

Acupuncture for Adults with Sickle Cell Disease (SCD): A Feasibility Study

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LIST OF ABBREVIATIONS

CON	College of Nursing
DMC	Data Monitoring Committee
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
ICD	Informed Consent Document
IRB	Institutional Review Board
LAR	Legally Authorized Representative
OHRP	Office of Human Research Protections
OPRS	Office for the Protection of Research Subjects
PI	Principal Investigator
SAE	Serious Adverse Event
SCD	Sickle Cell Disease
SOP	Standard Operating Procedure
UIH	University of Illinois Health

1.0 Project Summary/Abstract

Our long-term goal is to demonstrate the effectiveness of acupuncture for the treatment of adults with chronic pain of sickle cell disease (SCD), a debilitating pain syndrome characterized by acute and chronic pain. The objective of this study is to explore the feasibility and acceptability of acupuncture with adult sickle cell patients. We will conduct the study with adults with chronic pain from SCD, 18 years old or greater. They will all receive acupuncture. Treatments will be twice weekly for 5 weeks for 30 minutes. At baseline and post-treatment, subjects will complete measures that include pain, fatigue, anxiety, depressive symptoms, injustice experience, pain catastrophizing, and be interviewed about their feelings about receiving acupuncture. Subjects will also complete a measure of study acceptability, the Protocol Acceptability Scale for Treating SCD with Acupuncture at post-treatment. We will describe the procedures and potential challenges to implementing the acupuncture protocol and the range in the subjects' Acceptability Scale scores. We expect to identify and rectify any procedural problems subjects will report regarding the 10-session study protocol.

2.0 Background/Scientific Rationale

Every 30 minutes, every day, a person dies from a prescription opioid overdose in the United States (US). Further, opioid use is associated with a myriad of adverse outcomes.¹ Sickle cell disease (SCD) affects millions of people worldwide and is the most common lethal genetic blood disorder in the US, affecting about 100,000 people, mostly people of African and Hispanic background. Pain is the most common complication of SCD and is also a marker of clinical severity.² People with SCD are a population living with a high burden of chronic pain, high prescription opioid use,³ and health care disparities.⁴ Many with SCD are treated long term with oral opioids and when hospitalized for acute pain are treated with parenteral opioids.

Given this level of opioid use, it is crucial to consider complementary and integrative health (CIH) therapies as a method to decrease exposure to opioids while maintaining adequate pain control. One CIH therapy shown to be acceptable to people with SCD is acupuncture. Acupuncture typically involves inserting small needles into specific points on the body.¹ It is shown to decrease pain and provide an alternative to opioid use.²⁻⁴ Importantly, it is now covered by Medicare and Medicaid and is thus widely available and no longer tied to socioeconomic disadvantage. If successful, our project will drastically improve clinic-based pain management and help to reduce reliance on opioids and prevent opioid use disorder.

Acupuncture

There are few studies of acupuncture for the treatment of SCD. Two were pediatric studies^{5,6} and both reported pain reduction. A third study, which was an uncontrolled retrospective review, treated a total of 24 inpatient and outpatient adults during acute vaso-occlusive crisis with individualized acupuncture point prescriptions.⁷ Nine inpatients received a median of 3 treatments and had a reduction in pain of 2.1 on a 0-10 pain rating scale. Fifteen outpatients received a median of 4 treatments and had up to a 75% reduction in pain. The fourth uncontrolled study treated 10 adults with a total of 16 acute vaso-occlusive crises; subjects reported a decrease in pain in 15 of 16 acute vaso-occlusive crises.⁸ Because there have been only two trials on using acupuncture for adults with SCD, it is important to generate data on feasibility, acceptability, and protocol revisions for a future fully powered RCT of a standardized acupuncture protocol.

3.0 Objectives/Aims

Aim: To determine the feasibility (recruitment, retention, completion) and acceptability of performing acupuncture on 15 adult subjects with SCD.

Hypothesis: Acupuncture therapy will be feasible (80% recruitment, retention, completion) and acceptable to adults with SCD.

Impact: Acupuncture therapy has the potential to significantly reduce the pain and associated symptoms of SCD by offering therapy that is complimentary to optimal medical management. Symptom management is critical for reducing disability and improving quality of life for people with SCD.

