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Acceptability and Feasibility of a Mindfulness-based Intervention for Pain Catastrophizing among Persons with Sickle Cell Disease

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Abstract

Purpose: Few investigators have developed and tested non-pharmacological interventions for helping persons with sickle cell disease (SCD) manage persistent pain. The purpose of this pilot study was to examine the feasibility and acceptability of a mindfulness-based intervention (MBI) in adults with SCD and chronic pain, and to gather preliminary data on its efficacy.

Design and Methods: Data on feasibility and acceptability, including recruitment, retention, and attendance rates, were collected during a single-site, randomized control trial (RCT). Participants were randomized to either a 6-session group telephonic MBI or a wait-listed control. Pain catastrophizing was assessed at baseline and post-randomization weeks 1, 3, and 6.

Results: Seventy-eight adults were recruited; 18 (23%) declined to participate; 60 were randomized to either the MBI ($N=40$) or control ($N=20$). Of those, 14 (35%) from the MBI and 12 (60%) from the control group withdrew immediately after randomization, resulting in 34 evaluable cases (MBI: $N=26$; control: $N=8$). Among the 26 assigned to MBI, the median number of sessions attended per person was four; seven (27%) attended all six sessions. Qualitative findings indicated that MBI participants viewed the program as acceptable and liked the telephonic format, community, and content. Reductions in pain catastrophizing outcomes were observed post-intervention.

Conclusions and Clinical Implications: A MBI is feasible and acceptable for persons with SCD experiencing chronic pain. A larger RCT to establish MBI efficacy on pain and related outcomes for SCD will provide nurses and other clinicians caring for persons with SCD and chronic pain non-pharmacological, behavioral pain management options.

Keywords

pain management; sickle cell disease; interventional pain management; chronic pain

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Background

Persons with sickle cell disease (SCD) experience a variety of acute and chronic complications, with chronic pain being one of the most prevalent and challenging to manage. Estimates show that at least half of individuals with SCD experience chronic pain (Smith et al., 2008) and 78% use long or short-acting opioids for management (Smith et al., 2015). Frequently, persons with chronic pain in SCD often engage in pain catastrophizing, defined as pain-related rumination (constantly thinking about the pain), helplessness (feeling as if one can do nothing about the pain), and magnification (exaggerating the pain from uncomfortable to unbearable), which is associated with increased pain intensity, pain behavior, analgesic consumption, frequency and duration of hospital visits, and reduced daily activities (Bakshi, Lukombo, Belfer, & Krishnamurti, 2018; Finan et al., 2018; Painpinto & Bonner, 2012; Sanders, Labott, Molokie, Shelby, & Desimone, 2010). Given the significant negative impact of chronic pain on quality of life and health outcomes among patients with SCD, there is a great need for more pain management options, particularly non-pharmacological behavioral approaches, in this vulnerable population.

To date few non-pharmacological behavioral interventions have been trialed specifically for persons with SCD (Williams & Tanabe, 2016). This is a significant gap and inconsistent with recent pain management and opioid prescription guidelines from multiple sources. In 2016, the Centers for Disease Control and Prevention (CDC) recommended non-pharmacologic therapy and non-opioid pharmacologic therapy as the first lines of pain management therapy. If opioid therapy is deemed necessary and prescribed, the CDC guidelines recommend combining opioid therapy with a non-pharmacological approach, such as cognitive behavioral therapy (CDC, 2016). While the CDC recommendations clearly state that they do not apply to SCD, and National Heart, Lung, and Blood Institute (NHLBI) recommendations should be followed, they do speak to the current opioid crisis and need for non-pharmacologic options for persons suffering with chronic pain. Along similar lines, the National Institutes of Health Interagency Pain Research Coordinating Committee (IPRCC) published the National Pain Strategy, which emphasized the need for developing “integrated, multimodal, and interdisciplinary treatments” for chronic pain, and improving access to high-quality pain services for vulnerable populations, such as those with SCD (IPRCC, 2016). In 2014, the NHLBI published treatment guidelines for SCD-associated pain (NHLBI, 2014). This report noted that, while adding non-pharmacological approaches to manage chronic pain in SCD may be helpful, the quality of available evidence to support the use of non-pharmacological pain treatments for persons with SCD is currently very low and more research is needed in this area.

There are a number of reasons why SCD-associated pain is a particularly appropriate model in which to test a MBI. Patients with SCD have been shown to catastrophize more than patients with other types of chronic pain, and importantly, this catastrophizing is context specific (Mathur et al., 2016). MBIs, which include mindfulness meditation, teach the individual to refocus the mind on the present moment by anchoring to the breath, movement (e.g., walking), or a word or phrase (e.g., lovingkindness meditation); this approach allows the individual to reframe present experiences (Keng, Smoski, & Robins, 2016) thus addressing context-specific influences on pain. Moreover, neuroimaging studies (Brewer &

Garrison, 2014) have shown that MBIs affect the functioning of the cingulate cortex, which is responsible for emotion formation and self-referential processing, or rumination, one of three aspects of pain catastrophizing. Other imaging studies have shown that MBIs reduce activation of the thalamus, which is the key structure in the brain that modulates pain (Zeidan et al., 2011). Studies of chronic pain in SCD demonstrate that there is a time effect, such that pain catastrophizing leads to increasing sensitization and a lowered threshold for pain crises (Mathur, et al., 2016). MBIs may mitigate the time effect by increasing focus on the present as opposed to past experiences or future worries. Lastly and importantly, a recent systematic review of MBIs for pain found that MBIs were associated with small improvements in pain, depression, and quality of life (Hilton et al., 2017). However, none of the 38 RCTs investigated MBIs for SCD-associated pain. Thus, despite the potential benefits of MBIs, the generalizability of this approach for persons with SCD experiencing chronic pain is unknown and necessitates further investigation.

