Participants will be given the URL to the guided relaxation program. The study personnel will provide guidance to participants for creating username and strong password; study personnel will not create usernames and passwords for participants unless the participant needs assistance. Participants can use the login information to access the secure study website just as they would any secure website such as bank accounts.

All participants will be assigned a study ID number and their data will be identified only with that code number. The link of the code numbers to the subject identifiers will be kept separate from the study data. Only the investigators and key personnel will have access to the code/master key.

For added security, your information will be protected by a federal Certificate of Confidentiality. This Certificate means that information the researchers have promised to protect cannot be

obtained from the researchers by any means, legal or otherwise. The Certificate does not stop you or a family member from disclosing or agreeing, in writing, to allow the researchers to disclose this information. The only exceptions to the Certificate are to (1) report de-identified statistical data to the federal government (e.g., National Archive of Criminal Justice Data) for auditing and evaluation purposes; (2) if child, elder, and/or disabled adult abuse or neglect, or the threat of imminent self-harm or harm to others is disclosed, the researchers may inform the appropriate authorities; and/or (3) to report a communicable disease (such as tuberculosis (TB) or HIV/AIDS) to public health officials.

A description of this study 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 are the costs for participating in this research study?
There are no costs to you for participating in this research study.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?
You will receive $20 for completing your first study visit, $20 for completing your follow up at 6 weeks, $20 for completing your 12 week follow up, and $40 for completing your 24 week follow up. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $100. You will receive your payment within approximately 30 days after each study visit. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Participants who are randomized to acupuncture will be given $10 in addition at each appointment to offset the cost of traveling for the acupuncture sessions.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.

The researchers and/or the NIH also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

If you choose to no longer be in the study and you do not want any of your future information to be used, you must inform the researchers in writing at the address on the first page. The

researchers may use your information that was collected prior to your written notice.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Ardith Doorenbos and her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record. If you receive medical care from other institutions and you have agreed to share your medical record information through EPIC Care Everywhere (as described further in the UI Health Notice of Privacy Practices), the information from the other institution(s) may be used in the research. The specific information includes:

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (e.g., race, ethnicity, financial information)
- Results of physical examinations
- Medical history
- Results from hemoglobin electrophoresis blood tests
- Certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Prescription opioid use

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, NIH, as required to conduct the research and/or confirm the results of the research.
- With non-UIC collaborators of the research study:
  - Miriam Ezenwa, University of Florida College of Nursing
  - Nimish Shah, Duke University College of Medicine
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws.

Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

How will your health information be protected?

The researchers and the NIH agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study does not have an expiration date but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:

Dr. Ardith Doorenbos
845 S. Damen Ave.
MC 802
Chicago, IL 60612

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of this form.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent