Exploring the Impact of a Digital Behavioral Health Intervention on Pain Management and Psychosocial Support in Sickle Cell Disease: Insights from the CaRISMA Trial

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Abstract

Background: Chronic pain is prevalent among adults with sickle cell disease (SCD) and can be worsened by psychosocial factors such as depression and inadequate social support. Effective behavioral interventions (i.e., cognitive behavioral therapy, CBT) exist for chronic pain in various populations; however, few have been developed to address chronic pain in SCD. Several barriers have restricted the development and dissemination of CBT pain interventions in SCD, such as limited accessibility and time constraints. Digital interventions provide accessible and cost-effective pain management tools, offering self-management strategies, real-time monitoring, and personalized treatment options. Yet, there is limited data regarding patients' experiences with such intervention within the sickle cell population. The Comparing the Effectiveness of Education Versus Digital Cognitive Behavioral Therapy for Adults with Sickle Cell Disease (CaRISMA, clinicaltrials.gov NCT04419168) trial evaluated the effectiveness of a digital CBT intervention compared to a digital educational intervention for pain management in SCD.

Objective: This study aimed to gain a deeper understanding of the lived experiences of participants in the CaRISMA trial and to determine how to better adapt this intervention to SCD population. The study examined individuals' overall experience with the trial and their perspectives of the trial components, including a health coach, a chatbot-delivered digital CBT program, and an electronic pain diary.

Methods: Respondents were randomly selected to participate in semi-structured interviews at 1) baseline, 2) at the end of the intervention period at 3 months, and 3) post-intervention timepoint, 6 months or beyond. Interviews were audiotaped, transcribed verbatim, and analyzed using thematic analysis.

Results: A total of 48 participants (68.8% F, n=33) completed baseline interviews. Among them, 21 participants took part in mid-trial interviews, and 17 completed post-intervention interviews. Participants generally had a positive experience, highlighting the safe space the study provided to speak openly about SCD. Many found value in learning about the connection between pain and mental health, considering it an important aspect of their well-being. Feedback indicated that the health coach played a key role in offering personalized support and guidance. While the chatbot reinforced pain management strategies, its usefulness and engagement varied based on participants' prior knowledge of SCD. The pain diary helped increase self-awareness of pain patterns, but was perceived as tedious and irrelevant by those without current pain episodes.

Conclusions: The CaRISMA trial showed that participants valued the personalized support of the health coach, education about the connection between stress and pain, and the self-reflection fostered by the pain diary. These findings highlight the potential of digital, patient-centered approaches to address the multifaceted needs of SCD care. For digital interventions, the inclusion of personalized support with ongoing communication appears to be critical component that can influence treatment adherence and

effectiveness. Clinical Trial: clinicaltrials.gov NCT04419168

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Conclusion: This qualitative sub-study of the CaRISMA trial showed that participants valued the personalized support of the health coach, education about the connection between stress and pain, and the self-reflection fostered by the pain diary. These findings highlight the potential of digital, patient-centered approaches to address the multifaceted needs of SCD care. For digital interventions, the inclusion of personalized support with ongoing communication appears to be critical component that can influence treatment adherence and effectiveness.

Trial registration: clinicaltrials.gov NCT04419168
Keywords: behavioral; digital intervention; sickle cell disease; chronic pain; pain

Introduction

Sickle cell disease (SCD) is a genetic disorder characterized by recurrent acute episodes of severe pain, commonly referred to as "pain crises," and chronic pain that can persist between these episodes. The unpredictable nature of SCD-related pain, combined with the physical and emotional burden of living with a chronic illness, leads to high rates of depression, stress, and reduced social

support.[1, 2] Additionally, stress and depression can further exacerbate pain, creating a cycle in which physical and emotional distress reinforce each other. Historical pain interventions in SCD have focused on pharmacologic treatments, yet comprehensive biopsychosocial approaches that address both the physical and emotional aspects of SCD pain management remain limited. The 2019 American Society of Hematology (ASH) guidelines for the management of SCD recommend a comprehensive approach to pain management, including pharmacologic treatments alongside behavioral health interventions that address psychological and social contributors to pain.[1] Despite these recommendations, access to integrated biopsychosocial care remains limited, leaving many individuals with unmet behavioral health and psychosocial coping support needs.[3]

Digital behavioral interventions offer a promising avenue to expand access to behavioral health support, especially for individuals with chronic illnesses like SCD who face barriers to in-person care [3-7]; however, the use of digital interventions in SCD has been limited. Digital cognitive behavioral therapy (CBT) programs have demonstrated effectiveness in improving pain-related outcomes, coping skills, and mental health across chronic pain populations. However, there is limited evidence on the effectiveness and user experiences of digital behavioral health programs specifically designed for individuals with SCD, a population with unique medical, cultural, and psychosocial needs. Individuals with SCD have reported mixed experiences with available digital health interventions;some found these tools helpful for learning coping strategies and tracking symptoms, while others noted limitations such as insufficient personalization or a lack of cultural relevance to the unique challenges of SCD.[8, 9]