There is a clear need for validated, non-pharmacologic pain management options for patients with SCD, and MBIs may fill this important gap. Thus, the purpose of this pilot randomized control trial (RCT) was to examine the feasibility and acceptability of a telephonic MBI for adults with SCD and chronic pain. We also explored the effect of MBI on pain catastrophizing, which has been commonly used as a clinical outcome in determining the success of interventions that target chronic pain (Ezenwa et al., 2018; Martin et al., 2018).

Methods

This study was registered with [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02394587) (NCT02394587), and received institutional ethics board approval. A protocol paper published previously described the methods in detail (Williams, Silva, Simmons, & Tanabe, 2017). In brief, we conducted a single-site, unblinded, pilot RCT examining feasibility and acceptability in the context of a study comparing a telephonic MBI program to a wait-listed control condition in adults with SCD and chronic pain. Participants were recruited over a 7-month period from an outpatient, comprehensive, interdisciplinary SCD center in the Southeast. Recruitment strategies included meeting with potential participants in person before and after clinic visits and using mailed opt-out letters with phone follow-up. Eligible participants were those who: (a) self-reported a diagnosis of SCD, (b) were at least 18 years of age, (c) self-identified as having chronic, non-cancer pain that persisted on most days for at least 6 months and adversely affected function or well-being, (d) could speak, understand, and read English, (e) had access to phone (cell or landline), and (f) had access to a CD or mp3 player for home practice. Exclusion criteria included: (a) having previously participated in a MBI (e.g., mindfulness-based stress reduction, mindfulness-based cognitive therapy or intervention); or (b) being a regular practitioner of mindfulness, including yoga.

After providing informed written consent, participants were randomly assigned via computer to either the MBI or wait-listed control group using a sequential block randomization. Using a 2:1 treatment allocation, eligible participants in each sequential block of 15 were assigned to either MBI ($n=10$) or control ($n=5$). A total of four blocks of 15 participants was used to randomize 60 adults (40 MBI, 20 control). All participants were assessed at baseline, prior to initiation of treatment, and weeks 1, 3, and 6, which corresponded to sessions 1, 3, and 6

of the MBI. Enrolled participants had the option to complete assessments either online or via mailed paper forms after they were randomized, and, after leaving the clinic.

Within two weeks of randomization, those assigned to the MBI started the program, which included six weekly, 60-minute telephonic group classes led by the same certified MBI instructor with over 10 years of mindfulness instructional experience, including two years leading telephonic groups and group-based MBIs for research. The MBI was developed in consultation with experts in clinical management of SCD (e.g., pain management providers, social workers, psychologists) and mindfulness clinicians. An iterative process that matched the needs of persons with SCD and chronic pain (e.g., common symptoms, emotions, and stressors) to MBI topics and skills resulted in the following six sessions: (1) breath awareness, (2) body scan, (3) walking meditation, (4) loving kindness, (5) choiceness awareness, and (6) overview and conclusion. (See *Authors Omitted for Blind Review* for a more in-depth description of this iterative process, the link between the six sessions and the original MBSR program, and session descriptions.) Loving-kindness was included as a skill based on studies suggesting that mindfulness and compassion are interrelated (Tirch, 2010) and Cullen's (2011) work on mindfulness-based interventions, which describes the "broader use of mindfulness [that] could be widened even further to include the four *brahma viharas*" (sublime states), one of which is loving-kindness (p.187). All sessions were constructed to spend the same amount of time on learning new mindfulness skills, practicing mindfulness, and questions and answers. Wait-list control participants received usual care from the SCD clinic and had the option to take the MBI upon completion of their study participation. Retention strategies for intervention participants included reminder texts, calls, or emails (their choice) the morning of each session with the session time and call-in number. Retention strategies for all participants included monetary compensation of \$10 after receipt of baseline assessments or participation in the first MBI session, \$20 after receipt of week 3 measures or participation in MBI session 3, and \$30 after receipt of the follow-up measures or participation in MBI session 6. Additionally, study staff contacted all participants weekly to bi-weekly to remind them of their study participation, upcoming due dates for assessments, and when compensation checks had been mailed to their home address.

Measures

Feasibility.—We evaluated feasibility based on the ability to recruit, enroll, randomize, and retain participants. Specifically, we examined the number of individuals: (a) recruited, defined as screened for eligibility; (b) enrolled, defined as consented; and (c) randomized, defined as consented individuals who met the eligibility criteria and were randomized to a treatment group. Among those randomized to receive MBI, we examined: (a) intervention completion, determined by number of intervention sessions attended.

Sample Characteristics.—At baseline, participants self-reported demographic and clinical characteristics, including their gender, age, race, SCD genotype, annual household income, education, hospital utilization per person (e.g., number of emergency department [ED] visits and hospital admissions over the last two years), and disease-related complications (e.g., stroke, acute chest syndrome, vaso-occlusive crises).

