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ORIGINAL ARTICLE

Developing an Implementation Blueprint for the NIH HEAL Initiative GRACE Trial: Perspectives on Acupuncture and Guided Relaxation for Chronic Sickle Cell Disease Pain

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Abstract

Objective: This study aimed to explore perspectives of people living with sickle cell disease (SCD) and SCD clinic providers and staff about the use of acupuncture and guided relaxation for treating chronic SCD pain. Data obtained were to inform an implementation blueprint for an effectiveness implementation clinical trial (GRACE Trial) testing whether acupuncture or guided relaxation reduces chronic pain when compared with usual care.

Design: Qualitative research design.

Methods: We conducted 33 semistructured interviews with people with SCD and SCD clinic providers and staff. Interviews were transcribed and coded. A deductive content analysis process was used to identify themes.

Results: Four themes were identified: Receptivity to Acupuncture and Guided Relaxation, Limited Awareness, Complementary and Integrative Health (CIH) Therapy Preference, and Access Barriers. Both patients and clinic providers and staff were open to the use of acupuncture and guided relaxation for chronic pain treatment. After learning about these CIH therapies, some patients expressed a preference for one therapy over the other. They also discussed their ability to successfully engage with each therapy. There is a need to dispel misconceptions about the therapies by increasing understanding of how each therapy is implemented and functions to reduce pain. We identified several potential barriers that might affect the success of the trial and future health system integration, including time, transportation, and technology.

Conclusion: This study is one of the first to present perspectives of both patients with SCD and clinic providers and staff on the use of acupuncture and guided relaxation for chronic SCD pain. Stakeholders' early

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input and perspectives highlighted that they welcome nonpharmacological CIH therapies. Implementation of a clinical trial and future health system integration will require the addressing misinformation and identifying strategies to overcome access barriers.

Clinical trial registration number: NCT04906447.

Keywords: sickle cell disease, chronic pain, acupuncture, guided relaxation, complementary integrative health, implementation

Introduction

ACUTE AND CHRONIC pain are frequent companions to the ~100,000 people living with sickle cell disease (SCD) in the United States. Abrupt and unpredictable acute pain episodes are the primary driver of health care utilization. More than half (55%) of adults with SCD reported having pain on most days in a 6-month period[1] with 29% having pain at least 95% of days.[1] Most pain days occur in the absence of an acute pain episode, that is, most adults with SCD have chronic pain. Despite the prevalence and impact of pain for those with SCD, few effective pain relief treatments beyond opioids have been identified.

Complementary and integrative health (CIH) therapies can reduce pain and potentially, opioid use.[2–4] Acupuncture, a body-based therapy that includes insertion of needles at specific locations in the body, is feasible with adult patients who have SCD and may reduce their pain.[5–7] Similarly, relaxation interventions, such as guided relaxation and mindfulness, are feasible, acceptable, and have shown a reduction in pain and/or stress.[8–10] However, small sample sizes limit the generalizability of these preliminary studies.

In the United States, disparities in CIH use are well documented.[11,12] For example, people from minoritized groups, such as those that identify as Black or Hispanic or are from lower socioeconomic status, are less likely to use CIH therapies compared with other demographic groups.[11] SCD predominantly affects people who are Black or African American in the United States. A single-site cross-sectional survey of 450 adult patients with SCD showed that younger female patients, with more education, and higher household income were more likely to use CIH for pain management.[13] While there is growing interest in CIH therapies, people with SCD reported a lack of access to CIH therapies[14] with barriers being insurance coverage and costs, transportation, and limited information about CIH therapies.[5,13–15]

To fill these effectiveness and implementation gaps, our team is conducting the GRACE Trial, *Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain,* using a Sequential Multiple Assignment Randomized Trial design.[16,17] Adults with chronic SCD pain ($N=366$) are recruited and randomized to one of two CIH interventions or usual care. The goal of this 3-arm, 3-site trial is to assess the effectiveness of acupuncture and guided relaxation for SCD pain compared with the usual care group as measured at 6, 12, and 24 weeks. Those assigned to acupuncture receive 10 sessions over 5 weeks. Those assigned to guided relaxation receive access to video sessions ranging from 2 to 20 min to be viewed daily over 5 weeks. Those assigned to usual care receive the standard of clinical care for SCD. After 6 weeks, participants are rerandomized if there is less than a three-point improvement in their pain impact score. Simultaneously, we are evaluating implementation at the patient and institutional levels to identify and compare barriers and facilitators across three participating health systems.

Before initiating the trial, we sought input from patients with SCD and their clinic providers and staff to inform a planning blueprint for the GRACE Trial, and if effective, lay the groundwork for future health system integration of these CIH therapies. This effort is pertinent for a deeper understanding of acupuncture and guided relaxation for treating chronic pain from the perspectives of individuals with SCD and those providing their clinic care.