4.0 Eligibility

- Adults with SCD who have had a moderate to severe level of pain (≥ 3 on 0-10 scale) related to SCD within the last 3 months, receiving care at the UI Health SCD clinic will be eligible to participate.

4.1 Inclusion Criteria

- Adults with SCD who have had a moderate to severe level of pain (≥ 3 on 0-10 scale) related to SCD within the last 3 months, receiving care at the UI Health SCD clinic will be eligible to participate.

4.2 Exclusion Criteria

- Pregnancy
- Physically or cognitively unable to complete the study procedures

5.0 Subject Enrollment

- The primary providers at the UI Health SCD clinic will determine if a patient is eligible for the study.
- Eligibility will be assessed using the Eligibility Checklist. (See Appendix A for Eligibility Checklist).
- The PI or other key research personnel will give out a flyer describing the study to each eligible patient during clinic visits, and explain the general aspects of the study. The flyer also has a contact number for potential subjects to use if interested.
- Patients who express an interest in the study will meet with the PI or other key research personnel, who will explain the study in detail, answer questions, and obtain informed consent.
- Upon consent, patients will be administered baseline study measures.

6.0 Study Design and Procedures

- This study is an unblinded, uncontrolled feasibility study.
- All subjects will receive acupuncture.
- Baseline measures will be taken prior to insertion of the acupuncture needles.
- The research assistant will confirm the subject's assigned code number before the start of each acupuncture session.
- The subject will lay face up on the acupuncture exam table.
- The acupuncturist will swab each of 18 acupuncture points with alcohol.
- Needle insertion will then be performed with a tapping in technique. The needles will be retained for 30 minutes; they will be twirled 3 times throughout the treatment. The needles will then be pulled.
- After the 10th acupuncture treatment the subject will complete data collection tools.

7.0 Expected Risks/Benefits

- Expected Risks: There is a risk of bruising or bleeding after the acupuncture needle is withdrawn. There is a risk that they may experience a negative reaction from acupuncture and thereby experience worse symptoms from participation in the study. If potential subjects are afraid of needles, they may not want to participate although the needles are very small. There is risk that some of the questions in the questionnaires may make the subject uncomfortable, nervous or tired. There is also the risk of loss of privacy or confidentiality, but we will avoid this and all other risks as much as possible.
- Expected Benefits: There may be no benefit to individual subjects, but the knowledge gained from this study is expected to help providers better manage SCD pain by having a better understanding of whether or not acupuncture reduces the pain of SCD.

8.0 Data Collection and Management Procedures

- All data will be collected on paper. All subjects will be assigned a code 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.
- Data management and preliminary data analysis procedures will be supervised by the contact PI (JS).
- The following measures will be completed by the subjects:

Table: Acupuncture for Adults with Sickle Cell Disease Questionnaires			
Construct	Operational Measure	1	2
Demographic data	Age, sex, race, employment status, comorbidities, marital status, number of household members, annual income, and educational attainment	x	S
PROMIS ¹³	Perceptions of pain intensity, global health, ¹⁴ pain interference, depressive symptoms, ¹⁵ anxiety, ^{9,10} anger, ¹⁵ sleep disturbance, ¹⁷ fatigue, ¹⁸ and self-efficacy ^{18,19} over the last 7 days, excellent validity across clinical contexts and high internal consistency across diverse racial-ethnic groups (Cronbach's α = 0.92 – 0.96) ²⁰⁻²³	x	x S
McGill Pain Questionnaire (MPQ)	It also documents pain quality via 78 descriptors, and pain pattern via 9 descriptors. ²⁴ The MPQ has demonstrated good reliability (α = .80). ²⁵	x	x S
Pain catastrophizing ²⁴	13-item scale; measures dimensions of the cognitive appraisal process of pain catastrophizing (magnification, rumination, helplessness); asked to indicate how much they experienced each item (thought/feeling). ^{25,26}	x	x S
Injustice Experiences Questionnaire (IEQ-chr) ²⁷	12-items; ¹¹ frequency rating for experiencing particular thoughts and feelings, such as "It all seems so unfair," and "Nothing will ever make up for all that I have gone through." ²⁸⁻³²	x	S
Credibility/Expectancy Questionnaire ¹²	6-items, feelings about acupuncture treatment expectancy and rationale credibility, test-retest 0.62-0.78, Cronbach's α 0.84-0.85. ¹²	x	S
Protocol Acceptability Scale for Treating SCD with Acupuncture	Assesses the acceptability of all study measures being completed and the study itself being completed. This scale will be measured after the last acupuncture session. ³³		x S
Cognitive interview	9 question interview regarding subject's feelings about receiving acupuncture	x	x I
	Source: S = Self-report survey, I= Interview		