Clinical trials in SCD face significant recruitment and retention challenges. Insufficient patient participation is a major impediment to the advancement of SCD research, with many studies terminating due to low enrollment.[10, 11] A systematic review of 174 SCD clinical trials found that 14% were terminated specifically for failure to enroll participants, with only 35% of completed

studies resulting in published manuscripts.[12] These challenges can be particularly pronounced for behavioral interventions, which require consistent engagement and are time intensive for the participants. In collaboration with the SCD community, our group developed a digital CBT application adapted for adults with SCD to address accessibility barriers. To explore the feasibility and impact of digital behavioral health tools in SCD, our group previously conducted a randomized controlled trial evaluating our digital CBT to digital SCD and pain education developed by one of our CBO partners, both interventions delivered through the same platform and tailored for for individuals with SCD. The study demonstrated improvements in pain and depressive symptoms highlighting the potential for digital interventions to address the biopsychosocial needs of this population.[13] However, about 40% of participants did not engage with the digital interventions, revealing significant barriers to sustained participation.

To better understand the determinants of digital intervention engagment, we previously conducted a qualitative study utilizing focus groups of adolescents and adults with SCD.[7] Participants identified five key engagement factors, including the importance of peer connection, personalized content and coaching, preferences regarding the coach's background (e.g., a coach with lived SCD experience), the value of journaling and symptom tracking, and flexible engagement options.[7] These insights directly informed the design of the Cognitive Behavioral Therapy and Real-Time Pain Management Intervention for Sickle Cell via Mobile Applications (CaRISMA), trial randomized participants to of two health coach-supported interventions: digital CBT vs digital patient education.[14] Participants also completed pain diaries during the study period. All components were designed to align with the preferences and barriers identified in our prior work, with the goal of creating a flexible, patient-centered digital platform for SCD pain management. In the primary outcomes study, we found that both the CBT and education intervention led to an improvement in pain interference, however, there was no significant difference between the arms.[15] The present qualitative study aimed to gain a deeper understanding of participants' experiences

with the CaRISMA trial, focusing on their perceptions of the health coach, chatbot, and pain diary components. By identifying key factors influencing engagement and satisfaction, we sought to better understand barriers to trial enrollment and retention in the SCD population, evaluate the potential for digital behavioral interventions to address this population's unique needs, and inform the implementation of culturally sensitive, patient-centered digital health interventions for individuals living with SCD.

Methods

The protocol for CaRISMA has been previously published.[14] The CaRISMA trial enrolled adults with SCD who reported chronic pain (i.e., pain at least 4 days a week over the past 3 months or longer). Participants of the CaRISMA trial were recruited from seven comprehensive sickle cell centers and from four community-based organizations (CBOs), either virtually or in person. Participants were randomized 1:1 to either digital CBT or Education arm. Both arms had access to a health coach and a chat system via a chatbot. All participants were asked to complete daily pain assessment via an electronic pain diary application. For this qualitative study, trial participants were randomly selected for semi-structured interviews at baseline. If a randomly selected participant declined to participate in the baseline interview, another participant was randomly selected until we had achieved a total of 48 interviews. This target was chosen based on a strong likelihood of achieving thematic saturation, the point at which additional interviews are unlikely to provide new insights.[1] We aimed to recruit a diverse group of trial participants, including individuals with both high (PHQ ≥10) and low (PHQ <10) depression scores, as well as those randomized to either the CBT or patient education arms. Participants who completed baseline interviews were invited to participate in follow-up interviews at mid-trial (3 months, end of intervention) and post-primary endpoint (between 6-12 months).

Intervention components

Digital CBT. The digital CBT arm included a 12-week, tailored program designed for adults with

SCD. It taught participants how to identify negative thoughts and emotions, utilize cognitive skills and problem-solving techniques, and apply effective coping strategies. The program focused on skill development through practice, homework assignments and regular check-ins with a health coach.

Digital Education. The digital education arm included comprehensive information about SCD and pain management through an interactive digital platform. Participants learned about chronic pain, lifestyle modifications, and SCD fundamentals while reinforcing their knowledge through interactive assessments. The program encouraged active learning by enabling users to discuss concepts with their health coach.

Health Coach. Health coaches—many of whom had personal connections to SCD as patients, caregivers, or advocates—offered weekly support through phone calls or text messages, depending on participant preferences. Their primary role was to provide emotional support and encourage active engagement with the digital platform. Each coach underwent comprehensive training and attended weekly group supervision sessions facilitated by a mental health professional and research lead.

Chatbot. The CaRISMA interventions were delivered by a scripted chatbot, shown in **Figure 1**, which was developed in collaboration with patients, families, and community partners Chatbot was accessed through Facebook Messenger app and offered tailored responses, educational materials, and motivational content in various formats including videos, GIFs, and images, all adapted to participants' inputs. It also provided round-the-clock conversational support, adapting responses to each participant's unique circumstances and needs. Users were able to monitor their progress through the program, revisit materials they had completed, and view their accomplishments via progress metrics and achievement rewards.