The Pain Catastrophizing Scale (PCS).—The PCS (Sullivan, 2009; Sullivan, Bishop, & Pivik, 1995) was included to assess pain catastrophizing across the six weeks, and obtain preliminary data on the efficacy of the MBI program. The PCS is a 13-item instrument that asked respondents to rate on a 5-point Likert scale ranging from 0 (not at all) to 4 (all the time) statements like: “I worry all the time whether the pain will end;” and “I anxiously want the pain to go away.” Total scores range from 0 to 52, with higher scores indicating greater pain catastrophizing. A total score of 30 or higher represents clinically significant catastrophizing (Sullivan, 2009; Sullivan et al., 1995). Additionally, we examined the three subscales of the PCS: (a) rumination (4 questions, range=0 to 16), which measures how frequently someone thinks about their pain; (b) magnification (3 questions, range=0 to 12), which measures the degree to which someone thinks the pain may cause a more serious problem; and (c) helplessness (6 questions, range=0 to 24), which measures the degree to which someone thinks they cannot do anything to improve the pain. Each of these three constructs coincides with elements of mindfulness practice.

Acceptability.—We qualitatively assessed acceptability of the MBI program using telephonic, semi-structured interviews (Creswell, 2008). Within each of the four blocks of 15 participants, 2–3 participants who completed at least one MBI session were randomly selected to take part in a brief phone interview within two weeks of the final MBI session. The interview included questions regarding barriers and facilitators to participation, benefits observed for pain and quality of life, content liked most and least, perspectives on home practice, and intentions to continue practicing mindfulness (citation omitted for blind review). Responses to these questions were deemed “acceptable” if the majority of participants responded positively to these questions.

Data Analysis

Statistical Analysis Software (SAS 9.3, Cary, NC) was used to conduct all statistical procedures for quantitative data. When statistical significance testing was conducted, nondirectional tests were performed with the level of significance set at 0.05. Feasibility measures, sample characteristics, and PCS pain catastrophizing for individuals with data (evaluative cases) were summarized using descriptive statistics. Wilcoxon Two-Samples Test and Fisher’s Exact Test were used to test for demographic and clinical differences at baseline in the MBI and control groups. We also examined the trajectory of change in the PCS total scores and subscale score across the four assessment points (baseline, week 1, 3, and 6) using descriptive statistics. Because the number of evaluative cases ($N=34$, Figure 1) was smaller than the target sample size of 60, we did not conduct the planned mixed-effects longitudinal analysis to test for a significant difference in change in pain catastrophizing in those assigned to MBI compared to controls.

Qualitative content analysis using an inductive, data-driven approach (Crowe, Inder, & Porter, 2015) was used to analyze the acceptability data from the semi-structured interviews. Digital recordings were transcribed verbatim and imported into *Atlas.ti* software (*version 7, n.d.*). Study personnel familiar ($n=3$) with the content of the MBI initially read the transcripts and extracted and coded those text passages that appeared relevant to the research

questions into themes or sub-themes. Discrepancies were resolved in a group meeting and the themes finalized.

Results

Sample Characteristics

Table 1 presents the baseline characteristics for the 34 evaluable cases. The average age was 36.8 years (range: 20 to 65), 38% were male, 62% were SS genotype, and 100% indicated African American/Black. For each person, the median number of: (a) ED visits was 4; (b) hospital admissions was 3; and (c) SCD-related complications was 3 during the past two years. The median PCS total score was 16, with observed scores ranging from 3 to 51. The MBI and control group did not differ significantly with regard to baseline demographics and clinical characteristics.

Feasibility

A total of 78 adults with SCD and chronic pain were approached and screened over a 7-month recruitment period, and 18 (23%) declined to participate for various reasons, including time constraints (most common reason) and pain that was verbalized by the patient as either ‘currently controlled’ (reported they did not need or desire additional support) or ‘too significant’ (reported pain was too intense to participate in a study) (Figure 1). All participants were recruited in-person at the SCD center after clinic visits with none recruited via mailed letters. The 60 participants who agreed to participate were subsequently consented, enrolled in the study, and randomized to either the MBI ($N=40$) or control ($N=20$) group.

Only 34 of the 60 individuals randomized (57%) were evaluated. A total of 26 (43%) did not provide any baseline or follow-up assessment data. Among the 40 randomized to MBI, 14 (35%) dropped out and never attended any MBI sessions. One MBI participant withdrew due to religious conflicts, and 13 were lost to follow-up and could not be contacted. Of the 20 control participants, 12 (60%) discontinued the study with 11 lost to follow-up. Thus, the analysis sample included 34 adults with SCD and chronic pain who were randomized to a treatment group and completed the baseline assessment. Among the 34 evaluable cases, 26 were assigned to MBI and 8 were assigned to the wait-list control group.

Table 2 presents the percent of participants attending each MBI session for the 26 evaluable cases randomized to the MBI program and the percent of MBI evaluable participants attending zero to six sessions. Over 60% of the 26 participants attended each session, with the exception of Session 5, which focused on sensory awareness. Three participants (11.5%) provided baseline assessment data but did not attend any sessions, whereas, seven participants (27%) attended all six sessions. The median number of sessions attended per person was 4, with 57% ($n=15$) present at four or more of the six sessions. Sixteen of the 26 MBI (62%) participants and 6 of the 8 controls (75%) completed the final PCS assessment at week 6.

