Abstract

Mindfulness-Based Cognitive Therapy and Self-Efficacy in People with Migraine

Objective: To examine the relationship between mindfulness-based cognitive therapy and self-efficacy in people with migraine.

Participants and Methods: This study is a secondary analysis of a phase 2b randomized clinical trial. 60 participants with a diagnosis of migraine were recruited through community outreach and from headache clinics in both Manhattan and the Bronx as part of the Mindfulness-Based Cognitive Therapy for Migraine (MBCT-M) randomized controlled trial. Participants were randomized after a month of daily diary monitoring to the MBCT treatment group ($n = 31$) or the waitlist treatment as usual group (WL/TAU; $n = 29$). Participants completed surveys at months 1, 2, and 4, that assessed Headache Management Self-Efficacy (HMSE), Trait Mindfulness, and Headache Disability. Participants randomized to the MBCT group also completed a daily electronic headache diary, which assessed daily mindfulness practice. A Pearson's r correlational analysis was run between month 1 scores on the Five-Facet Mindfulness Questionnaire (FFMQ) and HMSE. A series of linear mixed effects models were run to evaluate the changes in HMSE over time. A mediation was run to evaluate the extent to which HMSE from month 1 to month 4 is associated with improvements in the headache disability index (HDI) from months 1 to 4 in the MBCT and WL/TAU groups.

Results: The HMSE was not significantly associated with the FFMQ total or subscale scores at month 1 (*p*s > .05). Increases in self-efficacy were significantly larger for the MBCT vs. WL/TAU group $F(2, 60.58) = 3.69$, $p = .031$. Changes in FFMQ were associated with changes in

HMSE ($F(1, 48.27) = 5.01$, $p = .030$) although this did not differ by treatment group ($F(2, 59.104) = .423$, $p = .657$). Within the MBCT group (n = 31), both month $F(2, 53.79) = 3.69$, $p = .032$ and proportion of days meditated $F(1, 35.93) = 6.35$, $p = .016$ were associated with higher HMSE. Among MBCT completers (n = 25), changes in self-efficacy mediated changes in disability at month 4 compared to month 1 (indirect effect $B = -6.96$, 95% CI = 2.19, 13.72). Comparatively, within the WL/TAU group (n = 26) the indirect effect of the completers analysis revealed that HMSE did not significantly mediate changes in disability (indirect effect *B* 1.02 95% CI = -4.01, 0.98.

Conclusions: Participation in the MBCT-M intervention may significantly improve headache management self-efficacy over time within people with migraine. Additionally, self-efficacy mediated changes in time on disability, which is the primary outcome of the parent study. These findings provide strong preliminary evidence that self-efficacy may be an important change mechanism for mindfulness-based treatments for migraine.

Mindfulness-Based Cognitive Therapy and Self-Efficacy in People with Migraine

by

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Chapter I: Introduction

Migraine is a disabling neurological chronic condition with episodic attacks characterized by unilateral pulsating or throbbing pain, nausea and/or vomiting, and extreme sensitivity to light and sound. It affects 12% of the United States population and has a significant impact on quality of life, economic burden, as well as psychological well-being (Headache Classification Committee of the International Headache Society (IHS), 2013; Lipton et al., 2011; Vos et al., 2015). Management of migraine is a complex process that requires a disciplined use of medications as well as regimented behaviors to both prevent and cope with migraine attacks (Rosenberg et al., 2018). As such, regularly engaging in migraine management strategies is vital to improve the quality of life and well-being of people with migraine.

Self-efficacy has been identified as a key predictor and maintainer of behavior change (Dolce et al., 1986). Headache management self-efficacy is a patient's confidence to take actions to prevent headache attacks or to manage the disability and pain associated with those attacks (French et al., 2000). Past research has identified Cognitive Behavioral Therapy (CBT) and Biofeedback as a first-line treatment for people with chronic pain, including migraine (Ehde, Dillworth, & Turner, 2014; Nicholson, Nash, & Andrasik, 2005; Seng & Holroyd, 2010; Thorn et al., 2007). Self-efficacy is a central mechanism for change for CBT and Biofeedback in chronic pain and migraine.

Although CBT is an established treatment to reduce migraine frequency in people with migraine, not all people have reductions in frequency, improvements in quality of life, or decreased disability (Morgan et al., 2016). Some people with migraine have turned to third-wave behavioral treatments, which are all characterized by the cultivation of mindfulness. A recent study reported that around 50% of adults with migraine are already using complementary and alternative treatment modalities to help manage their migraine (Wells et al., 2011). Mindfulness-based interventions aim to improve quality of life through the cultivation of mindfulness, which is the ability to observe non-judgmentally and maintain awareness of the present moment (Kabbat-Zinn, 2006). Mindfulness-based interventions have been shown to improve perceived pain intensity, migraine related disability, and quality of life (Bakhshani, Amirani, Amirifard, & Shahrakipoor, 2016a; Feuille & Pargament, 2015; Grazzi et al., 2017).

Little is known about the impact of mindfulness-based interventions on migraine management, specifically self-efficacy. Understanding self-efficacy as a potential change mechanism for mindfulness-based interventions is imperative to advance the field and provide an additional behavioral treatment modality to lessen disability for people with migraine (Turner et al., 2016). The current study aims to address this gap with a secondary analysis of a randomized clinical trial on Mindfulness-Based Cognitive Therapy for people with migraine (MBCT-M). Sixty people with migraine were randomized to receive an 8-week manualized MBCT treatment (n = 31) or Waitlist Treatment as Usual (WL/TAU) (n = 29). The primary outcomes of the parent study indicate that disability scores on the Headache Disability Index (HDI) significantly decreased more for participants in the MBCT-M group compared to participants in the WL/TAU group ($p < .001$), but not for scores on the Migraine Disability Assessment ($p = .027$). There were no differences found between groups for pain intensity and headache days/30 days (Seng et al., 2019). For the parent study and the present study, mindfulness was measured using the Five Facet Mindfulness Questionnaire and Self-Efficacy was measured using the Headache Management Self-Efficacy questionnaire. The present study aims to evaluate: the month 1 relationship between that Five-Facet Mindfulness Questionnaire and Headache Management

Self-Efficacy measure (Pearson's r correlational analysis), the relationship between the MBCT-M intervention and Headache Management Self-Efficacy (linear mixed effects model), the relationship between at-home mindfulness practice and Headache Management Self-Efficacy (linear mixed effects model), and the association between changes in Headache Management Self-Efficacy and changes in the Headache Disability Index over the course of the study (mediation analysis).

Background & Significance

Migraine and Migraine Management. Migraine is a disabling primary headache disorder and it affects approximately 12% of the United States population (Lipton et al., 2011; Steiner et al., 2015). Migraine is a chronic condition with episodic attacks characterized by unilateral moderate to severe pulsating pain, nausea and/or vomiting, and extreme sensitivity to light and sound (Headache Classification Committee of the International Headache Society (IHS), 2013). According to a large national pharmacy chain study, approximately 50% of migraine patients endorse moderate to severe migraine-related disability and report needing bed rest during an attack (Foley et al., 2005). Globally, migraine is ranked as the second most disabling specific condition. Migraine is the leading cause of disability among all neurological disorders, and is the least publicly-funded neurological illness relative to its economic impact (Shapiro & Goadsby, 2007; Steiner et al., 2015; Vos et al., 2015). Migraine affects approximately 18% of women and 6% of men in the United States (Burch et al., 2019; Buse et al., 2012; Lipton et al., 2011; Messali et al., 2016). Twenty years ago, total estimated costs to the US as a result of disability attributed to migraine exceeded $13 billion per year (Hu et al., 1999); this number is certainly higher in today's dollars. Additionally, in 2002 the estimated total cost to employers of lost productivity as a result of headache was $19.6 billion in the US (Stewart et al., 2003).

Management of migraine is a complex process that requires a disciplined use of medications as well as consistency in behaviors to both reduce the frequency of migraine attacks (preventive strategies) and cope with migraine attacks in-the-moment (acute strategies) (Rosenberg et al., 2018; Seng et al., 2017). People with migraine use preventive medications daily to lessen the frequency of and prevent migraine attacks and acute medications to relieve the symptoms associated with a migraine attack. However, adherence to these medications is poor and the medication regimens are complex. Many factors can influence adherence to a medication treatment regimen, two of which are medication level characteristics and patient level factors. A large body of literature has demonstrated that medication level characteristics affect medication-taking behaviors and include: regimen complexity, medication side effects, and perceived medication efficacy (Dunbar-Jacob & Mortimer-Stephens, 2001; Gallagher & Kunkel, 2003; Katić et al., 2010; Rains et al., 2006). Patient level factors are less understood, but researchers posit that headache severity, self-efficacy, gender, socioeconomic status, and education may effect medication-taking behaviors (Cady et al., 2008; Cady et al., 2009; Landy et al., 2013; Diener et al., 2016).