Pain diary. Patients were asked to track pain levels daily through a mobile web app, as illustrated in **Figure 1**. They received text reminders during two-week assessment windows at the start of the study and at 3, 6, and 12 months. Between these formal tracking periods, they were encouraged to keep logging their pain scores in the app.

Qualitative Analysis

We applied a qualitative descriptive approach to data collection and analysis, aiming to directly capture and summarize participants' experiences, thoughts, and feelings related to the interview topics. This approach is frequently used in health and medical research to provide clear and practical insights.[16, 17] Here, we sought a holistic understanding of SCD patients' prior experiences with pain, depression, and treatment for either or both conditions.

Our interview guides (Appendix A) were designed to explore participants' experiences throughout the trial. Baseline interviews focused on participants' previous experiences with SCD pain management and their initial impressions of the study. Midpoint interviews gathered feedback on their experiences partway through the trial and any changes they had noticed. The final timepoint interviews sought information on durable effects and knowledge gained from their trial experiences.

Data collection and analysis were conducted by skilled qualitative researchers at the Center for Biostatistics and Qualitative Methodology's Qualitative Core, under the supervision of a qualitative methodologist. Concurrent with data collection, interviewers completed a summary template after each interview, to document key topics discussed and capture emerging themes. These summaries allowed the team to assess thematic saturation, which was achieved. A trained qualitative analyst inductively developed an initial codebook based on the content of the interviews. This draft codebook, complete with detailed code definitions, was circulated to the study team to ensure that it reflected relevant topical and theoretical themes important to the study team, as well as the content of the interviews. The codebook was slightly revised to incorporate new codes specific to themes emerging in the midpoint and final interviews.

Once codebooks were finalized, qualitative coding was completed with the assistance of MAXQDA 2022 software. For each data set, ten transcripts were co-coded and then reviewed by two independent, trained qualitative coders to ensure quality and consistency in coding. Any coding discrepancies identified were adjudicated by the coders to full agreement. The primary coder

completed the coding of the remaining transcripts following the standards established in the codebook and refined through the adjudication process. This coding served as the basis of a conventional content analysis [18], in which the primary coder prepared summaries describing participants' responses related to each interview guide domain at each time point. These summaries were reviewed by the qualitative methodologist and other study team members to identify the most relevant findings for reporting. Additional manuscripts are planned to present findings related to pain management and depression. This manuscript focuses specifically on participants' experiences with and perceptions of the CaRISMA trial. This study was approved by the University of Pittsburgh Institutional Review Board.

Results

Participant characteristics

A total of 48 participants completed baseline interviews (**Table 1)**. Of those 48, 21 completed a midpoint interview, and 17 completed a final timepoint interview following the conclusion of their interactions with CaRISMA. The mean age of participants was 36 years (SD) with majority women (68.8%, n=33). Most were recruited through clinic visits (79.2%, n=38), and 47.9% (n=32) had some college education. Over half (52.1%) were on disability with 33.3% (n=16) being employed. Of the participants, 43 (89.6%) screening positive on the PHQ-2 with mean PHQ-9 score of 10 (SD 5). As previously noted, interviews covered a multitude of topics. Here, we focus on participants' experiences in the trial, focusing on the unique aspects of the CaRISMA program, including the Health Coach, chatbot, and Pain Diary.

Table 1. Baseline demographic and clinical characteristics of study participants

Characteristic	n (%)

Age (Mean (SD)	36.1 (9.7)
Sex	33 (68.8)
Female	33 (68.8)
Male	15 (31.3)
Other	10 (20.8)
Education	
Some College or Higher	23 (47.9)
High School or Less	25 (52.1)
Employment Status	
Employed	9 (18.8)
Unemployed	14 (29.2)
On Disability	25 (52.1)
Pain interference (Mean, SD)	62 (7.2)
Average pain intensity	4.0 (2.5)
Number of pain diary entries (during 2-week reminder period)	9 (4)
Depressive symptoms (PHQ score)	
Mild (5-9)	17 (39.5)
Moderate (10-14)	8 (18.6)
Moderately severe (15-19)	12 (27.9)
Severe (20-27)	1 (2.3)

Overall experience

Most participants reported a positive overall experience with the CaRISMA study, emphasizing that it provided a “safe space” to learn and express themselves without fear of judgment. One participant mnote, “I enjoy doing it. I really enjoyed — like I said, I learned a lot. And I like the fact that I can say how I feel in a safe, safe space. […] the thing I think I appreciated the most about the study was, no matter what I say, good, bad, or indifferent, it is appreciated, and I felt safe. I can say it exactly how I feel” (P31).

Others appreciated the study’s focus on the connection between chronic illness and mental health, noting that such an approach was rare but much needed. One participant noted, “I feel like the study

went well. […] The fact that you guys thought of doing something like this to think on mental health and just treating symptoms differently, I felt like was great for the community because a lot of us did not know anything about CBT" (P68).