Institutional Review Board approval statement

Institutional Review Board approval from the University of Illinois Chicago (No. 2021-0065) was received before the initiation of study activities.

Materials and Methods

Design

We used a qualitative approach during the planning phase of the GRACE Trial. To promote rigor and trustworthiness, the procedures adhered to qualitative research guidelines.[18,19] An experienced member of the research team conducted in-depth interviews with patients with SCD and SCD clinic providers and staff. Participants completed informed consent before the interview. We followed a semi-structured interview guide to explore understanding and perceptions of the two CIH therapies and identified anticipated facilitators and barriers to uptake and health system integration. Field notes were taken during interviews and a brief memo was written after each interview. Interviews were transcribed verbatim, checked for accuracy, and deidentified before analysis.

Setting and sample

Each of the GRACE Trial health systems serves a large population with SCD: University of Illinois Hospital and Health Sciences System (UI Health), Duke University Health System (Duke), and the University of Florida Health System (UF Health). Combined, these systems serve more than 2300 patients living with SCD in urban, suburban, and rural settings. CIH therapies are not widely available at these SCD clinics.

Procedures

Potential participants were identified by clinicians in the SCD clinics, who would discuss the study with their patients. The contact information for interested patients was shared then with recruiters who reached out by phone and/or email to set up interviews. Email invitations were sent to clinicians and staff at each clinic to raise awareness about the study; they either responded to the email invitation or were called by a recruiter to invite them to participate in the interview. Following an informed consent process, interviews were conducted online through videoconferencing at a convenient time for the participant. The intent of the format and interview questions was to encourage participants to talk openly about their understanding and acceptability of acupuncture and guided relaxation as well as what may inhibit or support use of each CIH therapy. As part of the interview, the specifics of each therapy were briefly explained, including the number of sessions and duration of the intervention. Basic demographic information was collected at the end of the interview. A total of 33 interviews were completed from February through August 2021.

Analysis

Descriptive statistics were used to produce demographic characteristic summaries. To gain familiarity with each interview and the overall data set, coders read each transcript and associated notes multiple times. Transcripts were imported into MAXQDA, an application for managing, analyzing, and presenting qualitative data and the deductive content analysis process.[20–22] We used a predefined set of codes reflecting interview questions and the literature and added new codes as we proceeded. Each transcript was coded by a primary and secondary coder. Using analytic matrices, we displayed, sorted, and compared responses across cases to understand individual experiences, explore participants' perspectives about the two therapies, and synthesize variation across cases.[23,24] We analyzed and cross-checked the interview data and interpretations in and across each theme through team consensus. Similarities and differences and descriptions with quotes for each of the identified themes were provided to ensure that different perspectives were represented and supported the findings.

Results

A total of 33 participants were interviewed. All patient participants self-identified as African American or Black and as men ($n=9$) or women ($n=11$), and they ranged in age from 18 to 66 years (median 42 years). Four participants represented patient perspectives from UI Health, five were from Duke, and three were from UF Health. Eleven SCD clinic providers or staff (five physicians, two advanced practice nurses, two nurses, one physician assistant, and one staff person) were also interviewed.

We identified four themes that primarily reflect aspects of acceptability and feasibility. The first, *Receptivity to Acupuncture and Guided Relaxation*, captures a willingness to try or offer acupuncture and guided relaxation for the management of chronic SCD pain. The second, *Limited Awareness*, shows that there is a general lack of familiarity with these therapies. The third, *CIH Therapy Preference*, captures explanations for why one therapy may be preferred over the other as well as perspectives on being able to confidently complete expectations associated with that therapy. The last theme, *Access Barriers*, reflects the anticipated barriers to uptake of these therapies.

Receptivity to acupuncture and guided relaxation

Patients were asked about their understanding of and willingness to try acupuncture and guided relaxation for managing chronic pain. Generally, patients expressed an enthusiasm and willingness to try both therapies. They cited several reasons for this willingness, including being committed to SCD research and a desire for nonpharmacological options.

Patients committed to research expressed a desire for understanding and testing nonopioid approaches for the treatment of pain. For example, a 20-year-old woman noted, "*I'm very for research into sickle cell, better solutions, not even just a cure, but to better deal with sickle cell*." A 36-year-old male said, "*I think it's a good idea to try it [both therapies] to see how it works…Yes, I am willing. I'm definitely willing. Anything that will help narcotics or replace it or whatever, I'm willing to try*."