Both preventive and acute medication strategies require active engagement with different medication taking behaviors. Preventive strategies include daily medication use, most of which have side effects, infusions, or injections, which require regular doctor appointments and full coverage of insurance (Bangs et al., 2020; Kim et al., 2010). As such, these strategies require people with migraine to plan ahead and maintain a routine. Treating a migraine attack with an acute medication also poses challenges. The guidelines provided by the American Academy of

Neurology outline the pharmacological and behavioral treatment recommendations for optimal migraine care and include taking the acute medication early on in the migraine attack while the pain is mild and avoiding overuse of the acute medication, which is classified as ≥ 10 days/month for Triptans, Opiates and Barbiturates, and ≥ 15 days/month for NSAIDS (Seng, Robbins, & Nicholson, 2017; Silberstein, 2000). However, people with migraine often delay taking an acute medication until the pain is moderate to severe, which is associated with higher disability and less satisfaction with the acute migraine medication (Foley et al., 2005; Marmura et al., 2015; Rains et al., 2006; Seng et al., 2017). Additionally, nonadherence to acute medication treatment recommendations can result in the progression of migraine from episodic to chronic (Bigal et al., 2008). Due to the pathophysiology of this episodic disease, there is a need for behavioral treatments to either complement pharmacologic treatment or be used as a stand-alone treatment to aid in migraine management.

In addition to pharmacologic treatment, successful migraine management also requires people with migraine to engage in a number of consistent behaviors, routines, and usually requires lifestyle changes (Rosenberg et al., 2018). Behavioral recommendations include maintaining a regular sleep-wake schedule, a regular exercise routine, a regular and healthy diet, a regular practice of stress management or relaxation techniques, and a regular self-care routine (Buse & Andrasik, 2009). The World Health Organization encourages lifestyle changes to avoid triggers or external environmental factors that may increase susceptibility to migraine attacks, yet these lifestyle changes are often complex and require discipline. It is widely recognized that nonpharmaologic treatments for migraine are instrumental in providing a comprehensive treatment plan (Buse & Andrasik, 2009). As such, strategies to enhance migraine management are vital to improve the quality of life and well-being of people with migraine (Organization, 2006).

Background on CBT and Biofeedback in Migraine. Behavioral treatments, such as CBT, biofeedback, and relaxation have grade A evidence to reduce migraine frequency according to the American Academy of Neurology's evidence-based guidelines for migraine and are instrumental in providing a comprehensive treatment plan for migraine prevention (Buse & Andrasik, 2009; Ehde et al., 2014; Holroyd & Drew, 2006; Kaushik et al., 2005; Minen et al., 2020; Nicholson et al., 2005; Seng et al., 2019; Silberstein, 2000; Thorn et al., 2007). Relaxation strategies (e.g., deep breathing, progressive muscle relaxation, imagery) are foundational for most behavioral migraine treatment approaches. For CBT, behavioral strategies for people with migraine are designed to assist people in identifying and modifying behaviors that may maintain or precipitate unhealthy states, such as modifying suspected triggers and promoting engagement in healthy lifestyle routines (Singer et al., 2015). Several meta-analyses have evidenced 30-50% improvements in migraine outcomes for CBT (Andrasik, 2007; Buse & Andrasik, 2009; Martin et al., 2007; Penzien et al., 2002). Biofeedback uses physiological instruments to "feed back" information about physiological responses like skin temperature and electromyography to the patient, who uses this information to self-regulate physiological reactions to stressful situations (Holroyd & Drew, 2006). A meta-analysis of 55 biofeedback studies found a medium effect size ($d = 0.58$) for all biofeedback interventions and demonstrated that biofeedback was more effective than the control conditions in randomized controlled trials (Nestoriuc & Martin, 2007).

The United States Headache Consortium created evidence-based guidelines for the management and treatment of migraine and they emphasize the importance of nonpharmacologic treatments for people with migraine who (1) prefer nonpharmacologic interventions (2) do not tolerate pharmacologic treatments (3) exhibit contraindications for pharmacologic treatments (4) respond insufficiently to pharmacologic treatment (5) are pregnant or planning on becoming pregnant (6) have a history of long-term use of analgesic medications (7) exhibit a deficiency in coping skills or stress-management skills (Campbell, Penzien, & Wall, 2000).

Background on Self-efficacy and Migraine. Self-efficacy is an individual's belief in their ability to achieve a certain goal. Self-efficacy is a key component of Bandura's Social Learning Theory (Bandura, 1977) and has since been incorporated into a wide variety of health behavior change theories, including the Health Belief Model (Rosenstock, 1974), Theory of Planned Behavior (Ajzen, 1991), and Protection Motivation Theory (Rogers & Prentice-Dunn, 1997). Bandura extended Social Learning Theory as Social Cognitive Theory to emphasize the role of cognitions and observation in understanding and predicting behavior (Glanz et al., 2015). Bandura's Social Cognitive Theory posits that behavior is determined by the combination of personal cognitive factors and socioenvironmental factors. The Social Cognitive Theory outlines that the prediction of behavior and behavior change are regulated by agency (a personal sense of control) and forethought in addition to three cognitive influences: self-efficacy, outcome expectations, and knowledge (Bandura, 1991). It is posited that psychological procedures have the ability to alter the level and strength of self-efficacy, which is imperative to obtain a certain outcome. People are more persistent when facing obstacles and aversive experiences when they have higher perceived self-efficacy. Higher perceived self-efficacy is theorized to be associated with more active and effortful persistence when faced with obstacles and aversive experiences.

Self-efficacy has relevance for health promotion and disease prevention (Clark & Dodge, 1999). Self-efficacy beliefs alter expected outcomes and people with high self-efficacy expect favorable outcomes and view impediments to achieving those outcomes as surmountable by improving self-management skills and persistence (Bandura, 2004).

Background on CBT, Biofeedback, Self-efficacy, and Migraine. In the context of migraine management, self-efficacy refers to confidence in your ability to take actions to prevent headache attacks or to manage the disability and pain associated with those attacks (French et al., 2000). Holroyd et al., (1984) conducted a seminal study that demonstrated the importance of self-efficacy for headache management. Forty-three undergraduate students with tension headache were randomly assigned to one of four electromyographic (EMG) biofeedback-training conditions. The researchers implemented a 2 (EMG decrease vs. EMG increase) X 2 (high vs. moderate success feedback) design. Participants were manipulated to believe that they were accurately using biofeedback to decrease EMG activity; however, actual feedback was contingent on decreased levels of EMG activity for only half of the participants and increased EMG activity for the other half. Additionally, participants within these two groups viewed bogus video displays common to biofeedback trainings that were created to convince participants that they were achieving high success or moderate success. In addition to the biofeedback trainings, participants completed daily recordings of headache and medication use and completed self-efficacy and locus of control measures. Participants who received high success feedback had substantially greater improvement in headache activity (53%) than participants who received moderate success feedback (25%) regardless of actual changes in EMG activity. Self-efficacy improved substantially for participants in the high success groups and changes in self-efficacy and locus of control were significantly correlated with improvements in headache activity $p < .01$. Additionally, improvements in headache activity were not correlated with change in EMG occurring during biofeedback training $r(38) = .19$. In sum, results suggest that improvements in headache activity were mediated by self-efficacy induced by performance feedback rather than actual reductions in EMG activity.

Behavioral migraine management has been associated with increased self-efficacy in people with migraine. Seng and Holroyd (2010) conducted a secondary analysis on data from a randomized clinical trial to examine the maintenance of changes in expectancies associated with different combinations of medications and psychological treatments for migraine in 176 people with migraine. Specifically, the researchers investigated increases in self-efficacy and locus of control resulting from behavioral migraine management. The results indicate that headache management self-efficacy significantly increased in the behavioral migraine management condition compared to groups that received only medication ($p < .001$).