The Pain Catastrophizing Scale (PCS)

Table 3 presents the median PCS total and subscores at each of the four assessment points during the six weeks for the MBI and control groups. For the control group, there was a slight increase in median PCS total and helplessness subscale scores from baseline to week 1, and then a decrease between week 1 and week 6. In addition median magnification and rumination subscale scores slightly decreased between baseline and week 6 for the controls. For the MBI group the median for the PCS total and subscale scores increased from baseline to week 1, and then decreased over subsequent weeks for all four PCS outcomes.

Acceptability

Qualitative interviews were conducted with nine (34%) of the MBI evaluable cases who were selected randomly. This interview sample consisted of six females (75%), with a mean age of 38 years. At baseline, their average total score on the PCS was 11 (SD 6.9, range 7 to 19). Table 4 presents the two overarching themes that emerged from the analysis, intervention structure and intervention effect, subdivided into seven and three categories each with representative quotations. The quotations have not been edited in order to retain the free, spontaneous nature of the participant responses.

Intervention Structure.—Participants identified seven key themes related to the structure of the MBI: (1) the communal aspect, (2) the remote delivery, (3) the reminders about class, (4) the time, (5) the content, (6) barriers to participation, and (7) suggested modifications. Participants reported enjoying the community aspect of the MBI. They were able to converse with other persons with SCD and chronic pain, listen to their experiences, and be reminded they are not alone. The group also helped participants generate ideas on how mindful exercises (e.g., breath awareness) could be implemented in their daily lives. Participants appreciated the remote delivery via telephone, noting that the call-in process was easy, they could hear each other's voices, and the format facilitated participation that they otherwise would not have been able to achieve due to barriers like transportation, disability, and child care. Participants noted that individualized text and email reminders the day of each mindfulness session facilitated participation, because they did not have to remember when to call or what number to dial. Most participants believed that 1-hour sessions were sufficient to learn concepts and meditation skills, although one participant thought longer sessions would have been helpful. Participants had varying opinions about what time the intervention should occur, but all agreed that afternoons were better than mornings. There was general support for the content and exercises taught. Most participants viewed the mindfulness exercises as useful. However, several participants commented that they did not have time to perform the mindful eating exercise and another did not enjoy the loving kindness exercise, but was able to recognize how it could be helpful to others. Participants described very few barriers, and those that were described were specific to the participant versus an issue with the MBI that was applicable to others. As noted above, the most common barrier was the day and time of the intervention not meeting everyone's needs or preferences. Participants suggested only a few modifications, such as including teenagers and younger individuals with SCD, adding 'levels' to the intervention that a participant can progress through, and including visualization exercises.

Intervention Effects.—There were three identified themes regarding intervention effects. These included: (1) pain, (2) emotion regulation, and (3) practice. Participants noted mixed effects of the MBI effects on pain. Two participants stated that the MBI was only helpful for acute pain, three participants described it as being helpful for acute and chronic pain, and one person described it as being somewhat helpful for generalized pain. One participant reported experiencing increased acute pain associated with the body-scan exercise, stating that focusing on a part of the body that was already hurting increased the focus on the area and made the pain worse. Complete pain reduction was never achieved, but patients reported feeling better equipped to tolerate pain by using mindfulness exercises. Participants also noted the ability to regulate anxiety and anger more easily describing increased capacity to focus on their breath to calm down when they began feeling anxious or angry. Mindfulness worked better for acute anxiety than chronic anxiety for one patient. All participants stated that they would continue practicing mindfulness after the study, and would recommend a MBI program to others with SCD and chronic pain. Most participants practiced the mindfulness exercises at home or at work, usually in the morning or evening, and typically by themselves.

Discussion

The goal of this pilot RCT was to explore the feasibility and acceptability of an abbreviated 6-session MBI that was targeted for persons with SCD and chronic pain. Our preliminary findings suggest that an abbreviated MBI is feasible and acceptable for persons with SCD and chronic pain, and may have potential benefits on pain catastrophizing that should be explored in larger future trials.

Recruitment and Enrollment.

We did not experience major barriers with participant recruitment or enrollment, despite the fact that many had never heard of MBIs. Furthermore, 100% of participants were minority group members (i.e. African Americans) whose recruitment into clinical trials has historically been challenging (Paskett et al., 2008) due to mistrust of researchers (e.g., Tuskegee syphilis experiment; CDC, 2015) and poor experiences within the healthcare system (Paskett et al., 2008). However, studies of MBIs that have recruited only minority samples have reported few recruitment difficulties, including studies with traumatized minority and refugee groups (Hinton et al., 2013), African American women with PTSD and a history of intimate partner violence (Dutton, Bermudez, Matas, Majid, & Myers, 2013), and ethnic minorities with substance use disorders (Witkiewitz et al., 2013). Our study demonstrated the same positive experience with recruiting a predominately minority sample to participate in a MBI.

Of the two recruitment strategies, in-person and by mail, only in-person recruitment was feasible and it was also relatively successful with 77% of approached participants enrolling in the study. One difficulty encountered with in-person recruitment was limited recruitment time. Patients recruited in the clinic were approached either immediately before or immediately after their appointment. In both scenarios there was a limited amount of time to

build rapport, explain the study, discuss inclusion and exclusion criteria, review the consent form, and allow subjects time to complete the baseline assessment forms.

MBI Attendance and Retention.