9.0 Data Analysis

- Descriptive statistics will be conducted. Descriptive statistics (frequency, percentage, means, and standard deviations) were summarized at baseline. We reported pain intensity, pain interference and other pain related outcomes before and after the acupuncture intervention.

10.0 Quality Control and Quality Assurance

- The study is low risk; therefore, we do not anticipate any serious adverse events from the acupuncture intervention. The PI will provide oversight for the de-identification of the data. The PI will review all data collection forms on an ongoing basis for: data completeness, data accuracy and protocol compliance.

11.0 Data and Safety Monitoring

- The study is low risk. However, the research team will monitor the safety of subjects during study procedures. In the event of injury related to this research, treatment will be available through the UIC Medical Center. However, the patient or third party payer, if any, will be responsible for payment of this treatment. Patient subjects will remain under the care of their usual provider, who will be available to give them usual care if needed. Any unanticipated problems related to the study procedure will be immediately reported to the IRB.
- Data Security: Each participant will be assigned a code number and their data will be identified only with that code number. Only the PI will have access to the code/master key. All questionnaires will be collected on paper and stored in a locked cabinet in the locked PI's office.

12.0 Statistical Considerations

- This is a feasibility study and has not been powered. The data will be descriptive in nature.

13.0 Regulatory Requirements

13.1 Informed Consent

- Informed consent will be obtained either by the PI or other key research personnel who have obtained IRB and HIPAA certifications. The RA will have been trained by the PI on the informed consent procedures. It will be obtained on paper.
- The consent process will be completed in person and in a private area at either the UIH SCD Clinic or the acupuncture exam rooms on the 2nd floor CON.

- Subjects will be informed that they will receive 2 acupuncture treatments for 30 minutes each week for 5 weeks, for a total of 10 treatments.
- Informed consent documents will be stored in a locked file cabinet in the locked PI's office. The study team will have access to the informed consent documents.

13.2 Subject Confidentiality

- All measures will be completed in a private exam room with soundproof walls on the 2nd floor of the UIC CON.
- The link between the research data and code number will be destroyed after all manuscripts are published.

13.3 Unanticipated Problems

- Any unanticipated problems related to the study procedure will be immediately reported to the IRB.

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APPENDICES

APPENDIX A:

Acupuncture for Adults with Sickle Cell Disease (SCD): A Feasibility Study Eligibility Checklist

Yes No

Inclusion criteria:

- ≥18 years-old with a diagnosis of SCD
- Had a moderate to severe level of pain (≥ 3 on 0-10 scale) related to SCD within the last 3 months
- Speaks/reads English
- Receiving care at the UI Health SCD clinic

Exclusion criteria:

- Pregnant
- Physically or cognitively unable to complete the study procedures

APPENDIX B, MEASURES:

Demographic Measures

Sickle Cell Disease Participant Characteristics

Variable	Category
How old are you	
What is your marital status	Single
	Married/Partnered
	White
What is your race	Black/African-American
	Native American/Alaska Native
	Hispanic
What is your income	<40k
	40-50k
	50k+
How much education have you had?	< HS, HS, Vocational School
	Some college or Associates degree
	Bachelor's degree or higher

Pain Intensity – Scale

Please respond to each item by marking one box per row.