CBT and biofeedback target migraine management by enhancing self-efficacy and aiding patients to employ an internal verses external locus of control (Bandura, 1977; Singer et al., 2015). Higher self-efficacy has been associated with positive migraine outcomes and lower self-efficacy with negative migraine outcomes in various studies since Holroyd et al. (1984). French et al., (2000) aimed to construct and validate a measure of headache-specific self-efficacy and to examine the relationship between self-efficacy and headache-related disability. Three-hundred and twenty-nine participants (77% women) with tension-type headache and 29% with a migraine diagnosis completed a series of study measures including the headache management self-efficacy scale, headache-specific locus of control scale, headache disability inventory, a depression and anxiety inventory, and headache index. A subset of participants ($n = 262$) also completed daily headache recordings for four weeks. Results indicated a positive correlation between headache management self-efficacy and headache-specific locus of control ($r = 0.40$), which suggests that people who were confident about managing their headache also believed that factors that influence their headache were potentially within their control. Participants who used positive psychological strategies to manage their headache also had higher self-efficacy scores and self-efficacy was correlated with prevention (r = 0.54) and management (r = 0.55) of headaches.

Self-efficacy is a central change mechanism for CBT in chronic pain and migraine. Thorn et al., (2007) conducted an randomized clinical trial to examine the efficacy of CBT for people with chronic headache. Thirty-four people with chronic headache were enrolled in a 10-week CBT treatment and 11 people with chronic headache completed a waitlist self-monitoring period. The treatment included cognitive restructuring and cognitive/behavioral coping to address catastrophizing. The researchers ran a multivariate analysis of variance, which indicated that changes reported by participants in the CBT treatment group were significantly greater than those reported by participants in the waitlist condition. Univariate tests also indicated significant differences in change scores for the CBT and waitlist groups for headache management self-efficacy, measured by the Headache Management Self-Efficacy questionnaire $p < .001$, $d = -.80$. These changes remained significant at follow-up in relation to pretreatment scores for the Headache Management Self-Efficacy questionnaire, and effect sizes were large $d = -.58$, $p < .01$.

Background on Mindfulness. Mindfulness-based interventions may serve as an alternative non-pharmacological treatment for health populations like people with migraine. Mindfulness is based on the 2,500 year-old Buddhist tradition of being aware, non-judgmentally, of the present moment (Germer, 2013). Mindfulness often uses the breath to integrate the mind and the body. Within mindfulness, the breath is used as an anchor for one’s attention to the present moment both physically and mentally, and it contains a meta-cognitive component which promotes the awareness of observing one’s mental processes (Bishop et al., (2004). Jon Kabat-Zinn adapted the concept of mindfulness to be used in the clinical settings of medicine and psychology in the US. In 1979, Kabat-Zinn developed the Stress Reduction and Relaxation Program, which he later named Mindfulness-Based Stress Reduction (MBSR) (Kabat-Zinn, 2003). In 1982, Kabat-Zinn conducted a MBSR study with 51 participants with chronic pain. Among the 51 participants, 88% reported significant decreases in pain perception, with half reporting at least a 50% reduction (Kabat-Zinn, 1982).

MBSR has demonstrated efficacy to improve coping for a variety of stress-related health conditions. A 2004 meta-analysis reviewed 20 empirical studies from the past two decades on MBSR and health related outcomes, such as pain, cancer, heart disease, depression, and anxiety. The results indicated an effect size of approximately 0.5 ($p < .0001$) with homogeneity of distribution in both studies with control groups and studies without control groups (Grossman et al., 2004). Although the sample of studies was relatively small, the results suggest that MBSR may be a beneficial behavioral intervention to help individuals cope with clinical and nonclinical health related problems.

Segal, Teasdale, and Williams (2002) later developed Mindfulness-Based Cognitive Therapy (MBCT), which combines cognitive behavioral therapy (CBT) methods with mindfulness meditation concepts from MBSR. MBCT contrasts with MBSR because it incorporates cognitive therapy elements to facilitate cognitive de-fusion, or a detachment from one's thoughts. MBCT uses cognitive therapy tools and psychoeducational components from CBT (Fjorback et al., 2011). The researchers developed MBCT to reduce the relapse of major depressive disorders. MBCT uses mindfulness to aid patients in becoming aware, non-judgmentally, of their automatic thoughts and internal experiences (Segal et al., 2002). MBCT is also effective in treating chronic pain and improving quality of life, stress, and mood (Ball et al., 2017). MBCT is the treatment modality of the parent study on which this secondary analysis is based.

Mindfulness and Migraine. In contrast to the first-wave treatments, little is known regarding the change mechanisms of MBCT. The question is important: people with migraine are increasingly turning to the practice of mindfulness as a complementary approach to migraine management, despite lack of evidence (Gu et al., 2015). According to the 2007 National Health Interview Survey, approximately 50% of adults with migraine were using complementary and alternative medicine - mainly, mind-body therapies such as meditation, yoga, and mindfulness (Wells et al., 2011). Results of the survey research indicate that adults with migraine started to practice complimentary and alternative medicine because they perceived existing biomedical treatment options to be either ineffective, costly, or both.

A small pilot study suggests MBSR is both safe and feasible for people with episodic migraine (Wells et al., 2014). An RCT of 19 people with episodic migraine were randomized to either the MBSR (n = 10) or usual care (n = 9) condition. All participants completed paper diaries for the duration of the study, and participants randomized to the MBSR condition attended 8 weekly 2-hour sessions, plus one 6-hour mindfulness retreat day. The research team found non-significant decreases in migraines per month (MBSR 3.5 to 1.0 vs control 1.2 to 0; 95% CI -4.6, 1.8). There was a significant improvement of self-efficacy and mindfulness scores in the MBSR vs control group (13.2 [95% CI 1.0, 30.0] and 13.1 [95% CI 3.0, 26.0] respectively). These results should be interpreted with caution as the analyses were inadequately powered due to the small sample size. Although the headache outcomes from this pilot trial were non-significant, the analyses were under-powered so future research is needed.

A slightly larger, more recent study in a mixed chronic headache sample (migraine and tension-type headache) found that 8-week MBSR (n = 20) vs. treatment as usual control group (n = 20) reduced pain intensity (η^2 = 0.49, p = 0.001) (Bakhshani, Amirani, Amirifard, & Shahrakipoor, 2016b). Further pilot studies suggest mindfulness interventions for headache disorders may increase self-control. Nash-McFeron (2006) examined the effects of MBSR in 40 chronic headache patients (not solely migraine). Participants were randomized to either a mindfulness meditation group (n = 20; 8-weekly 1.5-hour group sessions) or a waitlist group (n = 20). The MBSR group reported a significant increase in self-control on the SCI Domain Specific Sense of Control Scale, which measures sense of self-control in the domains of body, mind, relationships, self, environment, and vices (η^2 = .174, p < .006). The mindfulness meditation treatment group reported a trend toward reduced headache pain (η^2 = .90), but the between-group difference was no longer significant after Bonferroni correction, which might not have been supported in a larger sample size.

Day et al. (2014) is the first study of MBCT for any headache condition. The MBCT intervention integrated cognitive therapy strategies from CBT to increase adaptive thought processes and decrease maladaptive thought content with relaxation strategies from MBSR. The MBCT protocol aimed to combine reducing rumination and catastrophic thinking from CBT while also reducing perceived stress and increased psychological well-being. Day and colleagues conducted an unblinded, parallel-group randomized clinical trial to investigate the feasibility, tolerability acceptability, and initial efficacy estimates of MBCT (n =19) compared to delayed treatment (n = 17) in people with headache disorders (migraine n = 31; tension type headache n = 4; new daily persistent headache n = 1). Participants in the MBCT condition attended 8-weekly 2-hour group therapy sessions and completed daily online meditation practices. Participants in both the MBCT and delayed treatment groups completed a daily headache diary. The results indicated that the MBCT treatment is feasible, tolerable, and acceptable. For the primary outcome of pain severity, participants in the MBCT group reported significantly greater reductions in pain interference ($d = -1.29$, $p < .01$) but not pain intensity ($p = .23$) compared to the delayed treatment group. Participants in the MBCT group also reported significant increases in headache management self-efficacy (MBCT group pretest M(SD) = 116.89(11.28) MBCT group posttest M(SD) = 129.05(29.83), delayed treatment pretest M(SD) = 124.74(18.20), delayed treatment posttest M(SD) = 123.41(17.72); $p = .02$, $d = .82$. Though the results are promising, additional research is needed with larger sample sizes, a more migraine-tailored treatment protocol, and more homogenous patient groups to evaluate the clinical effect of MBCT on migraine outcomes and explore the relationship between mindfulness and key cognitive mechanisms, such as headache management self-efficacy.

Taken together, the series of pilot studies of mindfulness-based interventions (MBSR and MBCT) within the migraine population show promise to reduce migraine-related disability/quality of life interference and potentially even migraine symptoms. However, many of the studies used a mixed headache sample, which make results difficult to generalize. Further, all results should be interpreted cautiously due to the small sample sizes and inadequate power. Thus, it is imperative to continue studying mindfulness-based interventions for migraine related outcomes such as disability and migraine management.