Additionally, several participants found the exploration of the link between pain and depression particularly valuable, highlighting the need for greater awareness of this relationship within the sickle cell community. One participant noted:

> Yeah, it was good overall. I think that I was quite impressed that there's something being studied about, you know, like taking care of the relationship between chronic illness and mental health. I hadn't seen that before so that was a good one for me. Yeah, so it was good generally. (P107)

Despite these positive aspects, participants also expressed a desire for more follow-up and reminders throughout the study. Many felt that regular check-ins and clearer communication could have improved their engagement and overall experience:

> Yeah, I feel like that's, that's, that would help the study be so much more successful or everybody's feeling on the same page, just because — I mean, not saying that it's not successful now, but I feel like, you know, if you have people checking me in frequently and letting you know, hey, you know, you had this option, this option, this option, you maybe should try it out, see if this helps, whatever. It was just it was a lack of communication. (P104)

Participants expressed mixed preferences regarding in-person versus social media-based engagement, with some valuing the sense of community and real-time connection that in-person meetings offer, while others appreciated the convenience and accessibility of digital platforms. One participant emphasized the benefits of in-person interactions, stating, "It would be nice to be in-person, you know, we all get together now" (P110). Another noted the challenges of an in-person engagement:

> Oh, I like in-person. Um, the only thing is, you know, distance, transportation, things like that, schedules of people that are working, you know. But in-person is always a good one, because you, for me, the most important thing about any person is a sense of community, um, and connection to someone else in real-time, right. But other than that, I think on, like, a walk through a study, because, you know, scheduling conflict, and time and transport and all those

things might make in-person maybe a bit more difficult. (P107)

Participants also had mixed opinions on the most effective social media platform for engagement, with some favoring Snapchat due to its AI chatbot feature, which they believed could enhance interactions and provide a more conversational experience. Others preferred Instagram, citing its widespread use and strong messaging capabilities, suggesting that a more active presence with regular updates and resources could increase engagement. Another participant recommended a separate app for the study. If a separate app is not feasible, then Instagram is the next best option:

> Yeah, I, I think, I think the app will be the best route. But if, if you couldn't, if, if it was added on other social media platform, I feel like Instagram will be a real, a real good one, because I think Instagram is probably more widely used, especially when it comes to, like, messaging. Um, so I, I think it will be, yeah, I think you'll get more of a reach on Instagram. Because I've been on CaRISMA Instagram page, and, I mean, it's, it's okay, but it don't, it don't really have [inaudible 0:37:19.1] life on it. You know, that, that will be the only thing that they will have to do is just bring more life to the page (P 68).

Others saw value in leveraging existing platforms to reach a broader audience. Overall, participants highlighted the importance of selecting a platform that aligns with user preferences while ensuring consistent engagement and accessibility.

Health Coach Experiences

Participants appreciated that the health coach had sickle cell disease *or* knew someone (e.g., a family member) who has sickle cell disease. Participants thus felt understood by the health coach. For instance, one participant said, “I just like to be able to talk to my coach, because she’s going through what I’m going through. So, it’s, it’s good to be able to talk to somebody” (P30). Another participant similarly said, “I loved it [the health coach]. It was like, you know, talking to somebody that I can, you know, relate to. Um, that was, that was a great thing. You know? Easy to communicate. You know” (P40).

Talking to someone who was knowledgeable proved to be very helpful. This led to enduring effects beyond the health coach interactions, with participant noting that they learned the importance of

talking and reaching out to someone when they are upset or in pain. In at least one case, a participant sought counseling after completion of the CaRISMA program, as a result of learning how helpful it could be to talk to someone:

> There is one thing that we did choose to implement, which was, you know, just kind of self-care and mental health check-ins, and that's something that on the side of after speaking with my CaRISMA coach about that, that's something that I decided to sign myself up for. So, I signed up for counseling through my church and we have little weekly check-ins; so that's been very helpful. […] So yes, I, I would, I would think that, that was definitely was something that, that's helpful in the event that there is a depression or anxiety episode that rises. (P53)

Participants also appreciated that the health coach was willing to be flexible when scheduling meetings, as the health coach understood the unpredictability of SCD. For instance, one participant said,

> I feel like she's […] very helpful. She's, uh, very, like, mindful of my time and my, my situation, like she understands that there are some days where I could just really just be ready to collab and have a long conversation. And then there are other days where I may not feel well and I'm not interested in really just talking on the phone, especially if I'm in the hospital or at home trying to relax. So, that's why I like; she comes in and texts and if, if we scheduled an appointment and that's not good day, she's very flexible. So, uh, I kinda like how everything is going with, with the coach that I have. (P53)

Many participants valued the fact that their health coach had personal experience with SCD, making interactions more meaningful. One participant noted, "I just like to be able to talk to my coach because she's going through what I'm going through. So, it's good to be able to talk to somebody" (P30).

