Informed Consent Form

TITLE: Integrative Training Program for Pediatric Sickle Cell Pain (I-STRONG for SCD): Optimizing Feasibility and Acceptability

NCT NUMBER: NCT06110754

IRB APPROVAL DATE: October 13, 2023

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RESEARCH SUBJECT CONSENT FORM

TITLE: Integrative Training Program for Pediatric Sickle Cell Pain (I-STRONG for SCD): Optimizing Feasibility and Acceptability

PROTOCOL NO.: None
WCG IRB Protocol #20225098
STUDY00005410

SPONSOR: National Institutes of Health, National Center for Complementary and Integrative Health

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STUDY-RELATED PHONE NUMBER(S): [redacted]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or believe you have experienced a research-related problem, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last 5 months.

Why is this research being done?

The purpose of this research is to answer the question: how can we improve a group training program tailored specifically for teens with chronic sickle cell disease (SCD) pain that teaches skills to strengthen the mind and body to improve everyday functioning and reduce pain symptoms? You are being asked to be in this research study because you are a teen or parent of a teen with frequent pain and this training may improve your physical and emotional health. The program will be tailored to address challenges related to frequent or chronic sickle cell pain.

The program, called I-STRONG for SCD (Integrative Strong Body and Mind Training for Sickle Cell Disease), may help improve everyday functioning and pain symptoms in teens with chronic pain related to SCD. Our goal is to find out how teens and parents (or "Participants") respond to this program and get feedback about how we can continue to modify it to best fit their needs.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include:

Baseline Study Visit: You and your teen will complete several surveys at a baseline visit. Teens will also complete a brief walk evaluation. Teens will complete a brief daily pain diary and wear an activity monitor for 7 days.

Group Treatment Sessions: Treatment sessions will be conducted by telehealth. Each group session will last about 1.5 hours, twice a week and will teach new skills to improve chronic pain management and help teens do the activities they want to do without pain getting in the way. Parents will learn the same skills along with strategies to support their teen's use of skills at home. One booster session will be offered 1-2 months after completing the program to help problem-solve any difficulties Participants may have had. All sessions will be audio-video recorded and will only be reviewed by research staff to make sure that the training program is being provided accurately.

Follow-Up Assessments: All Participants will complete the same assessments at the end of treatment, and at 3-months after the end of treatment.

Feedback Interview: At the end of the program, Participants will be asked to do an interview to share their opinions about the program. This will be used to make the program better in the future.

Compensation: ALL of these procedures will be paid for by the study. For your time and participation, each Participant will receive $30 after completing each assessment (baseline, post-treatment, 3-month follow-up). To reimburse cellular data and WiFi usage for telehealth sessions, each Participant will receive $60 for every attended treatment session. Each Participant will also each receive $100 for completing the qualitative exit interview. Participants will also receive $10 per day for wearing an activity monitor for up to 7 consecutive days.

Could being in this research hurt me?

The study will take time. The program that is being tested 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. The most important risks or discomforts that you may expect from taking part in this research include emotional discomfort, fatigue, loss of privacy and breach of confidentiality.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include sharing your experiences and insights during interviews and treatment sessions.

Possible benefits to others include helping the researchers answer the study question. Learning how to use mind and body strengthening skills may help to manage sickle cell pain and develop confidence in doing activities without pain getting worse. Although we do not know for certain if the program will help reduce pain, this study will allow us to develop better treatment.

What other choices do I have besides taking part in this research?

Instead of being in this study, the alternative is not to participate. Your usual medical care will not be affected if you choose not to participate.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form “you” generally refers to the research subject. If you are being asked as the parent or guardian to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.

- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to find out how teens with frequent and chronic pain and sickle cell disease respond to a new training program called I-STRONG for SCD (Integrative Strong Body and Mind Training for Sickle Cell Disease) and get their feedback about how we can continue to modify the program to best fit their needs. I-STRONG for SCD focuses on teaching a combination of pain coping skills (also known as cognitive-behavioral therapy) and neuromuscular movement exercises (similar to physical therapy). Together, these skills and strategies may help teens reduce pain and get back into their everyday activities.

This treatment program along with usual medical care has been shown to reduce pain and improve physical and emotional health in teenagers with other chronic pain conditions. As part of our ongoing research studies, we gathered feedback from parents and their teenagers who have both chronic pain and sickle cell disease to develop the I-STRONG for SCD training program specifically for chronic sickle cell pain. This training program is tailored to the specific needs of a teen with SCD and their family to address the unique challenges related to chronic sickle cell pain that might make it hard for teens to engage fully in daily life.