Rationale/Hypotheses

Despite theoretical rationale and promising early results, no study has investigated self-efficacy as a change mechanism for mindfulness in migraine. The pilot study conducted by Day et al., (2014) provided preliminary evidence that headache management self-efficacy improved over time for mixed headache participants in the MBCT condition, but it did not investigate self-efficacy as a mechanism of change for more distal headache-related outcomes.

Self-efficacy is theoretically an important change mechanism across all behavior change interventions. Mindfulness-based interventions attempt to teach a new skill (mindfulness) with the rationale that learning this skill will improve daily functioning and coping with migraine. Although self-efficacy is not a core component of mindfulness, we posit it is a behavioral treatment mechanism that transcends theoretical orientation and study protocol. This notion is important because if a change mechanism is common across behavioral treatment modalities, therapists can use routine assessment to track progress and identify components of treatment plans that are particularly helpful for individual patients.

The current study is a secondary analysis of a Phase 2b randomized clinical trial two-arm parallel design to test the superiority of MBCT compared to WL/TAU to reduce headache-related disability. The present secondary analysis study aims to evaluate the relationship between mindfulness and headache management self-efficacy. The study will use monthly survey data and daily diary data from 60 participants. Mindfulness will be measured using the Five Facet Mindfulness Questionnaire (FFMQ) and self-efficacy will be measured using the Headache Management Self-Efficacy (HMSE) questionnaire. Disability will be measured using the Headache Disability Index (HDI). The following specific aims were designed to achieve the goal of this dissertation:

Aim 1: Evaluated the relationship between mindfulness and headache management self-efficacy (HMSE). The purpose of this aim was to see if people with migraine (n = 60) who had higher levels of trait mindfulness (FFMQ) at month 1 also had greater HMSE at month 1.

- Hypothesis 1a: Higher levels of mindfulness (FFMQ) at month 1 will be associated with higher month 1 levels of HMSE in people with migraine (n = 60).

Aim 2: Evaluated the relationship between mindfulness-based intervention and headache management self-efficacy.

- Hypothesis 2a: The slope and change of HMSE from months 1, 2, and 4 will be greater for participants in the MBCT-M (n = 31) group compared to participants in the WL/TAU (n = 29) group.
- Hypothesis 2b: Participants who reported increases in mindfulness (FFMQ) over the study (month 4 – month 1) will report larger slope increases in self-efficacy (HMSE) (month 4 – month 1).

Aim 3: Evaluated the relationship between mindfulness practice and HMSE.

- Hypothesis 3a: Within the MBCT-M group (n=30), a higher proportion of days of mindfulness practice over recorded meditation days will be associated with a larger slope increase in HMSE from month 1 (randomization) to month 4.

Aim 4 (Exploratory): Evaluated the extent to which HMSE from month 1 to month 4 are associated with improvements in the HDI month 1 to month 4 in the MBCT-M (n = 31) vs. WL/TAU (n = 29).

Innovation

A growing body of research has enhanced our knowledge that people with migraine are turning to complementary and integrative treatments, including mindfulness. Mindfulness-based interventions are growing in popularity for a variety of clinical populations. However, little is known about how mindfulness impacts migraine-related disability for people with migraine.

The proposed study will add to the literature on the efficacy of mindfulness as an alternative treatment, which may influence self-efficacy to improve people with migraine's confidence in migraine management. The parent study is the largest mindfulness-based intervention with people with migraine to date. The 8-week individualized MBCT-M treatment itself is innovative, as previous research has employed a group-based format.

The proposed study also uses a daily measure of mindfulness practice, which is delivered using the electronic daily diary. This daily mindfulness measure is an innovative way to measure mindfulness over time in comparison to the weekly or monthly survey measures, which have been used in the past. Additionally, the electronic daily diary itself is an innovative way to track people with migraine, as the majority of previous research has been conducted with paper diaries. Paper diaries have a number of limitations. Instead of filling out the paper diary every day, some people complete multiple diary entries on the same day, which introduces the problem of retrospective recall bias. The electronic daily diary in the present study alerted participants at a pre-specified time every day, which lessens the probability of recall bias (Allena et al., 2012).

Lastly, the present study is the first of our knowledge to investigate self-efficacy as a change mechanism for mindfulness in migraine. We are evaluating this aim by using a relatively new software (MEMORE version 2.1 Mediation and Moderation for Repeated Measures), which is a macro for SPSS and SAS that estimates mediation models for two-instance within-subject/repeated measures designs (Montoya & Hayes, 2017). This methodology is a new and exciting way to conduct meditational analyses and will allow us to make inferences about self-efficacy as a change mechanism for MBCT-M.

Chapter II: Methods

Participants and Recruitment

Participants were recruited from neurology office referrals and local and online advertisements in the broader New York City and tri-state areas. Flyers were posted in the Manhattan and Bronx communities in yoga studios, colleges, and coffee shops. Participants were also recruited through social media forums like Craigslist and Twitter. Inclusion criteria were a) currently meeting International Classification of Headache Disorders (ICHD)-3 beta headache diagnosis for migraine using a semi-structured clinical interview and the validated American Migraine Study/American Migraine Prevalence and Prevention Study migraine diagnostic screener, b) self-reported and prospective diary-confirmed ≥ 6 headache days per month, c) aged 18-65, d) ability to read English, and e) capacity to consent. Exclusion criteria were a) continuous headache over the course of 30 days, b) initiation of a preventive migraine treatment within four weeks of the baseline assessment or a plan to initiate preventive migraine treatment during the duration of the study, c) severe psychiatric illness that would interfere with participation in the treatment, or d) inability to adhere to headache diary during baseline period (recorded fewer than 26/30 days).

All participants were screened online and through a phone call with a research coordinator. Participants then attended an in-person intake session with a doctoral student. Dr. Seng and Dr. Buse supervised all intakes and inclusion criteria were reviewed again at this time. During the in-person intake visit, doctoral students conducted a semi-structured interview assessing for psychiatric and medical history. Prospective participants also completed measures of headache symptom severity, migraine-related disability, cognitive functioning, and self-report anxiety and depression measures. All participants provided written informed consent.

Procedures

The parent study received ethics approval by the Einstein IRB (2015-4684) and the study protocol was registered at clinicaltrials.gov (NCT02443519), PI Elizabeth K. Seng. The study initially enrolled patients in July 2015 and concluded in September 2018.

The parent study is a two-arm parallel RCT to test the superiority of MBCT-M compared to WL/TAU. All participants completed a baseline questionnaire, which included demographic information, migraine symptom severity information, and psychosocial surveys. The baseline questionnaire was collected using REDCap, which is a secure data capture system provided by Albert Einstein College of Medicine (Harris et al., 2009). All participants completed a 30-day daily headache diary as a baseline-monitoring period prior to randomization. The headache diary was administered on either an iPhone or iPod touch. The intention of the baseline-monitoring period was to ensure that participants met inclusion criteria and to collect baseline data. At the conclusion of the 30-day monitoring period, all participants completed the same set of measures that comprised the baseline questionnaire (month 1). Once participants completed the 30-day monitoring diary period and month 1 measures, study staff reviewed inclusion criteria. If participants met the criterion, they were randomized to either the MBCT-M treatment group or the Waitlist Treatment as Usual (WL/TAU) group. Participants who were randomized to the MBCT-M treatment group continued to use the daily diary and attended 8-weekly in-person MBCT-M sessions. Participants who were randomized to the WL/TAU no longer used the daily diary. All study participants completed psychosocial surveys at baseline, month 1, month 2, and month 4. Participants were compensated up to $70 for completion of the surveys.

During the 8 weeks of the treatment period, MBCT-M participants continued to use the daily diary and attend weekly therapy. Sessions lasted 75 minutes and were facilitated by a trained doctoral student. All doctoral students attended individual and group supervision with Dr. Seng or Dr. Buse who are licensed clinical psychologists and experts in the field of migraine research.

The MBCT-M treatment protocol was adapted from Day et al. (2014), which piloted the feasibility, tolerability, and acceptability, of a group based MBCT treatment. The 8 treatment sessions of the parent study were adapted from content in Day and colleagues' (2014) group sessions for headache pain. Each treatment session was comprised of psychoeducation, cognitive exercises, and in-vivo mindfulness meditation practices, which the doctoral students led. Participants completed "homework" in between sessions, which included mindfulness meditation practices that were introduced in sessions, cognitive exercises, and activity planning of nourishing activities. The majority of the sessions were completed in person, but up to three sessions were permitted to occur over the phone, as a result of the unpredictable and disabling nature of migraine attacks, which prevented participants from attending in-person sessions.