Some participants lamented limited interactions with their health coach, wishing that they had more time to get to know them. For example, one participant said, "I kinda wish I had the, more time to talk to her more, so we could kinda get like a better understanding of each other" (P67). The participant added that, ideally, they would like to speak to the health coach "every week because with sickle cell stuff can change so quickly, so you never know what I could be doing this week or

what could happen next week. So, I would say, like, every week but I know, like, schedules and work and school and different stuff puts a burden on me trying to check in with her every week. So, I mean, text messages is fine, but conversation is different than texting, so, that's what I mean" (P67).

Chatbot Experiences

Most participants found the chatbot to be helpful, barring technical difficulties. Participants primarily enjoyed the chatbot if they gained new insights from it. Some participants said that the information they learned helped to reframe the way they think about their SCD. One participant found this to be an enlightening experience:

> I actually learned something new. I didn't think I was going to learn anything. […] So we know that the sickle cells are crescent shaped. […] Well, I learned that different types of, you know, genotypes sometimes the sickle cells are shaped differently. Because I have [inaudible] mine are more shaped like crystals instead of crescents. So that was new. I was like what! And I love crystals [laugh]. You know, they kind of made me like the sickle cell a little bit. Like okay, girl, we're twins! […] I really did not know that. I was like oh my God I've had sickle cell for 34 years and I did not know that" (P82).

Some participants found the chatbot helpful in reinforcing pain management strategies, while others felt it provided limited new information for those already knowledgeable about their condition. For participants who gained new insights, the chatbot was a valuable learning tool.

Some participants also noted that the insight they gained challenged certain "preconceived notions" they held about SCD:

> Um, yeah, there's been…um, information that I…probably didn't think about…before. On that. And, that you had, um — you know, it's just like you think this is logically, this is certain information you had in your head about stuff, and you find out that, oh, my god, that they makes sense, this, this — do you understand what I mean? […] Okay. So, if I had a preconceived notion on a particular aspect of sickle cell; I don't know, if for any reason like…it could be like an old wives' tale. And then, on looking, going through that I get a different information and I'm like, oh, that makes sense; why did I ever think this is what it was? Yeah, that's what I mean. (P69)

In contrast, participants who did not find the chatbot to be helpful reported that it did not teach them anything new. The participant explained that the chatbot was more useful for "people who […] don't

know much about their own disease":

> To be honest, I think it was more unhelpful to me, because the questions that it asked are, are questions that I already know the answer to. Does that make sense? Like, um, some people don't know what kind of sickle cell they have, or they don't know their triggers or, or things like that. And my mom taught us growing up, like, to be able to speak for yourself when you went to the doctor, so I know what kind of sickle cell I have. I know — you know what I'm saying — my triggers, I know, um, my medications and the dosages and stuff like that. So, it would be helpful for some people who aren't really, I guess who don't know much about their own disease. Does that make sense? But I…I think I know my disease and my body pretty well to where that was, it wasn't helpful to me. (P80)

Frequently, participants who did not use the chatbot suggested that it should take a more proactive role in encouraging participants to interact with it, rather than relying on users to engage on their own. For example, when asked what would improve their use of the chatbot, one participant asked for a reminder: "Train the bot to just kind of reach out and be, like, 'Hey, you haven't answered the question or asked a question in a couple days; is everything good or would you like to resume"-type thing" (P39). The need for reminders was particularly salient for anyone who did not regularly interact with Facebook Messenger outside of the study, and might therefor not see it in the course of their day.

Pain Diaries

One participant added that filling out the pain diary—and being able to show the pain diary to their healthcare providers—was very helpful:

> And also, to see that part in the, in the study where they was asking, like, how you feel, like that was, that's something I wish was everywhere, honestly; I wish I had that everywhere. I wish you could, like, show the doctors how you feel and whatnot, because even if they did put it everywhere, I feel like if it was standardized, they probably would know how to deal with different pain levels, you know, and, and that would probably be able to help them structure, um, medication doses. Like I feel like that would be so helpful cuz they can see it, and it's not more of you trying to struggle and explain it to them; they already see it; they know exactly how this is affecting you. This is, this is what works for them, many other warriors on this level; let's give them the same — and I'm telling you, I feel like it would be so helpful. I feel like that needs to be implemented in every hospital for every, every person just — or not anybody. Um, but yeah, I, I, I think that was probably the, the biggest thing for me. (P68)

Some participants found completing the pain diary daily redundant or tedious, particularly on pain-free days, leading them to develop their own strategies to manage this task. One noted:

> To me personally because it would come every day. I would get the email for it every day. And at a certain point it felt redundant if I wasn't in pain for a few days or weeks at a time. Having to fill it out every day. So it got to the point where if I had pain I would say okay yeah I'll go fill it out now. Instead of every day putting no pain" (P115).

Some participants appreciated completing the pain diary daily, even on pain-free days, as it allowed them to track their symptoms and emotions. It also helped them reframe their experience, reminding them that not all days are "bad" and that pain episodes eventually subside. For example, one participant stated:

> I mean, I like the pain diary because then it shows me, like, you know, what I write. Pretty much write down everything on my own. To do it every day just to know okay I'm feeling bad this day but this day I was okay. So that kind of helps" (P104).