In the past 7 days...		Had no pain	Mild	Moderate	Severe	Very severe
PAINQ16	How intense was your pain at its worst?....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAINQ19	How intense was your average pain?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
		No pain	Mild	Moderate	Severe	Very severe
PAINQ21	What is your level of pain right now?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Global Health**Please respond to each question or statement by marking one box per row.**

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global02	In general, would you say your quality of life is:.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global03	In general, how would you rate your physical health?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global09r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
		Completely	Mostly	Moderately	A little	Not at all

In the past 7 days...		Never	Rarely	Sometimes	Often	Always						
Global01r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1						
Global02r	How would you rate your fatigue on average?	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1						
Global07r	How would you rate your pain on average?	<input type="checkbox"/> 0 No pain	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10 Worst pain imaginable

Pain Interference

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAIN11	How difficult was it for you to take in new information because of pain?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN12	How much did pain interfere with your enjoyment of life?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN13	How much did pain interfere with your ability to participate in leisure activities?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN14	How much did pain interfere with your close personal relationships?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN15	How much did pain interfere with your ability to concentrate?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN16	How much did pain interfere with your day to day activities?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN17	How much did pain interfere with your enjoyment of recreational activities?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ11	How often did you feel emotionally tense because of your pain?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ12	How much did pain interfere with the things you usually do for fun?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ13	How much did pain interfere with your family life?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ17	How much did pain interfere with your relationships with other people?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ18	How much did pain interfere with your ability to work (include work at home)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ19	How much did pain make it difficult to fall asleep?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ20	How much did pain feel like a burden to you?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ22	How much did pain interfere with work around the home?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ31	How much did pain interfere with your ability to participate in social activities?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ34	How much did pain interfere with your household chores?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ35	How much did pain interfere with your ability to make trips from home that kept you gone for more than 2 hours?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ36	How much did pain interfere with your enjoyment of social activities?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ48	How much did pain interfere with your ability to do household chores?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ49	How much did pain interfere with your ability to remember things?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ56	How irritable did you feel because of pain?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ14	How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
PAININ16	How often did pain make you feel depressed?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ24	How often was pain distressing to you?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ26	How often did pain keep you from socializing with others?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ29	How often was your pain so severe you could think of nothing else?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ32	How often did pain make you feel discouraged?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ37	How often did pain make you feel anxious?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ38	How often did you avoid social activities because it might make you hurt more?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ40	How often did pain prevent you from walking more than 1 mile?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ42	How often did pain prevent you from standing for more than one hour?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...					
		Never	Rarely	Sometimes	Often
		1	2	3	4
		5			
PAININ46	How often did pain make it difficult for you to plan social activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ47	How often did pain prevent you from standing for more than 30 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ60	How often did pain prevent you from sitting for more than 30 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ61	How often did pain prevent you from sitting for more than 10 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ52	How often was it hard to plan social activities because you didn't know if you would be in pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ53	How often did pain restrict your social life to your home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PAININ55	How often did pain prevent you from sitting for more than one hour?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the past 7 days...					
		Never	Once a week or less	Once every few days	Once a day
		1	2	3	4
		5			
PAININ54	How often did pain keep you from getting into a standing position?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

LEVEL 2—Depression—Adult*
 *PROMIS Emotional Distress—Depression—Short Form

Name: _____ Age: _____ Sex: Male Female Date: _____

If the measure is being completed by an informant, what is your relationship with the individual receiving care? _____

In a typical week, approximately how much time do you spend with the individual receiving care? _____ hours/week

Instructions: On the DSM-5 Level 1 cross-cutting questionnaire that you just completed, you indicated that *during the past 2 weeks* you (the individual receiving care) have been bothered by “no interest or pleasure in doing things” and/or “feeling down, depressed, or hopeless” at a mild or greater level of severity. The questions below ask about these feelings in more detail and especially how often you (the individual receiving care) have been bothered by a list of symptoms during the past 7 days. Please respond to each item by marking (✓ or x) one box per row.