Measures/Instruments

Demographics. Participant demographic data, which included age, gender, race, ethnicity, education level, employment status, and marital status, were captured at the intake appointment and through baseline questionnaires.

Self-Efficacy. The Headache Management Self-Efficacy Scale (HMSE) is a 25-item self-report measure that captures the confidence a person has in their own abilities to prevent headache attacks and manage their pain (French et al., 2000). Response options are on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree), Appendix A. Items inquire about the confidence a person with migraine has in their abilities to prevent migraine attacks (e.g., “I can prevent headaches by changing how I respond to stress”) and the confidence a person with migraine has in managing their head pain (e.g., “I can do things that will control how long a headache lasts” ; French et al., 2000). The researchers developed this measure by reviewing existing measures of self-efficacy related to pain, disability, and coping. The researchers pilot tested the measure, which revealed ambiguous or redundant items, which they then removed or reworded. Cronbach’s alpha demonstrated strong internal consistency for the 25-item total score ($\alpha = .90$). Construct validity was assessed by examining the association between the HMSE and headache-specific locus of control (HSLC), coping activities (ICE-H) headache-related disability (HDI), and psychological distress (BDI;TAI). The HMSE was correlated with the HSLC ($r = -0.64$), ICE-H ($r = 0.55$), the HDI ($r = -0.24$), but was not correlated with the BDI ($r = - 0.09$). The HMSE demonstrated good internal consistency ($\alpha = .87$) in the present sample, which is consistent with the literature (French et al., 2000).

Mindfulness- Five Facet Mindfulness Questionnaire (FFMQ). The FFMQ is a 39-item self-report measure that contains five subscales: Observing, Describing, Acting with Awareness, Non-judging of Inner Experience, and Non-reactivity to Inner Experience (Baer et al., 2006). Response options are on a 5-point Likert scale, spanning from 1 (never or very rarely true) to 5 (very often or always true), Appendix B. The FFMQ has demonstrated good internal consistency ($\alpha > .70$), and adequate incremental and construct validity (Baer et al., 2006). The FFMQ is a widely used measure of mindfulness (Choi, 2015; Goldberg et al., 2016). The FFMQ demonstrated excellent internal consistency (FFMQ total $\alpha = .91$) in the present sample, which is consistent with the literature. In addition to the total score, the five subscales all demonstrated good to excellent internal consistency: Observe α = .79, Describe α = .90, Act with Awareness α = .881, Non-judgement α = .90, and Non-react α = .82.

Disability. The Headache-Related Disability Index (HDI) is a 25-item self-report measure that captures the functional and emotional impact of headache on daily activities (Jacobson, Ramadan, Aggarwal, & Newman, 1994). Response options are "yes" (4 points) "no" (0 points) and "maybe" (2 points). A total score of 72+ indicates complete disability, 50-68 indicates severe disability, 30-48 indicates moderate disability, 10-28 indicates mild disability, and 0-10 indicates no disability, Appendix B. The measure has strong internal consistency (α = .89), test-retest reliability (r = .78) and high construct validity (Jacobson et al., 1995). The HDI demonstrated excellent internal consistency (α = .90) in the present study, which is consistent with the literature.

Daily Diary Measures

Practicing Mindfulness. Daily mindfulness practice was measured in the daily diary with the question: "Did you practice mindfulness meditation today?" with response options "yes" or "no". The variable was created by taking the proportion of days that participants responded "yes" to practicing mindfulness over the amount of daily diary days that each participant recorded. It should be noted this was the final question in the daily diary for participants in the MBCT-M group.

Data Analysis Plan

All analyses were conducted using SPSS version 25.0 (SMSS IBM, New York, USA). Data was singly-imputed for participants who completed at least 50% of questionnaire items to account for occasionally missing items in questionnaire data. Prior to analysis, variable distributions were examined for normality and statistical techniques were chosen in accordance with variable distributions. Demographic characteristics for study participants are described including age, ethnicity, race, gender, employment status, and education level. The values are reported using means, standard deviations, or counts and percentages based on the normality and distributions of the variables.

T-tests and Mann-Whitney U tests were used to determine if the MBCT group and WL/TAU groups differed significantly for the baseline variables. Bivariate analyses were run between participant demographics and baseline HMSE scores to determine if we should control for any demographic variables in the main analyses. The two groups differed significantly in age - participants in the WL/TAU group were significantly older than participants in the MBCT group (M = 44.2 years vs M= 36.2 years, p = .006). All models were run twice as unadjusted and adjusted models for age.

Visually inspecting Akaike's information criterion determined the best fitting covariance structure for each model and models were run with a first-order autoregressive covariance structure (AR1). All betas reported throughout the document are unstandardized.

The data analysis for each of the specific aims is listed below:

Aim 1 Evaluated the relationship between mindfulness and HMSE.

- <u>Hypothesis 1a</u>: Higher levels of mindfulness (FFMQ) at month 1 will be associated with higher month 1 levels of HMSE in people with migraine (n = 60).

To evaluate this aim and determine the strength and direction of the association between mindfulness (FFMQ) and self-efficacy (HMSE), a Pearson's r correlational analysis was calculated using the baseline scores on the FFMQ and the HMSE. Analyses were run for the FFMQ total score as well as the five FFMQ subscales: Observe, Describe, Act with Awareness, Non-judgment, and Non-react. No adjustments were made, as there were no significant covariates, which were identified in preliminary analyses.

Aim 2a: Evaluated the relationship between mindfulness-based intervention and HMSE.

- Hypothesis 2a: The slope and change of HMSE from months 1, 2, and 4 will be greater for participants in the MBCT (n = 31) group compared to participants in the WL/TAU (n = 29) group.

In these intent-to-treat (n = 60) analyses, t-tests and Mann-Whitney U tests were used to determine if the MBCT-M group and WL/TAU groups differed significantly on any of the baseline variables. A linear mixed effects model was run to assess differences in changes of self-efficacy over time for months 1, 2, and 4 for participants in the MBCT-M group compared to the WL/TAU groups. Akaike's Information Criterion determined the best fitting covariance structure as AR1.

- Predictor: MBCT-M vs WL/TAU
- Outcome: HMSE scores at months 1, 2, and 4
- Fixed Effects: Treatment group, month, and treatment group*month
- Random Effects: Intercept and month

Predictors were treatment group (MBCT-M vs WL/TAU) and outcomes were HMSE at months 1, 2, and 4. MBCT treatment group, month, and treatment group*month served as fixed effects. The random effects were intercept and month. A significant interaction between MBCT-M treatment and time indicates differential changes in self-efficacy in the treatment condition. Both unadjusted and adjusted models for the covariate of age were run.

Aim 2b: Evaluated the relationship between mindfulness-based intervention and HMSE.

- Hypothesis 2b: Participants who reported increases in mindfulness (FFMQ) over the study (month 4 – month 1) will report larger slope increases in self-efficacy (HMSE) (months 1, 2, and 4)

Mixed models for repeated measures were used to evaluate this hypothesis.

- Predictors: Changes in FFMQ (month 4 – month 1), month, treatment group
- Outcomes: HMSE scores at months 1, 2, and 4
- Fixed Effects: Treatment group, month, FFMQ change score, month*FFMQ change score, treatment group*month, treatment group*FFMQ change score, month*FFMQ change score*treatment group
- Random Effects: Intercept and month

Predictors were changes in FFMQ, computed by calculating a change score from month 1 FFMQ and FFMQ at month 4 (month 4- month 1). Self-efficacy, measured by the HMSE, at months 1, 2, and 4 was the outcome. The fixed effects were month, FFMQ change score, and their interactions. The random effects in the model were intercept and month. Any non-significant group by month three-way-interactions were removed from the model to determine if a significant relationship exists between changes in headache management self-efficacy and changes in mindfulness between month 1 and month 4 in the treatment group compared to the WL/TAU group.

Aim 3: Evaluated the relationship between mindfulness practice and HMSE

- Hypothesis 3: Within the MBCT-M group (n= 31), a higher proportion of mindfulness practice per month will be associated with a larger slope increase in HMSE (month 1, 2, 4)

This analysis was conducted on the subgroup of participants who were randomized to receive the MBCT-M treatment (n =31).