Participants also appreciated having a record of their pain and pain medication usage. As one participant described it:

> Not that I enjoy, but I do look forward to the daily pain diary; it just, it does make me stop and think about, you know, what pain I'm in and have I taken meds and do I, you know, what can I do to not decrease but to minimize the pain and, in turn, minimize, I guess, the amount of medication. So that is helpful" (P58).

Thus, participants felt that the pain diary helped to increase their awareness of their pain, feelings, helping them make more informed decisions about their pain management strategies.

Discussion

Digital health interventions have emerged as a promising tool to enhance chronic pain management and coping. Based on feedback from people with lived experience, we designed the CaRISMA trial to equip adults with SCD with the tools, resources, and support systems necessary to improve long-term chronic pain outcomes. To our knowledge, the CaRISMA trial is the first study to evaluate the effectiveness of a peer-supported digital CBT intervention for chronic pain management in adults with SCD. In the primary CaRISMA trial, we found that both digital interventions (CBT and Education) resulted in improvements in the primary pain outcome, pain interference, at 6 months. [15] Additionally, greater engagement with health coaches was associated with greater improvements in pain interference (manuscript pending submission). The current qualitative study bolsters our

understanding of the CaRISMA digital intervention by exploring participants' overall experiences with the interventions and their key components, including the health coach, chatbot, and pain diary.

Overall Experience

Overall, participants reported a positive experience with the CaRISMA trial, appreciating the safe space provided for open discussions and the opportunity to learn about the connection between pain and mental health. While some participants indicated a preference for face-to-face interactions, many acknowledged potential obstacles including transportation difficulties, conflicting schedules, and physical health restrictions. The reported challenges are consistent with previous findings demonstrating that in-person meetings may be less feasible for individuals with chronic conditions like SCD and highlight the critical role of digital interventions.[19] Regarding the delivery platform, some participants valued engagement via social media (e.g., Facebook, Instagram), appreciating its convenience, accessibility, and ability to provide on-demand support. Participants also had varying opinions on which social media platform would be most effective, with some favoring Snapchat due to its chatbot feature, while others preferred Instagram for its broad user base and messaging capabilities. Given the evolving nature of social media, leveraging multiple digital platforms may enhance engagement by catering to diverse communication preferences. Alternatively, considering the shifting landscape of social media usage, consolidating resources into a single, dedicated application, separate from social media, could provide a centralized and streamlined user experience. This finding is supported by results from the iCanCope, a randomized trial in which younger participants were more likely to engage with a dedicated mobile app than a web-based CBT platform.[6] These findings highlight the importance of offering flexible, accessible digital health interventions that accommodate the unique needs, preferences, and logistical challenges faced by individuals living with chronic conditions like SCD.

Health Coach Experience

Participants strongly valued their health coach's lived experience with SCD, highlighting the need

for culturally concordant and condition-specific health coaching. In other chronic disease populations, tailored peer support has contributed to enhanced trust, self-efficacy, satisfaction, engagement, and adherence by offering emotional support, shared experiences, and practical guidance.[20-22] In the CaRISMA trial, many participants appreciated that their health coach had SCD or personal connections to someone with SCD, which contributed to feeling understood and supported. Some participants also reported that interactions with their health coach motivated them to seek mental health counseling, demonstrating the intervention's potential for long-lasting impact that possibly extends beyond pain management.

Participants valued the health coaches so much that some desired more frequent interactions. For example, some participants said weekly check-ins would have helped them feel more supported. We designed the CaRISMA program to consist of weekly check-ins; however, the unpredictability of pain episodes for both participants and health coaches interfered with check-ins. Our findings are aligned with previous studies demonstrating that more frequent, flexible check-ins improve engagement and adherence in chronic disease populations. [23, 24] To optimize future interventions, health coach check-ins should be frequent and adaptable, incorporating scheduled and on-demand support. A multi-modal approach, incorporating text messages, phone calls, and video check-ins, could help meet individual needs.

Chatbot Experience

The chatbot received mixed responses; some participants found it helpful for reinforcing pain management strategies, while others felt it provided limited new information. Digital interventions incorporating chatbots have been recognized as an effective way to deliver behavioral coaching, track symptoms, and strengthen patient engagement.[25] In the CaRISMA trial, the chatbot provided an on-demand resource for pain management education, symptom tracking, and self-care recommendations. While some participants had a positive or eye-opening experience with the feature, others suggested that the chatbot should be more proactive, initiating conversations and

providing reminders rather than waiting for users to engage. Previous research highlights that adaptive, AI-driven chatbots that tailor responses based on user engagement and knowledge levels improve overall effectiveness in digital health interventions. [25, 26] This approach could be incorporated into future digital interventions for adults with SCD.