While patients largely demonstrated an enthusiasm for the therapies, a few indicated some reluctance. Those reluctant to try acupuncture worried about the needles while reluctance to guided relaxation related to previous experiences and ability to focus. A 51-year-old woman said, "*I don't know. I don't know if I would like [acupuncture]. I don't know if it would work. I've heard it works, but it's just… getting needles poked in me. I don't know. I don't know what I think about that.*"

SCD clinic providers and staff also expressed enthusiasm for acupuncture and guided relaxation and most thought that their patients would be receptive to these therapies because they do not involve medications. One physician said that patients are:

> "*…pretty open to trying things that they think may have some evidence, as long as we explain them well and are very clear about the risks, especially if it's nonpharmacologic. I think a lot of people kind of don't like taking pills, so introducing some more holistic type therapies, I think they will be very receptive to it.*"

Limited awareness

Despite enthusiasm for these therapies, several patients and clinic team members expressed a low level of understanding of these therapies. For example, a 24-year-old female patient bluntly stated, *"I know nothing about of guided relaxation."* A 38-year-old female patient said, *"The only thing I know about [acupuncture] is what I see in the movies or on the internet."* A staff member expressed both enthusiasm and limited awareness, he said:

> "*I think it sounds great. I wonder if I'll be able to* [get] *acupuncture myself, I've never had it… I'll be the demo guy… yeah experience it. Then I can really tell the patients. Some of the patients will* [ask] *have you done it*?"

Limited knowledge was more evident for acupuncture. A provider said:

> ''*Well… I don't know much about acupuncture. I've never had it done myself. Never seen it done just other than things you see on TV, shall I say. And as far as guided relaxation, that's pretty easy and simple… I think those can be helpful. So, but for me, I guess you could say, I don't really have any hesitation. But if I did, it will be because I don't know much about it.*''

Many patients did ask for more information about acupuncture. They wanted to know how it works and about the side effects and benefits. A 22-year-old male patient noted:

> ''*I would like to know how big the needles are, what's the scenario that I'll be placed in when the acupuncture is going on, side effects, what could happen if it goes wrong, how am I supposed to feel afterwards. Almost kind of like when they prescribe a new medicine, and they describe the whole run down of it.''*

A 45-year-old male patient conveyed misinformation about acupuncture ''*consists of me shaving my hair off my head, I'm not doing it*'' indicating how this would affect his decision about using this therapy. Increasing awareness and knowledge was considered important by participants. A physician said, ''*People are always asking about side effects. So, if you can kind of preempt that upfront to say, these are the side effects, this is the most dangerous thing that you can experience, which is not that bad.''* Because guided relaxation does not require engaging with a professional, there were no additional concerns expressed about it.

CIH therapy preference

Providers and staff did not express a preference for either of the CIH therapies. In reference to guided relaxation, a 63-year-old female patient pointed out that patients will *''just be glad to hear something that can make you relax…I think that'll be good for the body and mind.''* Patients often framed their preference in a balanced way, as a 22-year-old male patient said that guided relaxation ''*sounds more up my alley. I would definitely pick guided relaxation over acupuncture if I had a choice. But yeah, that [acupuncture] sounds interesting...*'' Several patients expressed fears about the acupuncture needles as driving their preference. A 28-year-old woman said, ''*I don't like needles, and literally getting my blood drawn is like the worst thing ever. And I've been getting my blood drawn all my life. So, acupuncture needles, I don't know*.''

Patients often considered their previous experiences and/or ability to complete expectations with each therapy when they expressed a preference. A 32-year-old male patient said, ''*In my opinion and with experience, I have never known relaxation to help with pain*.'' Another 20-year-old female patient noted: *''I don't think guided relaxation will work for me…just like sitting still for like two minutes, like I fidget…Ma'am I have ADD, I can't do that. Like 'empty our mind,' no.''* A 24-year-old female pointed out that she already incorporates elements of guided relaxation when managing her pain. She stated,

> *''The calming and sounds and visuals, often times when I'm going through crisis, I try to talk myself into a mind over matter stage and this is very similar to that.''* She continued, *''I don't think I would have any difficulties with getting acupuncture other than like I said, with me being in more than enough pain, I probably wouldn't be able to stay still enough.''*

Access barriers

Patients and providers identified several access barriers, including time, transportation, technology, and online data plans (e.g., cellular or internet data plans). A nurse cited the many common barriers that patients have when getting regular care:

> *Sometimes patients will tell you 'Oh, I had like no transportation.' One of those is that, or 'I had no babysitter who will watch my baby.' …Another thing is, 'I had no time I'm working.*

A 24-year-old female patient commented on the duration of the therapies: *''I just think five to six weeks sound a little long… my own concerns would be for transportation and actually making it on time…''* A 36-year-old male patient described the time needed to complete the 10-session acupuncture protocol over 5 weeks this way:

> *So, I used to have a job that people would go to dialysis, and they go three times a week. Acupuncture will be my dialysis…It's like a punishment. And that's what I feel about having to go somewhere two times a week. But at the same time, I'm willing to try it because I don't know what kind of relief that will give me that two times a week.*

Because the guided relaxation intervention is delivered through the internet, both patients and providers discussed potential technology barriers. One patient, a 63-year-old woman, stated, *''I don't have the internet out here. That's why I use my phone for everything.''* A 45-year-old male said, *''Only thing I do is text on my phone and call and text people, that's it… I could barely get on this video call [for the interview].''* Additionally, a provider noted potential frustration due to internet reliability as it could impede a relaxing situation. Another provider said guided relaxation may be more accessible than acupuncture:

> *I think the guided relaxation techniques initially might work better because there's something that they can access from their phone. They don't have to go outside of the home with that. The acupuncture trying to do that twice a week for five weeks, might have a little bit more barrier because of the fact, we do have some patients that work.*

Discussion

This is one of the first studies to incorporate perspectives of both individuals with SCD and clinic providers and staff to explore health system support, acceptability, feasibility, and potential use of acupuncture and guided relaxation for SCD-related pain management. If either of these interventions are effective for treating chronic SCD pain, these data represent the first step toward producing a blueprint guiding future integration of CIH therapies into clinic care for those with SCD.

Patients with SCD are motivated to seek new options for pain relief, especially since many describe their pain as not well controlled.[13,25] Patients also voice that the initiatives in the United States aimed at reducing opioid prescribing has limited their access to opioids and negatively affected their care.[25] This nationwide response to the opioid epidemic has them urgently seeking alternative therapies, but with limited support.[25] Our study underscores that people with SCD and the SCD clinic team have a growing interest in integrating nonpharmacological CIH therapies into pain management plans. Participants were overwhelmingly open to acupuncture and

guided relaxation, which supports the high acceptability outcomes of pilot studies completed with adults with SCD.[13,25]

Our findings showed that both patients and providers had a limited understanding of both acupuncture and guided relaxation. Before these CIH therapies will be fully embraced by the SCD patient community and integrated as a part of pain treatment within the health system, there is a need to dispel myths and misinformation to increase patient and provider knowledge about acupuncture and guided relaxation. Our results are similar to Ho et al.'s that focused on integrating acupuncture into pain management for patients hospitalized with cancer.[26] They asserted that to be fully integrated into the health system, acupuncturists will need to establish trust with hospital staff and be able to adapt their explanations about acupuncture to be culturally, linguistically, and scientifically accessible to patients and the health care team.[26] A multipronged approach, including informational videos, demonstrations, and trainings, will be needed should these therapies be effective for chronic SCD pain.

Although acceptability and enthusiasm are high, several barriers related to social determinants of health will affect our trial and future health system integration of these therapies.[27] Some barriers are related to limited resources (e.g., transportation and travel costs, ability to take time off work, time spent receiving a therapy, childcare, technology, fees for online data plans) and others are specific to the therapy (e.g., older adults who may not be comfortable with mobile technology and specific travel needs for those with limited mobility). For the GRACE Trial, we made three adaptations to facilitate optimal uptake of the therapies so that effectiveness can be rigorously evaluated. First, we produced informational videos for each therapy to reduce misinformation and increase understanding. Second, we allocated a travel stipend to those randomized to acupuncture because 10 travel days over 5 weeks is intensive compared with expectations for clinic care. Third, participants without reliable technology or internet/data plans are provided with tablets and/or cellular hotspots for the duration of the guided relaxation intervention.

These access barriers are not unique to people who have chronic SCD pain and evidence-based implementation strategies will be needed to overcome these access barriers in support of heath equity.[4]

Conclusions

Our study is one of the first to explore perspectives of both patients with SCD and clinic providers and staff on the use of acupuncture and guided relaxation for chronic SCD pain. We identified four themes and several solutions that our team has used to make the GRACE Trial more participant centered. While the effects of CIH therapies on chronic SCD pain are yet to be determined, stakeholder engagement concerning these interventions is a priority. Stakeholders' early input and perspectives highlighted that they welcome CIH therapies. Our research team was able to address specific misunderstandings and implement measures to begin to overcome some of the identified access barriers.

Authors' Contributions

M.R.K., E.R., V.A.dM., and C.L.P. were responsible for data acquisition, analysis, interpretation, and drafting the article. A.A., M.O.E., and J.M.S. substantially contributed to the data analysis. J.M.S., H.L., A.Z.D., N.S., and R.E.M. critically revised the work for important intellectual content. All authors provided final approval of the version to be published and agree to be accountable for all aspects of the work.

Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCCIH or the National Institutes of Health or its HEAL Initiative.

Author Disclosure Statement

No competing financial interests exist.

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