Approximately 57% of participants completed at least four mindfulness sessions, and this was deemed acceptable for this sample given that nonadherence rates for outpatient clinical appointments among adults with SCD have been reported as high as 87% (Cronin et al., 2018). Non-adherence to scheduled appointments has been associated with gender, developmental period, minority status, history of previously missed appointments, and low SES (Cronin et al., 2018; Crosby et al., 2009). Similarly, attendance rates of 50% or less have been well documented for chronic pain samples enrolled in MBI and non-MBI interventions, and our rates exceeded these benchmarks. A recent literature review reported MBI dropout rates for persons with chronic pain to be between 2–50%, with loss to follow-up ranging from 8% to 52% (Bawa et al., 2015). Other non-MBI and remotely delivered web-based interventions have also suffered intervention attendance rates as low as 35% (Christensen, Griffiths, & Farrer, 2009; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012; Toivonen, Zernicke, & Carlson, 2017).

Acceptability.

In general, patients who were randomly selected to participate in interviews perceived the telephonic MBI as acceptable and easy to access and consume. Telephonic delivery of the MBI was convenient for patients who lacked means of transportation by removing travel time to and from a clinic and providing additional flexibility to participants that were employed or had other responsibilities requiring their physical presence. No patient refused or was ineligible to participate because they did not have access to a phone.

Telephonic therapies have been successfully used in other chronic diseases to treat adults with depression, anxiety, and illness-specific symptoms. For instance, meta-analyses of telephone delivered cognitive behavioral therapy (CBT) have shown improved health outcomes, demonstrated non-inferiority with in-person CBT, and reported lower attrition rates than face-to-face psychotherapy among patients with chronic illness (Muller & Yardley, 2011). Other telephone-delivered therapies such as dialectical behavioral therapy, acceptance and commitment therapy, and mindfulness-based cognitive therapy for depression have also been shown to be feasible and acceptable approaches for symptom management (Ost, 2008). For chronic pain specifically, Heapy et al. (2015) found that technology-assisted psychological interventions delivered via telephone, interactive voice response, and the Internet were equally efficacious at improving self-management among adults. Conversely, a study of remotely delivered therapies among children and adolescents with chronic pain, found that internet-based therapies (vs. telephonic therapies) were most beneficial in reducing pain severity (Fisher, Law, Palermo, & Eccleston, 2015). Future studies should investigate how the choice of technology for delivery of MBIs may differ for various populations and age groups.

In SCD, we are unaware of any studies that have investigated the acceptability of a remotely delivered intervention for pain. Smartphones in SCD have been previously used to remotely

monitor pain and symptoms (Jacob et al. 2012; Jacob, Duran, Stinson, Lewis, & Zeltzer, 2013; Shah, Jonassaint, & De Castro, 2014), facilitate patient-provider communication (Jacob et al., 2013), and provide home-based symptom management (McClellan et al., 2009). To our knowledge this is the first study that demonstrates the acceptability of a telephonically conducted intervention for pain in persons with SCD, and it is the first MBI for pain. Importantly, the telephonic MBI was found to be acceptable for persons with SCD and chronic pain that reported more medical complications.

The PCS pain catastrophizing scores slightly improved from baseline to week 6 for participants in the MBI. Although the sample size was small for pilot study, this is encouraging when considering the future role of MBIs in helping persons with SCD manage pain non-pharmacologically. It is important to note that PCS and all three subscale scores did increase from baseline after the week 1 session, but then decreased between weeks 1 and 6. This is consistent with at least one other study of a MBI for other types of chronic pain (Cherkin et al., 2016), and it may reflect a temporary increase in attention to pain as participants are learning mindfulness skills, which then dissipates with increased practice.

Limitations

This study has several limitations. We were not able to standardize the day of the week the MBI session was conducted, or the start and stop time across the MBI cohorts, due to the instructor's availability. We wanted a highly experienced MBI instructor who had previously done telephonic MBI and MBI for research to ensure the content was taught consistently and well in this distance-based format. Instructors with this extensive and specific MBI training and research experience are limited and as such, her schedule was booked with other projects. To fit the grant/project timeline we needed to be flexible with her schedule. Ideally, each MBI cohort would have started on the same day of the week (e.g., Wednesday) and at the same time (e.g., 5:00pm). The lack of a consistent schedule may have affected attendance rates. Another limitation was that due to time constraints with recruiting before and after clinic appointments (e.g., limited time in the waiting room before appointments and transportation or other reasons limiting available time after appointments), we allowed participants the choice of completing online or mailing in paper responses. This approach contributed to a high number of missing baseline assessments and post-intervention follow-up (e.g., 3 month, 6 month). Relatedly, we randomized participants prior to completion of their baseline assessments versus waiting to randomize until after participants returned their questionnaires. This approach may have compromised the integrity of the randomization process, although there were no differences between demographic and clinical characteristics between the MBI and control participants. The time window in which assessments were collected also was extremely lenient. In other remote MBI studies, assessments are typically collected immediately following a MBI training session (Klatt, Buckworth, & Malarkey, 2009; Ouweneel, Leblanc, & Schaufeli, 2012); participants in our study were given up to a week to complete their assessments. Reported outcomes for pain catastrophizing should also be interpreted cautiously due to the small sample size. Moreover, neither median nor mean PCS scores in either the MBI or control groups indicated clinically significant catastrophizing, so the feasibility and acceptability of a MBI is unknown for

patients with higher levels of pain catastrophizing. Lastly, we compensated participants for completion of their assessments, and this may have inflated participation rates.