How long will I be in this research?

Patients and parents will participate up to 5 months.

What happens to me if I agree to take part in this research?

We are asking about 12 teens and young adults who have chronic pain and sickle cell disease ages 12-18 years old to participate in this study. We are also asking parents or caregivers of the participating patients to be in the study. Parents will answer separate parental surveys, give us information about themselves and their teens, and participate with teens in the training program.

If you and your child are eligible and want to be part of the study, you and your child will participate for 5 months (21 study visits). The study involves a combination of 1) assessments (3 study visits), 2) group treatment sessions (17 study visits), and 3) a feedback interview (combined with a survey visit).

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to participate in the following activities:

Assessment Visits: Parents and teens will complete an assessment of surveys. We will ask parents and teens to complete brief questionnaires about demographics, the teen's pain, sleep, mood, physical functioning, quality of life, and medication use. Teens will complete a brief daily pain diary and wear an activity monitor for 7 days. All surveys can be completed in-person or at home using online or paper-and-pencil questionnaires, depending on teen and parent preference. Teens will complete a brief walking evaluation during an in-person visit. Assessments will be completed at baseline (before starting the program), post-treatment, and 3-months after treatment. Parents will also report on any changes to their teen's medical treatment or medications.

Treatment Program: All teens will participant in the I-STRONG training program, which is 16 sessions in a group format with 3-6 teens with SCD. I-STRONG for SCD includes topics that were identified by teens with chronic sickle cell pain and their parents as important skills for all teens with chronic pain and sickle cell disease. Some examples of topics include learning how to identify and manage stress, how to stay active and involved in everyday activities without letting pain get in the way, how to talk to others about their pain and what they need that may help, how teens can be a good coach for themselves when pain gets overwhelming or changes their mood, and strategies to help parents be able to support their teens in living the life they want. These skills will be combined with neuromuscular movement training, which is like physical therapy exercises but specifically designed to strengthen the body and move safely without making pain worse. The movement training includes an introduction to the specific movements with education about proper form and technique, benefits of each movement, and how each movement helps improve daily activities (e.g., climbing stairs, walking briskly, sitting in class, waiting in line, bending to pick up an object). Movement training will use available household items (e.g., pillow, chair, wall) to support practice at home. Teens will also receive a Bosu Balance ball to use and keep for practicing movement exercises at home.

Treatment Sessions: The treatment sessions will be conducted by telehealth using a secure audio-video platform. Each session will last about 1.5 hour, twice a week. Each session will focus on teaching new coping skills (first half of session) and movement exercises (second half of session) to improve chronic pain management. Sessions will be led by a behavioral health coach (e.g., psychology provider) and a movement coach (e.g., physical therapist). Teens will be asked to practice the new skills and exercises at home between sessions and keep a brief diary of their practice, pain symptoms, mood, and sleep. At least one parent or guardian is required to attend 6 out of 16 sessions with their teen. All interested family members (parents, grandparents, siblings) are encouraged to attend sessions with their teen. Parents will also receive education and training in the skills your teen will be learning along with behavior management strategies to support your teen's use of skills at home. A booster session will be

offered 1-2 months after completing the program. Booster sessions focus on problem-solving any difficulties teens or parents may have had with using the skills at home or school. All sessions will be audio-video recorded and will only be reviewed by research staff to make sure that the content of the training program is being provided accurately and thoroughly to all participants. If your child misses a session, a makeup session may be scheduled before the next planned group treatment session so they can catch up with the group.

Feedback Interview: At the end of the program, parents and teens will be asked for feedback in a one-on-one interview lasting up to 60 minutes. Feedback may include how you liked the program, what you thought about the content of the program, and any suggestions or changes to the materials or format. Information from these interviews will be used to refine and modify I-STRONG for SCD. Interviews can be conducted in-person or by telehealth (audio and/or video) based on family preference.

Could being in this research hurt me?

All research comes with some risks. The risks for participating in this study could come from answering questionnaires, and participating in the treatment sessions, interviews, and advisory board and they are outlined below.