						Clinician Use
						Item Score
In the past SEVEN (7) DAYS....						
	Never	Rarely	Sometimes	Often	Always	
1. I felt worthless.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
2. I felt that I had nothing to look forward to.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
3. I felt helpless.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
4. I felt sad.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
5. I felt like a failure.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
6. I felt depressed.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
7. I felt unhappy.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
8. I felt hopeless.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
Total/Partial Raw Score:						
Prorated Total Raw Score:						
T-Score:						

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Emotional Distress - Anxiety – Calibrated Items**Please respond to each item by marking one box per row.****In the past 7 days...**

		Never	Rarely	Sometimes	Often	Always
EDANX01	I felt fearful.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX02	I felt frightened.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX03	It scared me when I felt nervous	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX05	I felt anxious.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX07	I felt like I needed help for my anxiety	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX08	I was concerned about my mental health ...	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX12	I felt upset.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX13	I had a racing or pounding heart.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX16	I was anxious if my normal routine was disturbed.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
		1	2	3	4	5
EDANX10	I had sudden feelings of panic.....	<input type="checkbox"/>				
EDANX20	I was easily startled	<input type="checkbox"/>				
EDANX21	I had trouble paying attention.....	<input type="checkbox"/>				
EDANX24	I avoided public places or activities	<input type="checkbox"/>				
EDANX26	I felt fidgety.....	<input type="checkbox"/>				
EDANX27	I felt something awful would happen.....	<input type="checkbox"/>				
EDANX30	I felt worried.....	<input type="checkbox"/>				
EDANX33	I felt terrified	<input type="checkbox"/>				
EDANX37	I worried about other people's reactions to me	<input type="checkbox"/>				
EDANX40	I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>				

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In the past 7 days...		Never	Rarely	Sometimes	Often	Always
EDANX41	My worries overwhelmed me	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX44	I had twitching or trembling muscles	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX46	I felt nervous	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX47	I felt indecisive.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX48	Many situations made me worry.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX49	I had difficulty sleeping	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX51	I had trouble relaxing.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX53	I felt uneasy.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX54	I felt tense.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX55	I had difficulty calming down.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Emotional Distress - Anger – Short Form 5a

Please respond to each item by marking one box per row.

In the past 7 days...

		Never 1	Rarely 2	Sometimes 3	Often 4	Always 5
EDANG03	I was irritated more than people knew ...	<input type="checkbox"/>				
EDANG09	I felt angry	<input type="checkbox"/>				
EDANG15	I felt like I was ready to explode	<input type="checkbox"/>				
EDANG30	I was grouchy	<input type="checkbox"/>				
EDANG35	I felt annoyed.....	<input type="checkbox"/>				

Sleep Disturbance – Calibrated Items**Please respond to each item by marking one box per row.****In the past 7 days...**

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep105	My sleep was restful.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep106	My sleep was light.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep107	My sleep was deep.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep108	My sleep was restless.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep115	I was satisfied with my sleep.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep116	My sleep was refreshing.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep125	I felt lousy when I woke up.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep20	I had a problem with my sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep44	I had difficulty falling asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep65	I felt physically tense at bedtime.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

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In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep67	I worried about not being able to fall asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep68	I felt worried at bedtime.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep69	I had trouble stopping my thoughts at bedtime.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep70	I felt sad at bedtime.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep71	I had trouble getting into a comfortable position to sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep72	I tried hard to get to sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep78	Stress disturbed my sleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep86	I tossed and turned at night.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep93	I was afraid I would not get back to sleep after waking up.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
Sleep110	I got enough sleep.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep42	It was easy for me to fall asleep.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Sleep45	I laid in bed for hours waiting to fall asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep50	I woke up too early and could not fall back asleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep07	I had trouble staying asleep.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep00	I had trouble sleeping.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
Sleep92	I woke up and had trouble falling back to sleep.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
In the past 7 days...						
		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was...	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

Fatigue – Short Form 6a**Please respond to each question or statement by marking one box per row.****During the past 7 days...**

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1	I feel fatigued	<input type="checkbox"/>				
2	I have trouble <u>starting</u> things because I am tired.....	<input type="checkbox"/>				
	In the past 7 days...					
3	How run-down did you feel on average? ...	<input type="checkbox"/>				
4	How fatigued were you on average?	<input type="checkbox"/>				
5	How much were you bothered by your fatigue on average?.....	<input type="checkbox"/>				
6	To what degree did your fatigue interfere with your physical functioning?.....	<input type="checkbox"/>				

General Self-Efficacy – Short Form 4a**Please respond to each item by marking one box per row.**

For the next set of questions, please read each sentence and rate your level of confidence in managing various situations, problems, and events.