- Predictors: Proportion of days of mindfulness meditation practice and month
- Outcomes: HMSE scores at month 1, month 2, and month 4
- Fixed Effects: month, proportion of mindfulness practice, month*proportion of mindfulness practice
- Random Effects: Intercept and month

Proportion of mindfulness practice was the predictor and HMSE at months 1, 2, and 4 was the outcome. We used the day level measure of "Did you practice mindfulness today" with response options "yes" or "no" to calculate a person-level proportion variable, which accounted for missing daily diary data by taking the proportion of days practiced over the number of diary days recorded where a participant responded yes or no to this question.

31 participants who were randomized to receive the MBCT treatment were included in this intent-to-treat analysis. Of a potential total of 2,617 diary days, 755 (28.8%) were missing information about whether a participant practiced meditation that day, including 2 participants who did not record a single day of meditation. We took a conservative approach and singly-imputed 0s for days on which participants did not record the meditation practice question.

Akaike's Information Criterion determined the best fitting covariance structure. The final model utilized AR1 covariance structure.

Aim 4 (Exploratory): Explored the association between changes in HMSE and MBCT treatment effects **of disability on the HDI.**

We evaluated whether self-efficacy is a change mechanism for MBCT on the primary outcome of the parent study, which is headache disability as measured by the HDI. For this completer analysis, we first looked within the MBCT group (n = 25) to see if self-efficacy mediated disability, and then we ran the model again within the WL/TAU group (n = 26) and compared the indirect effects to detect if a true mediation was present.

To evaluate this aim, we used MEMORE version 2.1 (Mediation and Moderation for Repeated Measures), which is a macro for SPSS and SAS that estimates mediation models for two-instance within-subject/repeated measures designs (Montoya & Hayes, 2017). For this analysis X = Time 4 vs Time 1, Y = HDI 4 vs HDI 1, and M = HMSE 4 vs HMSE 1.

Power Analysis Plan

The statistical program G*Power Version 3.1.9.4 was used to calculate the adequate power analysis for the proposed analysis in Aim 1 and was based on a bivariate correlational model. The power analysis is based on Aim 1 to preserve degrees of freedom in this sample. As the sample size for the study has been determined, a post-hoc power analysis was conducted with parameters (1) two-tails, (2) effect size of $r = .20$, $r = .50$ or $r = .80$, which represents small, medium, or large effect size respectively, (3) $\alpha = .05$, (4) sample size of 60.

The study yields a medium effect size of 0.35. Day et al. (2014) conducted univariate tests of change scores in an MBCT treatment group compared to a delayed treatment group and reported an effect size of $d = .82$ for the HMSE.

Ethics

The Mindfulness-Based Cognitive Therapy for People with Migraine study was approved by both the Albert Einstein College of Medicine Institutional Review Board and the Montefiore Medical Center (2015-4684) and the study protocol was registered at clinicaltrials.gov (NCT02443519). All study personnel have received Collaborative Institutional Training Initiative (CITI) training. Licensed clinical psychologists supervised all doctoral students who conducted intakes and therapy. Additionally, all doctoral level students who conducted intakes or provided therapy attended a 6-hour training provided by Dr. Seng, the PI on the parent study. The risks and benefits of the study are outlined in the informed consent and in the below Risks and Benefits section.

Risks and Benefits

The risks and benefits for the Mindfulness-Based Cognitive Therapy for Migraine: a Randomized Clinical Trial are outlined in the IRB-approved informed consent. It is stated that the parent study posed greater than minimal risk; however, all study personnel were formally CITI trained and trained on study procedures. The risks to participation included accidental breach of confidential information, though this was highly unlikely given the confidentiality protection measures that we employed. Participant research records have been kept confidential and participant names are not used in any written or verbal reports. Participant information is connected to a code number that is separate from participant names and identifying information. The form that links participant names and code numbers is kept on a password protected lab computer and only trained study personnel have access to the file. The informed consent outlined that the only appropriate time for confidentiality to be breached was if participants gave study staff information that they are at risk of hurting themselves or others. All study staff was trained on how to appropriately deal with this situation, which included notifying the PI (Dr. Seng) and cautiously proceeding to alert the necessary authorities to ensure the safety of the patient.

Another risk to participants was that participants may have felt uncomfortable when answering questionnaire items about their headache symptoms, daily life, thoughts and beliefs about their headaches, mood, stress, and lifestyle. Participants were reminded that they could choose to not answer questions that made them feel uncomfortable.

A risk to participation in the mindfulness-based cognitive therapy was that the treatment itself asked participants to attend to sensations, thoughts, and feelings that they might not ordinarily experience in as much clarity or depth. This internal exposure may have caused participants discomfort, which may have increased to an intolerable degree. Study staff was trained to review this risk with patients and instructed to remind participants that they can stop the procedure immediately if this occurs. Therapy staff was trained in grounding techniques to use if participants experienced intolerable discomfort during sessions.

Benefits of participation of the parent study included a possible reduction in headache-related disability, a better understanding of headaches and behavioral factors that may influence headaches, such as mood, stress, and lifestyle factors. Benefits of the proposed study include a greater understanding of the influence of mindfulness on self-efficacy and headache management.

Chapter III: Results

Participant Characteristics

A total of 60 participants were included in the analyses with 31 randomized to the MBCT treatment group and 29 to the WL/TAU group. Table 1 presents characteristics of the full sample and by treatment group.

Participants were predominantly white (81.7%), women (91.7%) with an average age of 40 years. A little over half of the participants have obtained a graduate degree or higher (56%) and were employed full time (63.3%). Around half of participants met criteria for chronic migraine (51.7%) while 48.3% met criteria for episodic migraine.

Participants in the MBCT and WL/TAU groups did not differ significantly based on gender, ethnicity, race, education, employment status, marital status, or migraine status (chronic migraine vs episodic migraine). A significant difference in MBCT vs WL/TAU group was found for age; participants in the WL/TAU group were older than participants in the MBCT group (M = 44.2 years vs M= 36.2 years, p = .006) Table 1. Therefore, age-adjusted analyses were conducted as sensitivity analyses when relevant below.

Participants in the MBCT and WL/TAU groups did not differ significantly in their month 1 scores on the HMSE, FFMQ, or HDI (Table 2).

Table 3 presents the bivariate relationships for participant demographics for all study participants and baseline HMSE scores and is additionally divided into treatment groups. Independent samples t-tests were used for all analyses for participant demographics and baseline HMSE. There were no statistically significant results.

Main Analyses

For **Aim 1** analyses, a Pearson's correlation was conducted as both the HMSE and FFMQ were normally distributed according to the Shapiro Wilk test statistic (HMSE: Shapiro Wilk test of normality Statistic = .967 df = 56 Sig. = .134; FFMQ: Statistic = .985 df = 53 sig. = .760). No adjustments were made as no baseline variable was significantly related to any of the outcome measures. Baseline HMSE scores were not significantly correlated with baseline FFMQ total scores *p* = .175 (Table 4). Additional correlations between baseline HMSE and all five subscales of the FFMQ were run. HMSE was not significantly correlated with any of the subscales: Observe, Describe, Aware, Nonjudgement, and Non-react.

For **Aim 2a**, the linear mixed effects model showed a significant group*month interaction which demonstrates that self-efficacy for participants in the MBCT treatment group significantly increased over time $F(2, 60.58) = 3.69$, $p = .031$, (Table 5). Specifically, the significant between-group difference from the MBCT vs WL/TAU group occurred from month 1 to month 2 $t(88.42) = 2.72$, $p = .008$, and the increase was maintained over time (Figure 1). A linear mixed effect model adjusting for age was run. The significant group*month interaction remained significant while adjusting for age (month 2 vs 1 B = 9.72, SE = 3.58, $p = .008$; month 4 vs 1 B = 7.02, SE = 4.29, $p = .108$) (Table 6).

For **Aim 2b,** the linear mixed effects model of changes in mindfulness and changes in self-efficacy over time was run. There was no significant three-way interaction between month* group*change in FFMQ $F(2, 59.104) = .423$, $p = .657$ (Table 7). There was a significant main effect of FFMQ change score $F(1, 48.27) = 5.01$, $p = .030$, which indicates that greater changes in FFMQ was associated with higher HMSE (Table 7; Figure 2). There were no significant interactions. The three-way interaction was removed from the model and did not modify the results. An additional linear mixed effects model, adjusting for age was run and the results remained the same (Table 8).