Implications for Nursing Education, Practice and Research

Research.—Although we had few difficulties with participant recruitment or enrollment, only in-person recruitment was feasible. Despite mailing recruitment letters every other week, no patients were successfully enrolled using this approach. Recruitment of minority and vulnerable populations by mail may or may not be feasible, and this should be investigated in future studies. Relatedly, although we successfully enrolled participants through the clinic, there was extremely limited time to fully explain the study, enroll a participant, and obtain baseline data. Thus, we offered participants the option of online or mailed assessments with paid return postage. All participants chose mail, however, this approach resulted in lower response rates than desired. Future studies may consider scheduling the baseline assessment phone interview at enrollment for assessment completion within two days of enrollment, especially if there are barriers to online data collection strategies, such as lack of access to the Internet or low computer literacy. Email and text reminders were helpful and should also be used to remind participants to complete assessments. These reminders can include the link to the online survey. Finally, researchers should pilot test the length of time it takes to complete all measures and carefully consider the value vs. subject burden of each measure.

The NHLBI guidelines on SCD management report that the quality of available evidence to support the use of non-pharmacological treatments for persons with SCD is currently very low (NHLBI, 2014). Moving forward, multi-site randomized control studies are needed to further test for efficacy of MBI interventions for chronic pain management in persons with SCD. Ideally these randomized controlled trials would compare between different types of non-pharmacological treatments (e.g., CBT vs. MBSR) as well as explore the effects of MBI on pain and other important patient reported outcomes, including sleep, depression, fatigue, and anxiety.

Clinical implications.—Care of persons with SCD requires a multi-disciplinary team of healthcare professionals that include physicians, nurses, nurse practitioners, physician assistants social workers, and psychologists. Each of these healthcare providers, in particular nursing, has a unique opportunity to screen and refer patients who experience chronic pain to specially trained MBI clinicians, or integrative medicine centers for non-pharmacological interventions. Despite the potential positive effect of a MBI, there are numerous barriers that limit a provider's ability to make referrals. Common barriers from the providers' perspectives include lack of reimbursement by insurance companies (e.g., not covering complementary and alternative treatments, restricted number of hours for CBT), lack of financial motivation (e.g., no pay-for-performance clinician incentive), and for some, deficiency in education and awareness of potential benefits of non-pharmacological interventions (IPRRC, 2016). To overcome these barriers, systemic changes are needed within the healthcare system, specifically with how healthcare is delivered to make non-pharmacological interventions more readily accessible and easier for patients to receive. Nurses still have an important opportunity to learn some of the MBI techniques that may be

useful when caring for individuals in the hospital and in the clinic. Nurses can become trained on teaching mindfulness tools to patients, such as awareness of breath, body scan, and loving-kindness meditation. Moreover, nurses can help patients to understand the relationship between recognizing emotions, such as anxiety and pain catastrophizing, and how they may exacerbate pain. Finally, the waiting room is an opportune time to teach patients new skills. Comprehensive SCD clinics might consider setting up small tablets with headphones where patients can hear short lessons on mindfulness and pain management, and then listen to preprogrammed mindfulness practices while they wait for their appointments. Nurses also can work with patients to help identify possible other non-pharmacologic strategies, such as distraction, that can help manage but acute and chronic pain.

Conclusion

A group-based, telephonic, six-week MBI intervention was found to be both feasible and acceptable to persons with SCD and chronic pain. Preliminary data support a moderate to strong MBI intervention effect on pain catastrophizing. Additional work is needed to explore MBI effects on pain and pain-related outcomes for persons with SCD and chronic pain, including pragmatic trials that support seamless use of MBIs within the clinical setting.