The most common risks and discomforts expected in this study are:

- feelings of emotional discomfort when discussing their experience with sickle cell disease and pain management. Some questions might contain embarrassing or personal questions. Let us know if you have these problems. Teens or parents may choose not to answer a question for any reason.
- temporary increase in muscle pain/soreness and/or fatigue with the neuromuscular movement training. So far, participants have not reported any distress related to the assessments or the treatment, or had any injuries or pain flares. They report slight temporary soreness with the neuromuscular movement training as expected but this resolved within a day or two with rest and use of heat if needed.

The less common risks and discomforts expected in this study are:

- Some questions we ask may reveal depressive feelings and/or suicidal thoughts. In the event that your child indicates thoughts of self-harm, you will be contacted by the research staff to devise a plan for treatment and/or your child's safety.

Someone outside the study might see your or your child's personal information. We will do everything we can to keep this from happening. Information we collect will be stored securely and only study staff will see it.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost me money to take part in this research?

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Children's Healthcare of Atlanta will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Children's Healthcare of Atlanta will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Children's Healthcare of Atlanta and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Children's Healthcare of Atlanta will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about how teens with chronic sickle cell pain respond to the program and if it helps them manage their chronic pain. Although we do not know for certain whether the treatment will reduce pain, the treatment has helped teens with other chronic pain conditions. The study results may be used to help others in the future.

What other choices do I have besides taking part in this research?

If you choose not to join this study, you can get care outside of this study. Please speak with your medical care providers for referrals to psychologists, counselors, or physical therapists who can offer support for pain management. The study doctor will discuss these with you.

You do not have to be in this study to be treated for sickle cell disease or chronic pain OR to get psychological, behavioral health, or physical therapy services.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Medical Record

If you have been an Emory and/or Children's Healthcare of Atlanta patient before, then you already have an Emory and/or Children's Healthcare of Atlanta medical record. If you have never been an Emory patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory Atlanta 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 Children's Healthcare of Atlanta medical record you have now or any time during the study.

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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a

separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:
The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI 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. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

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

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory and Children's Healthcare of Atlanta may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.

- National Institutes of Health, National Center for Complementary and Integrative Health is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Greenphire, for the purpose of paying research incentive via ClinCard.

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory and Children's Healthcare of Atlanta that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the IRB, and Healthcare Compliance Offices, and the Office for Clinical Research.
- Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration, National Institutes of Health and others.
- 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 IIHI may be disclosed to the new institution and the institution's oversight offices.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team in writing at:

Soumitri Sil, PhD, ABPP
Children's Healthcare of Atlanta
[redacted]
Atlanta, GA 30322
United States of America

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. 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. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI 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. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Information about a Certificate of Confidentiality for this research:
The research site and investigator has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about you collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think you have experienced a research-related issue, talk to the research team at the phone number listed above on the first page.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact the Children's Institutional Review Board at 404-785-7477.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can withdraw you from the research project. Any data collected prior to your withdrawal may still be used by the study team. This data will be de-identified.

Will I be paid for taking part in this research?

Parents and teens will be compensated for their time and participation for each completed study visit.

Assessments: Parents and teens will each receive $30 for completing each assessment visit (baseline, end of treatment, and 3-months after treatment).

Treatment Sessions: To reimburse cellular data and WiFi usage for telehealth sessions, parents and teens will each receive $60 for every attended treatment session (16 treatment sessions + 1 booster session).

Feedback Interview: Parents and teens will also each receive $100 for completing the feedback interview at the end of the program.

Participants will also receive $10 per day for wearing an activity monitor for up to 7 consecutive days, totaling $210 over the course of the study.

If you do not finish the study, we will compensate you for the visits you have completed. You and your child will each get $1,210 total, if you complete all study visits. All other compensation will be prorated appropriately as per IRB guidelines.

You will be paid via ClinCard, a reloadable debit card. The ClinCard program is owned by a company called Greenphire. The study team will give Greenphire your name, address, date of birth and Social Security number as part of the payment system. Greenphire will only use this information to make sure you get paid. Greenphire will not use your information for any other purposes, and they will not give or sell your information to any other company. The study team will provide you more information about the ClinCard program following study enrollment.

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.

Statement of Consent:

- All children are required to assent
- If assent is obtained, have the person obtaining assent document assent on the consent form

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of adult subject capable of consent, child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
Printed name of teen or young adult subject	Date
Signature of parent consent for parent's own participation	Date
Printed name of parent subject	Date
Signature of person obtaining consent	Date

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent	Date