For **Aim 3,** Participants in the MBCT-M group (n = 31) recorded meditation practice on an average of 61.10, *SD* = 21.14, days during the treatment and follow-up period. The intent-to-treat linear mixed effects model of the proportion of mindfulness practice and self-efficacy from months 1, 2, and 4, within the 31 participants who were randomized to the MBCT group showed a significant main effect of proportion of days meditated $F(1, 35.93) = 6.35$, $p = .016$, which demonstrates the proportion of days that people meditated was significantly associated with self-efficacy at month 2 vs 1 B= 18.03, SE = 7.38, $p = .018$. There was also a significant main effect of month $F(2, 50.28) = 5.02$, $p = .010$, Table 9. The proportion of days meditated*month interaction was not significant (Figure 3).

A sensitivity analysis was run to investigate if the main effects remain significant when the non-significant interaction was removed from the model. The results remained the same with a significant main effect of proportion of days mediated $F(1, 34.55) = 6.64$, $p = .014$ and a significant main effect of month $F(1, 53.01) = 8.20$, $p = .001$, Table 10.

For **Aim 4**, we explored if changes in self-efficacy impacted changes in time on disability, which is the primary outcome of the parent study. Within the MBCT group (n = 25), self-efficacy mediated changes in disability at month 4 compared to month 1 (indirect effect B = -6.96, 95% CI = 2.19, 13.72). Overall, the HDI decreased by approximately 11 points from month 1 to month 4 (B = -11.88, 95% CI 5.39, 18.36). The significant indirect effect suggests that HMSE significantly mediated the relationship between time in the MBCT group and the HDI.

Comparatively, within the WL/TAU group (n = 26), overall, adjusting for nothing, the HDI only decreased by two points over time (B = -2.04 95%CI -2.93, 7.03). The indirect effect further reveals that within the WL/TAU group, HMSE did not significantly mediate the change in time on the HDI (indirect effect *B* = 1.02 (-4.01, 0.98) Figure 4.

Chapter IV: Discussion

This secondary analysis of a randomized controlled trial assessed the relationship between mindfulness and headache management self-efficacy. Within the MBCT group, self-efficacy significantly mediated the changes in time on headache disability, which was the primary outcome of the parent study. Although self-efficacy and mindfulness were not associated in a cross-sectional manner, when evaluated longitudinally, self-efficacy significantly improved over time for participants who were randomized to the MBCT-M group vs participants who were randomized to the WL/TAU. The results of this study provide strong preliminary evidence that self-efficacy may be a potentially important change mechanism in mindfulness.

To the best of our knowledge, this study is the first study to evaluate self-efficacy as a change mechanism for clinical outcomes in an MBCT intervention. As expected, the results of the present study support the claim that self-efficacy should be included as a potential change mechanism in third-wave therapies, specifically mindfulness, as it mediated the changes in time on headache disability within the MBCT group but not the WL/TAU group. There is a large body of research that has used CBT as a treatment modality for different disorders and health conditions including chronic pain and the literature reports evidence that self-efficacy is a mediator of change for CBT (French et al., 2000; Turner et al., 2007; Wilson et al., 2002). Although self-efficacy is usually conceptualized as a change mechanism in CBT-wave treatments, there is budding evidence that self-efficacy is relevant and important to behavior change in the third-wave treatments of Acceptance and Commitment Therapy and Dialectical

Behavioral Therapy (A & E, 2012; Khashouei et al., 2016; Moazzezi et al., 2015; Nourian et al., 2015; Wicksell et al., 2013). Self-efficacy is not explicitly included in psychological models guiding third-wave therapies (e.g., MBCT, MBSR, Acceptance and Commitment Therapy), but it is a transtheoretical construct and potential change mechanism for any treatment that teaches a new skill. The one exception is Dialectical Behavioral Therapy, whose theoretical model indicates that building a general sense of mastery builds competence and self-efficacy, which is purported to be paramount to behavior change within this treatment paradigm (Gross, 2007).

This study extends the growing literature that self-efficacy is a change mechanism across third-wave therapies. Self-efficacy is theoretically an important change mechanism across all behavior change interventions. Mindfulness-based interventions attempt to teach a new skill (mindfulness) with the rationale that learning this skill will improve functioning, coping with migraine, and disability. Engaging in the skill of mindfulness requires learning and understanding the tools of mindfulness, which include but are not limited to awareness of the breath, sitting quietly and non-judgmentally with thoughts, body scans, and activity monitoring. Although self-efficacy is not a core component of the theory behind mindfulness, we posit it is a behavioral treatment mechanism that transcends theoretical orientation and study protocol. This notion is important because if a change mechanism is common across behavioral treatment modalities, therapists can use routine assessment to track progress and identify components of treatment plans that are particularly helpful for individual patients by routinely assessing self-efficacy, regardless of specific approach or orientation.

To our knowledge, this is the first study to show that self-efficacy is a potential change mechanism for clinical outcomes in MBCT, which may in part be due to the lack of research thus far. There are also few studies that have cross-sectionally investigated self-efficacy and mindfulness (typically measured by the FFMQ) and the research that has been conducted has yielded inconsistent results (Caldwell et al., 2010; Tang et al., 2019; Turner et al., 2016). In fact, the present study provides evidence that contrary to expectation, baseline self-efficacy was not correlated in a cross-sectional manner to baseline mindfulness measured by the Five-Facet Mindfulness Questionnaire. Even though Headache Management Self-Efficacy and the Five-Facet Mindfulness Questionnaire were not correlated at baseline, cross-sectional associations do not necessarily tell us much about changes over the course of a treatment itself or what happens when people try to engage in behavior change. Cross-sectional relationships do not necessarily portend longitudinal treatment relationships.

On the one hand, a mindfulness-based treatment (MBCT-M) resulted in an increase in Headache Management Self-Efficacy scores over time. On the other hand, increases in mindfulness on the Five-Facet Mindfulness Questionnaire were not associated with these changes in self-efficacy. This is unexpected; a mindfulness-based treatment improved Headache Management Self-Efficacy scores, but it did not occur most in people who also reported improvements in mindfulness as measured by the Five-Facet Mindfulness Questionnaire. It is possible the Five-Facet Mindfulness Questionnaire is not accurately measuring mindfulness; it is also possible that mindfulness treatments are not imparting the constructs that are measured by the Five-Facet Mindfulness Questionnaire. Perhaps using the Five-Facet Mindfulness Questionnaire, a measure of trait mindfulness related to personality factors, is an incorrect measure to select when assessing changes over time. Research that investigated the psychometric properties of the Five-Facet Mindfulness Questionnaire compared to other mindfulness measures and a personality measure (Big Five), questions the linkage between the conceptualization of mindfulness and the Five-Facet Mindfulness Questionnaire measure. The researchers report that trait mindfulness appears to share about 50% of variance with the Five-Facet Mindfulness Questionnaire (Siegling & Petrides, 2014). Future research should continue to investigate the use of the Five-Facet Mindfulness Questionnaire and evaluate the appropriateness of use for behavioral treatments. Future research should also consider using alternative methods of measuring mindfulness change over treatment, including alternative surveys (e.g. Mindful Attention Awareness Scale, Cognitive and Affective Mindfulness Scale-Revised, Toronto Mindfulness Scale, and Southampton Mindfulness Questionnaire), or daily practice (Chadwick et al., 2008; Feldman et al., 2007; Lau et al., 2006; MacKillop & Anderson, 2007).

In this study, greater mindfulness practice was associated with higher self-efficacy over the course of the study. This is consistent with previous longitudinal research which reported daily mindfulness practice predicts increases in mindfulness and improves psychological well-being and negative affect (Keng et al., 2019; Snippe et al., 2015). This finding suggests that mindfulness practice and the Five-Facet Mindfulness Questionnaire are measuring something different. It is possible that for this study, the variable of mindfulness practice is a more appropriate measure of mindfulness than the Five-Facet Mindfulness Questionnaire. Future research should continue to investigate the role of daily mindfulness practice on self-efficacy, especially if self-efficacy is a change mechanism for mindfulness.

Aside from limitations of the Five-Facet Mindfulness Questionnaire as a measure of mindfulness, another reason why the baseline cross-sectional relationship may not be strong is because self-efficacy only makes sense in the context of tools. When you give people tools, they either feel confident or not to use them. *If* you give people tools *and* they feel confident that they can use them, then it will lead to positive change. However, if you do not give people tools but you ask them if they are confident to use them then the question no longer makes sense. Even though self-efficacy may be a good change mechanism for mindfulness, the baseline scores of self-efficacy may not be a great indicator of future change. Within the context of the present study, people with migraine in the MBCT-M group were given mindfulness and headache management tools and were taught how to use them. People with migraine in the MBCT-M group showed improvements in headache management self-efficacy over time. Participants in the WL/TAU group were not given the tools of mindfulness or taught how to use the tools and they did not have significant increases in self-efficacy over time.

