INFORMED CONSENT

PINPOINT: GAMING TECHNOLOGY TO ENGAGE ADOLESCENT SICKLE CELL PATIENTS IN PRECISION PAIN PHASE II

(5R44MD010746)

NCT04579926

09/09/2021

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Randomized Control Trial

TITLE: PINPOINT: Gaming Technology to Engage Adolescent Sickle Cell Patients in Precision Pain Management - Phase II

PROTOCOL NO.: R44 MD010746
IRB Protocol #20182261

SPONSOR: National Institute on Minority Health and Health Disparities, NIH

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United States

STUDY-RELATED PHONE NUMBER(S): Julia Berteletti, MSW
303-565-4321

This consent form may contain words that you do not understand. Please ask the Principal Investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

Your child is being asked to be in a research study. The purpose of this consent form is to help you decide if you want your child to be in the research study. Please read this form carefully. In order for your child to be in a research study you must give your informed consent and your child must provide his/her assent. “Informed consent” includes:

- Reading this consent form,
- Having the Principal Investigator or staff explain the research study to you, and
- Asking questions about anything that is not clear.

You should not allow your child join this research study until all of your questions are answered. If your child takes part in this research study, you will be given the option to download or save/print copy of this consent form.

PURPOSE OF THE STUDY

The purpose of this study is to test an app for use with sickle cell disease patients who are 13 to 17 years old. We have developed a Pain Assessment Tool to describe and categorize specific types of pain experienced by adolescents with sickle cell disease. The Pain Assessment Tool has been translated into a mobile app named *Pinpoint*, which aims to engage adolescent patients and improve pain specification.

RANDOMIZED CONTROL TRIAL PROCEDURES

A study introduction session will take about 60 minutes to complete. Your child will be asked to download the *Pinpoint* app to his/her smartphone or tablet and be shown how to use the app. Your child will be assigned to a cohort. Based on the cohort your child is randomized into, your child may be asked to use the *Pinpoint* app for 4, 8 or 12 weeks. You will have the option to use the app to access general sickle cell-related information. You will also be able to see the Pain Diary information your child enters only if your child chooses to share it with you. You and your child will be asked to complete surveys during the introduction session, at 4 weeks, 6 weeks, 8 weeks, 12 weeks and, depending on which cohort you are assigned to, you may be asked to complete a survey at 16 weeks.

When the trial for your child's cohort is over, you and your child will meet with us again, via videoconference, for an exit interview. You and your child will complete your final survey at this time (12-week or 16-week survey, depending on which cohort your child is assigned to). You and your child will also rate you and your child's experience with the *Pinpoint* app. We ask that you and your child complete a brief questionnaire related to your experience with using the *Pinpoint* app. The feedback will be documented and used to adjust the app.

RISKS AND DISCOMFORTS

There are no known risks for participating in this research.

NEW INFORMATION

You and your child will be told about any new information that might change your decision to allow your child be in this study.

BENEFITS

There are no direct benefits for participating in this study. However, you may benefit from the knowledge that you have helped evaluate the *Pinpoint* app, which, in the future, may help teens with sickle cell disease.

COSTS

There are no costs associated with this study, except for your time.

PAYMENT FOR PARTICIPATION

You will receive a $10 gift card after each study assessment (baseline, 4-week, 6-week, 8-week, 12-week, and possibly 16-week) for your participation. Your child will receive a gift card after each study assessment as follows:

- Baseline survey: $30 gift card
- Follow-up surveys (4-week, 6-week, and possibly 12-week): $20 gift card
- Final survey (either 12-week or 16-week): $40 gift card

You may receive up to $50 in gift cards for your participation and your child may receive up to $130 for their participation.

ALTERNATIVE
This is not a treatment study. The alternative is to not participate in this study.

CONFIDENTIALITY
Study information collected about your child will be given to the sponsor. "Sponsor" means any persons or companies that are working for or with the sponsor or owned by the sponsor. This information may be shared with the Department of Health and Human Services and WCG IRB.

The online consent form that you agree to will be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies,
- the sponsor;
- WCG IRB;

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your child's identity will not be given out during those presentations.

CERTIFICATE OF CONFIDENTIALITY
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you or your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your child's participation in this study is voluntary. You or your child may decide not to participate. You or your child may leave the study at any time. These decisions will not result in any penalty or loss of benefits to which you or your child are entitled.

Your child's participation in this study may be stopped at any time by the Principal Investigator or the sponsor without his/her consent for any of the following reasons:

- if it is in your child's best interest;
- if your child does not assent to continue in the study after being told of changes in the research that may affect him/her;
- or for any other reason.

SOURCE OF FUNDING FOR THE STUDY
Funding for this research study is provided by the National Institute on Minority Health and Health Disparities (NIH).

CLINICALTRIALS.GOV
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.

QUESTIONS
Contact Julia Berteletti, MSW at 303-565-4321 for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your child's rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who independently review research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not agree to allow your child to participate in this study unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to let your child be in this study, you will be given the option to download or save/print this consent form for your records.

CONSENT

I have read this assent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study. By electronically signing this consent form, I have not given up any of my legal rights.

ELECTRONIC CONSENT: Please select your choice below. You may print a copy of this consent form for your records. Clicking on the "Agree" button indicates that

- You have read the above information
- You voluntarily agree to allow your child to participate
- You are 18 years of age or older

☐ Agree

☐ Disagree