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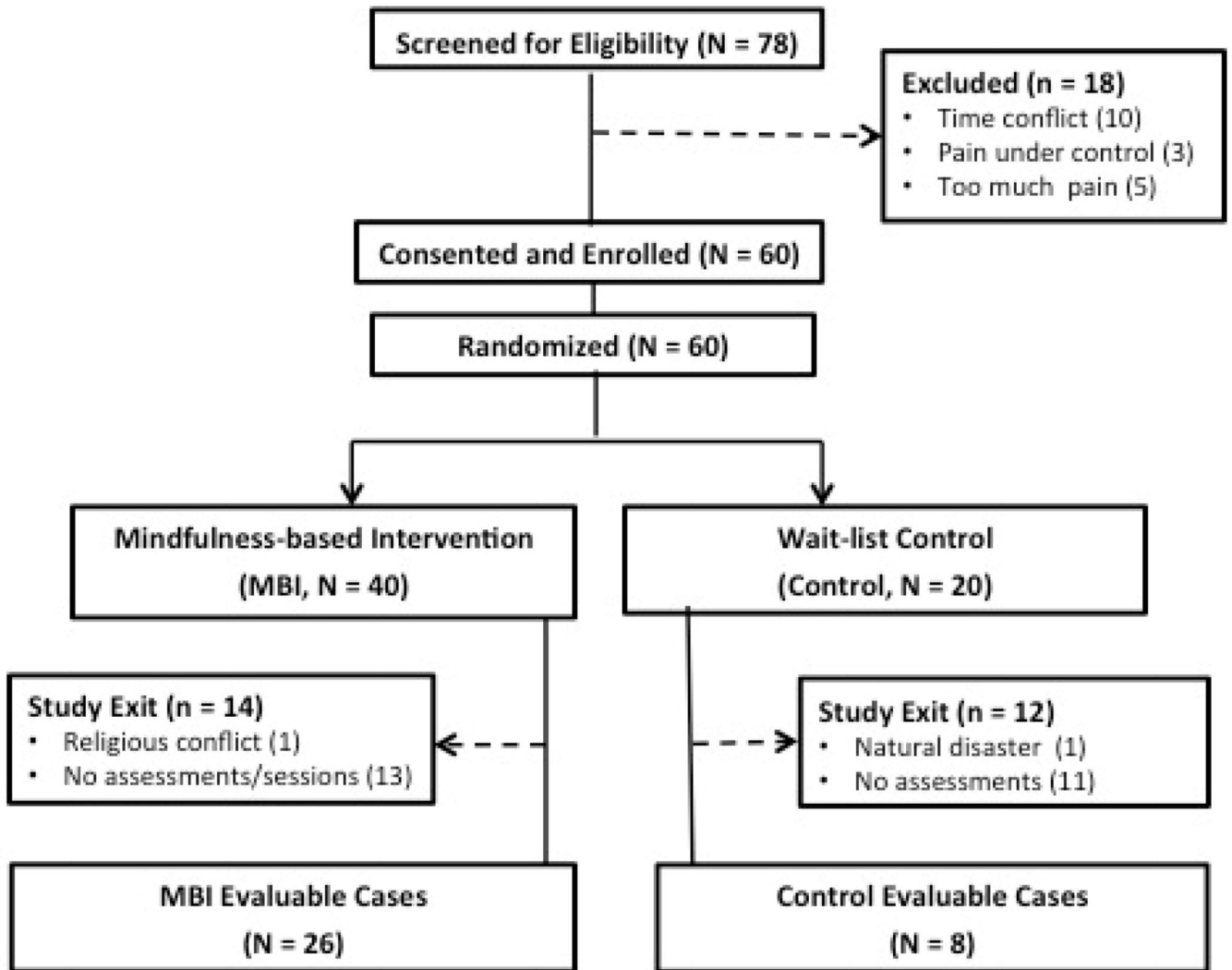


Figure 1.
Study Consort Diagram

Table 1.

Baseline Sample Characteristics (N=34)

Characteristic	Total N=34	MBI N=26	Control N=8	P
Male, n (%)	13 (38.2)	11 (42.3)	2 (25.0)	0.44
SS genotype, n (%)	21 (61.7)	15 (57.6)	6 (75.0)	0.46
Annual household income < \$50 K, n (%)	14 (41.1)	10 (55.56)	4 (57.14)	1.00
Education, n (%)				1.00
High school or lower	11 (32.3)	8 (40)	3 (37.5)	
College or higher	17 (50.0)	12 (60)	5 (62.5)	
Unemployed, n (%)	22 (64.7)	17 (65.38)	5 (62.5)	1.00
Insurance, n (%)				1.00
Medicare and/or Medicaid	19 (55.8)	13 (68.42)	6 (75)	
Private and/or other	8 (23.5)	6 (31.58)	2 (25)	
Age, median (IQR)	34.5 (28, 45)	34 (27, 45)	39.5 (31, 49)	0.26
ED visits, median (IQR)	4 (2, 8)	4 (2, 8)	3 (2, 4)	0.35
Hospital admissions, median (IQR)	3 (1, 5)	3 (1, 5)	3 (0, 3.5)	0.53
SCD-related complications, median (IQR)	3 (1, 5)	1.5 (1, 3)	3 (1.5, 3)	0.29
PCS Total Score, median (IQR)	16 (7, 24)	18 (7, 22)	14 (14, 24)	0.69

Median (IQR) = median (25th, 75th percentile); ED = Emergency Department; SCD=Sickle Cell Disease; PCS = Pain Catastrophizing Scale

Table 2.

MBI Session Attendance (N=26)

MBI sessions	Attendance, n (%)
Session 1. Breath awareness	17 (65.3)
Session 2. Body scan	16 (61.5)
Session 3. Loving Kindness	17 (65.3)
Session 4. Mindful Eating	16 (61.5)
Session 5. Sensory Awareness	14 (53.8)
Session 6. Summary	17 (65.3)
Number of sessions attended per person	Attendance, n (%)
No session	3 (11.5)
One session	3 (11.5)
Two sessions	0 (0.0)
Three sessions	5 (19.2)
Four sessions	3 (11.5)
Five sessions	5 (19.2)
Six sessions	7 (26.9)

Mean percent attendance per session = 62.1%; Median number of session attended per person = 4.

Table 3.