Pain Diary Experience

The pain diary helped some participants track pain trends, but others found it redundant and unnecessary on pain-free days. Daily pain diaries are widely used in both SCD and broader chronic pain populations to monitor pain patterns and inform treatment strategies. In previous studies, patient experiences with these diaries have varied, reflecting both benefits and challenges. For instance, in the Pain in Sickle Cell Epidemiology Study (PiSCES), 60% of participants submitted fewer than five months of the expected six months of pain diaries, indicating challenges in sustained daily reporting. [27] In the CaRISMA trial, some participants mentioned that tracking their pain helped them gain perspective on their condition, allowing them to recognize that not every day was a “bad” day. This is a sentiment echoed in prior research on digital self-monitoring tools for chronic pain.[8, 28] However, others recommended the use of the pain diary only when participants’ are experiencing pain. Research has shown that user fatigue is a common barrier to adherence in digital health interventions, particularly when data entry is required daily without immediate benefits.[8, 29, 30] To enhance usability, customizable pain tracking options, allowing participants to self-select tracking frequency might be helpful. Additionally, integrating mood tracking and other symptom assessments alongside the pain diary may provide a more holistic view of well-being.

Clinical Implications and Future Interventions

This study highlights the importance of tailoring digital behavioral health interventions to the unique needs of individuals with SCD, an underserved pain population. The findings suggest that a multi-component approach, integrating health coaching, chatbot support, peer engagement, and self-monitoring tools, can enhance engagement and effectiveness. Future trials should consider the

following recommendations: 1) enhanced health coaching that involves frequent and flexible coach check-ins, including on-demand support, to improve participant engagement; 2) an adaptive and interactive, chatbot that offers personalized education based on an individuals' knowledge, needs, and preferences; and 3) flexible and customizable self-monitoring tools, such as pain diaries, that allow users to adjust tracking frequency.

This study has several strengths. First, it examines participant experiences across multiple intervention components and provides a comprehensive understanding of how each element contributed to engagement and pain management. Second, it assesses participants' willingness and ability to use a mobile pain-tracking platform in a real-world setting, offering valuable insights for the design and implementation of future digital health interventions. However, the study also has limitations. First, this study does not account for participants' underlying mental health conditions or how these factors may have influenced their responses to the interventions. A deeper understanding of these variations could help refine and personalize future interventions to better address individual needs. Second, while we randomly selected participants for the qualitative interviews, there is a possibility of selection bias as not all invited participants agreed to participate. A total of 115 randomly selected participants were contacted to achieve our interview sample of 48. It is possible that factors beyond our control affected participant willingness to speak with us (e.g., those with particularly strong feelings about the trial, or those who were not experiencing a pain crisis when we attempted to reach them), potentially affecting the data collected. Similarly, some participants declined or did not respond to outreach attempts for midpoint and end of study interviews. While no clear patterns were observed in those who declined, it is possible that those who opted out differ in meaningful ways from those who participated.

Conclusion

Overall, participants found the CaRISMA program to be a supportive space for learning, self-

reflection, and symptom management. Digital interventions offer a scalable and accessible approach to addressing pain care disparities within the underserved SCD population. Regular, proactive communication emerged as essential for participant engagement, with inconsistent interaction likely contributing to dropout rates in this and similar studies. Future digital interventions should prioritize regular communication between participants, health coaches, and research teams to enhance retention and overall effectiveness. Additional research should focus on developing culturally appropriate, patient-centered, and adaptable interventions that address the diverse needs within the SCD population.

Acknowledgement

This study would not have been possible without the support of the sickle cell warriors who participated in the CaRISMA trial.

Conflict of interest: Dr. Charles Jonassaint has ownership in the company that develops the Painimation app, one of the exploratory outcomes measures for the trial.

Abbreviations
ASCQ-Me: Adult Sickle Cell Quality of Life Measurement Information System
CaRISMA: Cognitive Behavioral Therapy and Real-Time Pain Management Intervention for Sickle Cell via Mobile Applications
CBT: Cognitive Behavioral Therapy
CBO: Community-Based Organization
ED: Emergency Department
GAD: Generalized Anxiety Disorder
HRQoL: Health-Related Quality of Life
JMIR: Journal of Medical Internet Research
NIH: National Institutes of Health
PHQ: Patient Health Questionnaire
PROMIS: Patient-Reported Outcomes Measurement Information System
SCD: Sickle Cell Disease
UC: Usual Care
VOE: Vaso-Occlusive Episode

Appendix A. Semi-Structured Interview Guides

Baseline Interview guide

Today, we'll be talking about your experiences with sickle cell anemia, pain, depression, and treatment for those conditions. I'm going to ask about each of those individually, and then we'll have

some questions about this trial specifically.

To begin with, tell me about what it has been like living with sickle cell anemia. You can tell me about this in any way that you would like.

Now, tell me about the pain that you have experienced with SCA.

How does your pain affect your life?

What treatments have you used to treat your pain?

Tell me about your experiences using narcotics to treat your pain.