Rate your level of confidence.		I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
1	GSE11_0 I can manage to solve difficult problems if I try hard enough.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2	GSE14_0 I am confident that I could deal efficiently with unexpected events.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3	GSE19_0 If I am in trouble, I can think of a solution.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4	GSE20_0 I can handle whatever comes my way.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Ψ Injustice Experience Questionnaire

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Michael JL Sullivan

IEQ

Name: _____ Age: _____ Gender: _____ Date: _____

When injuries happen, they can have profound effects on our lives. This scale was designed to assess how your injury has affected your life.

Listed below are twelve statements describing different thoughts and feelings that you may experience when you think about your injury. Using the following scale, please indicate how frequently you experience these thoughts and feelings when you think about your injury.

0 – never 1 – rarely 2 – sometimes 3 – often 4 – all the time

- 1 Most people don't understand how severe my condition is.
- 2 My life will never be the same.
- 3 I am suffering because of someone else's negligence.
- 4 No one should have to live this way.
- 5 I just want to have my life back.
- 6 I feel that this has affected me in a permanent way.
- 7 It all seems so unfair.
- 8 I worry that my condition is not being taken seriously.
- 9 Nothing will ever make up for all that I have gone through.
- 10 I feel as if I have been robbed of something very precious.
- 11 I am troubled by fears that I may never achieve my dreams.
- 12 I can't believe this has happened to me.

...Total

Credibility/Expectancy QuestionnaireGroup Number _____
Study Identification Number _____
Number _____

Please answer each item by indicating the number that best describes your response.

1. At this point, how logical does the acupuncture seem to you?

1	2	3	4	5	6	7	8	9	10
not at all logical				somewhat logical					very logical

2. At this point, how useful do you think the acupuncture will be in reducing your pain?

1	2	3	4	5	6	7	8	9	10
not at all useful				somewhat useful					very useful

3. How confident would you be in recommending the acupuncture to a friend who experiences similar problems?

1	2	3	4	5	6	7	8	9	10
not at all confident				somewhat confident					very confident

4. By the end of the study period, how much improvement in your pain symptoms do you think will occur?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

For the last two questions, close your eyes for a few moments, and try to identify what you really feel about the acupuncture and its likely success. Then answer the following questions:

5. At this point, how much do you really *feel* that the acupuncture will help you to reduce your pain symptoms?

1	2	3	4	5	6	7	8	9	10
not at all				somewhat					very much

6. By the end of the study period, how much improvement in your pain symptoms do you really *feel* will occur?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Ψ Pain Catastrophization Questionnaire

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Michael JL Sullivan

PCS-EN

Client No.: _____ Age: _____ Sex: M(____) F(____) Date: _____

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all 1 – to a slight degree 2 – to a moderate degree 3 – to a great degree 4 – all the time

When I'm in pain ...

- ₁ I worry all the time about whether the pain will end.
- ₂ I feel I can't go on.
- ₃ It's terrible and I think it's never going to get any better.
- ₄ It's awful and I feel that it overwhelms me.
- ₅ I feel I can't stand it anymore.
- ₆ I become afraid that the pain will get worse.
- ₇ I keep thinking of other painful events.
- ₈ I anxiously want the pain to go away.
- ₉ I can't seem to keep it out of my mind.
- ₁₀ I keep thinking about how much it hurts.
- ₁₁ I keep thinking about how badly I want the pain to stop.
- ₁₂ There's nothing I can do to reduce the intensity of the pain.
- ₁₃ I wonder whether something serious may happen.

... Total

Updated 11/11

Part 2: What Does Your Pain Feel Like?

Some of the words below describe your present pain. Circle ONLY those words that describe it. Leave out any category that is not suitable. Use only a single word on each appropriate category - the one that applies best.