Pain Catastrophizing Scores (PCS)

Catastrophizing	MBI (N=26)								Control (N=8)			
	Baseline N=13	Week1 N=18	Week3 N=17	Week6 N=16	Baseline N=5	Week1 N=6	Week3 N=6	Week6 N=6	Baseline N=6	Week1 N=6	Week3 N=6	Week6 N=6
PCS Total Score	18 (7, 22)	25.5 (13, 32)	21 (16, 26)	13 (6.5, 24)	14 (14, 24)	16 (11, 17)	13.5 (12, 20)	13 (10, 15)	6 (3, 8)	6 (5, 7)	6 (4, 8)	5 (3, 6)
PCS Helplessness	6 (3, 8)	10 (2, 13)	7 (5, 12)	4.5 (3, 9)	5 (4, 9)	3 (3, 4)	2.5 (2, 4)	3 (3, 3)	3 (1, 6)	3 (3, 4)	2.5 (2, 4)	3 (3, 3)
PCS Magnification	3 (1, 6)	6 (3, 7)	5 (3, 6)	3 (1.5, 5.5)	4 (3, 4)	6 (5, 8)	6 (5, 8)	4.5 (2, 9)	6 (2, 12)	8 (6, 11)	6 (5, 8)	4.5 (2, 9)
PCS Rumination	6 (2, 12)	8.5 (5, 13)	8 (6, 11)	4 (3.5, 9)	6 (6, 11)	6 (5, 8)	6 (5, 8)	4.5 (2, 9)	6 (2, 12)	8 (6, 11)	6 (5, 8)	4.5 (2, 9)

Median (25, 75th percentile) reported

Table 4.

Representative Quotes of Acceptability Themes

Theme 1: Intervention Structure	
Category and Brief Description	Representative Quotes
Communal – social context, community, and connection	<p>“I think that worked out really well, particularly the conference calls where we were all able to hear each other. . . . we were all able to have a discussion, have a conversation.”</p> <p>“The conference call is a good format. I think I like that more so than having to come to a place and be there in person. I was more comfortable in my own space.”</p>
Remote – distance based, telephonic participation	<p>“Oh it was very easy. It wasn't difficult at all. I liked the fact that you could call in to a number. You could be anywhere you didn't necessarily be at home. You know, there were days where I didn't feel good but it didn't matter because I was in the comfort of my home. I could be laying down, and most of the exercises required that, you know, you were in a relaxed position anyway. So it was very easy to complete.”</p> <p>“...one time I called in from a hospital, I was getting an ultrasound done and I called in from there. I've been in the car and I've called in. I've been home. So those were the three places.”</p>
Reminders – day-of text or email with time and call-in number	<p>“And also you were texting us to remind us, as a reminder. So that really helped when you texted everybody and had a number and stuff up with that information so that we could be reminded.”</p>
Time – length and timing of sessions	<p>“I think that an hour was appropriate. It was enough time for the leader to go through the specific concepts and meditation types that we talked about.”</p>
Content – exercises learned and practice	<p>“Everything was useful, you know, get that quality time to do it while I was at work, while she was talking through it.”</p> <p>“I really didn't find anything that was not really useful. I mean I thought it was a lot of great techniques. So I really didn't find anything that was not really useful.”</p>
Barriers – issues affecting participation	<p>“Because of the time, I think, doing it later in the evening, would work better because 5:00 is when a lot of people are getting off work, or . . . I think later in the day might work out better.”</p> <p>“At first I had to eliminate everyone around me because sometimes my nephew comes over to my house and all that, and he's noisy and all that. I just had to take a step back and think about getting alone to myself, like it requires you.”</p>
Modifications – suggested changes to the MBI	<p>“The way the program is set up now is really great. What I would like to see is if there was, you know, like levels. Like this one was Level 1. And Level 2 would be like, for example, you take the breathing exercises and you incorporate that with some type of physical therapy kind of situation.”</p> <p>“I don't see how you can make it better. The only thing I said, the only one I didn't . . . [mindful eating exercise] it wasn't that I didn't like it, I'm just an overeater, and that's something I got to fix.”</p>
Theme 2: Intervention Effects	
Category and Brief Description	Representative Quotes
Pain – effects on acute and chronic pain – mostly helpful but some exceptions	<p>“But I've noticed that when I have spikes of pain, when it gets worse, being able to kind of sit down and calm myself and meditate has been helpful. Kind of like really acute episodes.”</p> <p>“So I've always found that if I'm feeling stronger mentally, emotionally, I tolerate the pain better. So the classes offered certain specific techniques to help with that. So the quality of life is just better because of that. Because when you . . . like 95% of my day is . . . I'm in pain in some form or fashion. So being able to have tools that will keep my mind strong helps me tolerate and deal with the pain.”</p> <p>“There was one, the body scan, wasn't helpful to me. It's focusing on the area where the pain is coming from, for me personally, isn't helpful. It makes it worse. For me to focus on the breath is definitely helpful.”</p>
Emotion Regulation – how the MBI helped with difficult emotions	<p>“Sure. It helped you not get angry quick. You know, it helped that. Take a deep breath.”</p> <p>“During the daytime when somebody getting an attitude, you know, you step back – you know they always say take a deep breath and don't respond.”</p> <p>“It would help you stay calm. It would help you get to know your body. And it will help you relax. Because people will blow up angry quick.”</p>

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Theme 1: Intervention Structure	
Category and Brief Description	Representative Quotes
<p><i>Practice – reports on when participants did homework and plans for future use</i></p>	<p><i>“I incorporate it every night where right before I go to bed, I’m already laying down, and I’m scanning where I’m hurting. Because at night you focus more on the pain because you don’t have anything else to do.”</i> <i>“I think that it changed my perspective because a lot of times when I am in pain I am totally focused on that pain, so this helped me do exercises where I’m not just focused on my pain. I can kind of work through it a little bit and do other things besides, just focus on the pain.”</i></p>