- How easy or difficult is it to access narcotics to treat your pain?
- Do you experience any stigma from healthcare providers or from friends or family as a result of using narcotics for your pain?
- Is there anything that you don't like about using narcotics to treat your pain?
- Is there anything about using narcotics to treat your pain that you think is valuable?
- How do you think that the opioid epidemic in this country has influenced your ability to access narcotics for your pain?

Are there any other ways that you cope with your pain?

Now, I'd like to talk about your experiences with depression. Would you describe yourself as depressed? Why or why not?

If you've been depressed, how has that affected your life?

How has it affected the pain that you experience from your SCA? Do you think that the pain and depression affect each other at all?

Has your depression ever affected your treatment for SCA? What about your pain from SCA?

Have you ever had any behavioral treatments for any condition – i.e., depression, for another issue or condition, or for your pain? By behavioral treatments, I mean anything that isn't a medication, like talk therapy.

If yes: How did you feel about that treatment? Was it helpful?

For everyone: What do you think about behavioral treatments in general?

As part of this study, you'll receive a form of behavioral treatment for your SCA pain, delivered to you via a smartphone. What are your thoughts about participating in behavioral treatment as part of this study? What are your thoughts about participating in it through a smartphone?

Have you had any interactions with your health coach yet? If so, tell me what those interactions have been like?

What, if anything, has been helpful about talking with them?

Is there anything that you don't like or would change about your interactions with your health coach?

Lastly, I'd like to ask about your decision to take part in this study. What made you want to participate? What are your hopes about what might happen as a result of being part of this study?

Have you ever participated in a study related to SCA before? If so, what was that like? Based on that experience, is there anything you think we should do, or should avoid, as part of this study?

That was my last question. Is there anything else that you think we should know?

3-month interview guide

First, tell me what you thought of the CaRISMA trial in general.

Do you feel that participating was helpful to you?

Did you have any problems at part of the trial?

Tell me about your interactions with your health coach?

What, if anything, was helpful about talking with your health coach?

What, if anything, did you not like or would you change about those interactions?

Now, I'd like to ask about the treatment you received. It is my understanding that you received (CBT/m-Education).

Tell me about your experiences with the CBT/m-Education?

- What did you think about the treatment in general?
- How did you feel about doing it on your phone?
- Has it helped you to manage your pain?
- What about your depression?
- Was there anything that wasn't helpful, or that you didn't like?
- Can you tell me one strategy or tip that you learned from it, that you've used?

Are there any strategies or tips that you have not used? Is there any reason you didn't use it?
Was there anything about CBT/m-Education that surprised you, or that you weren't expecting when you started?
Do you think any differently about behavioral treatments like CBT/m-Education than you did when you started?
Do you think that other people with SCA should receive CBT/m-Education to help them with their pain? Why or why not?
Next, I'd like to ask you about your experiences with SCA-related pain since starting this study. How has your level of pain and how you feel about it been in the last few months?
Have you had any pain crises since starting the study?
Did you deal with that any differently than you have in the past?
Have you used any narcotics to manage your pain in the last few months?
Was that experience any different than it was before participating in the study?
What, if anything, has motivated you to keep participating in this study?
Based on this experience, would you be willing participate in research again?
Can you tell me more about why or why not?
What, if anything, do you think this study has done well?
Is there anything the study could have done differently to improve your experience?
Are there any questions that you have about your SCA, or pain and pain treatment, that you wish we had better answers to?
That was my last question. Is there anything else that you think we should know?

6-12 month interview guide

Today, we're going to be talking about how you've continued to use what you learned in CaRISMA (or how and why you haven't), as well as how you are doing today.

You've now been done with the CaRISMA trial for (time period). As a reminder, CaRISMA was the

study where you received CBT/m-Education, and had a health coach, to help you with your SCA pain.

I'd like to ask you about your experiences with SCA-related pain since you completed the study. How has your level of pain been in the last few months?

How have you been dealing with your pain during this time period?

Have you had any pain crises since you stopped participating in the study?

If yes, how did you deal with that crises?

Did you deal with that any differently than you have in the past?

Have you used any narcotics to manage your pain in the last few months?

Was that experience any different than it was before participating in the study?

Have you been depressed at all since leaving the study? If so, tell me about what that has been like for you.

Have you used any of the strategies that you learned in CBT/m-Education to manage your pain since leaving the study? (if no, skip to next question)

If so, what strategies did you use?

What about to manage your depression? If so, what strategies did you use?

Have you used anything else that you might have learned from your health coach to manage either depression or pain since stopping the study? If so, what did you use? (if no, skip to next question)

Are there any strategies you have *stopped* using since leaving the study? If so, what are they? When did you stop using them? Are there any reasons you stopped using them?

Is there anything that you think this study did particularly well?

What, if anything, do you think that you think this study should have done differently?

Are there any questions that you have about your SCA, or pain and pain treatment, that you wish we had better answers to?

That was my last question. Is there anything else that you think we should know?

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Supplementary Files

Figures

CaRISMA components including chatbot interaction (left) and pain diary tracking (right).