1

Flickering
Quivering
Pulsing
Throbbing
Beating
Pounding

2

Jumping
Flashing
Shooting

3

Pricking
Boring
Drilling
Stabbing
Lancinating

4

Sharp
Cutting
Lacerating

5

Pinching
Pressing
Gnawing
Cramping
Crushing

6

Tugging
Pulling
Wrenching

7

Hot
Burning
Scalding
Searing

8

Tingling
Itchy
Smarting
Stinging

9

Dull
Sore
Hurting
Aching
Heavy

10

Tender
Taut
Rasping
Splitting

11

Tiring
Exhausting

12

Sickening
Suffocating

13

Fearful
Frightening
Terrifying

14

Punishing
Grueling
Cruel
Vicious
Killing

15

Wretched
Blinding
Intense

16

Annoying
Troublesome
Miserable
Unbearable

17

Spreading
Radiating
Penetrating
Piercing

18

Tight
Numb
Drawing
Squeezing
Tearing

19

Cool
Cold
Freezing

20

Nagging
Nauseating
Agonizing
Dreadful
Torturing

Part 3: How Does Your Pain Change with Time?

1. Which word or words would you use to describe the pattern of your pain?

1	2	3
Continuous	Rhythmic	Brief
Steady	Periodic	Momentary
Constant	Intermittent	Transient

2. What kinds of things relieve your pain?

3. What kinds of things increase your pain?

Part 4: How Strong Is Your Pain?

People agree that the following 6 words represent pain of increasing intensity. They are:

0	1	2	3	4	5
None	Mild	Discomforting	Distressing	Horrible	Excruciating

To answer each question below, write the number of the most appropriate word in the space beside the question.

1. Which word describes your pain right now? _____
2. Which word describes it at its worst? _____
3. Which word describes it when it is least? _____
4. Which word describes the worst toothache you ever had? _____
5. Which word describes the worst headache you ever had? _____
6. Which word describes the worst stomach-ache you ever had? _____

Qualitative Interview Guide Regarding Subject's Feelings about Receiving Acupuncture

1. What made you decide to join this study on acupuncture?
 - a. Tell me about any past experiences you had with acupuncture
 - b. Do others in your life use acupuncture?
 - c. Not satisfied with your level of pain?
 - d. Heard acupuncture is used to treat pain.
2. What were your expectations for getting acupuncture prior to participating in this study?
3. Think about your overall acupuncture experience, how would you describe your experience?
 - a. What do you think was happening in your body?
 - b. Did you learn anything from the process of getting acupuncture? What did you learn?
4. Describe how acupuncture affected your pain
 - a. Did anything change about how you think about or relate to your pain after going through acupuncture treatments?
5. Did anything about getting acupuncture surprise you?
6. How is the acupuncture healthcare experience different from other healthcare experiences you have had?
7. How did you feel about the acupuncturist?
 - a. Did the acupuncturist treat any medical issues other than pain? What was that like?
8. Tell me the reasons you would or would not continue to get acupuncture in the future.
9. Is there anything else you would like us to know about how acupuncture affected you and your overall experience?

Protocol Acceptability Scale for Treating Sickle Cell Disease with Acupuncture *

(select the most appropriate answer)

1. Was participating in this study too hard?
 Not hard at all
 Somewhat hard
 Too hard
2. Were the study instructions easy to understand?
 Easy to understand
 Somewhat hard to understand
 Too hard to understand
3. Were the study questions easy to see?
 Easy to see
 Somewhat hard to see
 Too hard to see
4. Did you feel rushed to complete this study?
 Not rushed at all
 Somewhat rushed
 Too hard to complete
5. Did you enjoy being in this study?
 Enjoyed participating
 Somewhat enjoyed participating
 Did not enjoy participating
6. What did you think of getting acupuncture?
 I liked it
 I did not like it
 I didn't like it or not like it
7. Did you think acupuncture was painful?
 It was not painful
 It was painful
8. Would you get acupuncture again?
 I would get it again
 I would not get it again
9. Do you think this study will be well received by other adults with sickle cell disease?
 Others will enjoy being in this study
 Others will somewhat enjoy being in this study
 Others will not enjoy being in this study
10. Do you think the study was:
 Too short
 Too long
 Right length

**Protocol Acceptability Scale adapted from Wilkie et al. 2003 & Wilkie et al. 2001*

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