Limitations and Future Directions

Although the study team recruited participants in a diverse urban location, the study sample was primarily white, educated, women, with a higher socioeconomic status and from one geographic location. The homogenous sample limits the generalizability of the results to minority populations and people from underrepresented groups. Although prevalence research reports a higher migraine prevalence in white women there is still a need to better include diverse populations in migraine research (Lipton et al., 2011). Population research also reports that migraine prevalence is higher in lower income households, which again supports a greater need to recruit and retain participants from a wider range of socio-cultural backgrounds for migraine studies (Stewart et al., 1992).

The study sample was highly educated with more than half of the study participants holding a graduate degree and the results may not generalize to people with a lower education level. The concepts presented in the MBCT intervention were at times complex and required strong cognitive abilities and critical thinking skills. The MBCT intervention also had a weekly-homework component, which may have been more of an obstacle for participants who had fewer years of formal education. It is of the upmost importance for future research to increase access to MBCT and to recruit and enroll participants from lower socioeconomic backgrounds and under-represented and resourced groups. A meta-analysis of 43 mindfulness studies reports that the majority of mindfulness interventions assign a significant home practice component. Additionally, the review suggests that little is known about the demographic variables that are associated with completing at home practice (Parsons et al., 2017). Future mindfulness research should include heterogeneous samples and should study which participants are engaging in the mindfulness practices, including meditations and skills outside of treatment sessions.

A strength of the current study is that the sample was comprised exclusively of people with a migraine diagnosis. Migraine is the most disabling headache disorder and there is a paucity of research on migraine, mindfulness, and self-efficacy (Bahra, 2011). However, we are unable to make any inferences for people with tension type headache, cluster headache, and chronic musculoskeletal pain. A similar randomized clinical trial with an 8-week mindfulness intervention for people with tension type headache found that participants who were randomized to the mindfulness group had a reduction in headache frequency when compared to the control group (Cathcart et al., 2014). The results of the present study should not be generalized to different headache disorders, but future research should consider investigating mindfulness within the various headache disorder populations and assess treatment outcomes.

To date, this study is the largest mindfulness study in a migraine population. Although the current study serves as preliminary data for the relationship between self-efficacy and mindfulness, the small sample size of 60 limits the strength and robust nature of the findings. The present study is still a phase 2b randomized clinical trial and was not a primary efficacy trial.

Additionally, the sample size was reduced in half for analyses that were divided into the MBCT-M and WL/TAU groups.

Though recruitment effort was strong, the study was highly burdensome on participants. Participants had to complete the electronic daily diary and answer monthly questionnaires that could take up to 75-minutes each. Furthermore, participants who were randomized to the MBCT group had to commute to and attend 8 weekly sessions that lasted up to 75 minutes, as well as complete weekly homework assignments and meditations outside of the weekly sessions. One way to mitigate burden could be to use teletherapy for the mindfulness intervention or group-based treatments. Another burden of the present study was the length of the daily diary, which resulted in missing diary data. Although we used imputation when possible, and conducted sensitivity analyses when appropriate, the missing diary data did impact the integrity of our results. Specifically, for the aim 3 analysis, of a potential total of 2,617 diary days, 755 (28.8%) were missing information about whether a participant practiced meditation that day, including 2 participants who did not record a single day of meditation. One way to improve upon this limitation is to shorten the daily diary questions to lower patient burden when completing the diary.

Lastly, the present study only investigated the variable of self-efficacy as a mechanism of change and did not explore other variables. Future research should consider other possible treatment specific change mechanisms, such as cognitive fusion or locus of control.

Clinical Implications

The results of the present study, which explored the nuances in the relationship between mindfulness and self-efficacy, may help clinicians better treat people with migraine. Mindfulness as an approach to migraine treatment is successful when people with migraine feel confident in their ability to engage in mindfulness and confident that their ability to engage in mindfulness will help them and achieve favorable outcomes. Just providing people with the tools of mindfulness (e.g. a body scan meditation) may not be efficacious without helping people feel confident that they can use these tools. It is important for clinicians to be aware of this "buy-in" factor and provide appropriate psychoeducation on mindfulness and migraine.

Mastery of skills is also an important factor. These protocolized treatments may not give clinicians enough time to facilitate mastery on novel concepts or ideas. An important clinical implication is that clinicians should be flexible and patient-centered when teaching mindfulness. It is advised that clinicians spend enough time on a skill or a concept to ensure that the patient feels comfortable and confident that they can use the skill.

It is also important for clinicians to consider which patients might benefit most from mindfulness. When considering who will benefit one must also consider the barriers to treatment. As the current study found, at home mindfulness practice is an important component of mindfulness treatment. The at-home practice component requires patients to have a quiet and comfortable space to meditate and time to do so. This practice may not be feasible for all patients for the logistic reasons mentioned, but also may not be feasible for patients with past trauma who may experience flooding when they are sitting quietly with their thoughts. Again, it is suggested that the clinician thoughtfully decide which tools are appropriate for which patients and which patients will "buy in" to the treatment of mindfulness.

Conclusions

This secondary analysis of a randomized controlled trial assessed the relationship between mindfulness and headache management self-efficacy. Migraine is a disabling primary headache disorder and management of migraine requires behavior change and engagement in routine behaviors such as maintaining regular eating schedules, routinely drinking water, and sleeping and waking up at regular times daily (Rosenberg et al., 2018). Behavioral treatments are a common way to treat and manage migraine. Most behavioral treatments include a behavior change component in order to manage this disabling disease. Self-efficacy is an important component of many health behavior theories because it is a key predictor and maintainer of behavior change (Dolce et al., 1986).

Participation in the MBCT-M intervention significantly improved headache management self-efficacy over time within people with migraine. Additionally, self-efficacy mediated changes in time on disability, which is the primary outcome of the parent study. Proportion of mindfulness practice was also related to increases in self-efficacy. Taken together, these findings provide strong preliminary evidence that self-efficacy may be an important change mechanism for mindfulness.

Higher headache management self-efficacy may help people with migraine take actions to prevent headache attacks or manage the disability and pain associated with those attacks (French et al., 2000), which was supported by the results of the present study. Mindfulness may alter the way a person with migraine relates to, thinks about, and feels about their condition and these changes in feelings and cognitions may in turn improve self-efficacy, such that a person may have a stronger belief that they are capable of managing their migraine (Frank Andrasik et al., 2016). If we can increase self-efficacy through a mindfulness intervention then people with migraine may manage their migraine more effectively, which in turn can reduce disability.

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Tables

Table 1.

Baseline Demographic Characteristics

Demographics	Total (N = 60) M (SD) or N (%)	MBCT (N = 31) M (SD) or N (%)	WL/TAU (N = 29) M (SD) or N (%)	Significance
Age	40.1 (11.6)	36.2 (10.6)	44.2 (11.5)	.006
Gender				
Male	5 (8.3%)	2 (6.5%)	3 (10.3%)	.938
Female	55 (91.7%)	29 (93.5%)	26 (89.7%)	
Ethnicity				
Hispanic/Latino	10 (16.7%)	5 (16.1%)	5 (17.2%)	.908
Non-Hispanic/Latino	50 (83.3%)	26 (83.9%)	24 (82.8%)	
Race				
White	49 (81.7%)	26 (83.9%)	23 (79.3%)	.903
Black/African American, Asian, All Else	11 (18.3%)	5 (16.1%)	6 (20.7%)	
Education				
College degree or less	27 (45.0%)	15 (48.4%)	12 (14.4%)	.614
Graduate degree	33 (56.0%)	16 (51.6%)	17 (58.6%)	
Employment				
Full-Time	38 (63.3%)	21 (67.7%)	17 (58.6%)	.642
Not full-time	22 (36.7%)	10 (32.3%)	12 (41.4%)	
Marital Status				
Single	34 (56.7%)	18 (58.1%)	16 (55.2%)	.999
Married/Living with domestic partner	26 (43.3%)	13 (41.9%)	13 (44.8%)	
Migraine Status				
Chronic	31 (51.7%)	16 (51.6%)	15 (51.7%)	.993
Episodic	29 (48.3%)	15 (48.4%)	14 (48.3%)	
Headache Days in Last Month	11.1 (5.1)	11.6 (4.6)	10.6 (5.6)	.765
Headache Days in Last 3 Months	32.2 (14.3)	32.8 (12.8)	31.6 (16.0)	.462
Pain Free Days	16 [10.0 – 20.0]	15 [10.0 – 20.0]	18 [9.0 – 20.0]	.947

Note. MBCT = Mindfulness-Based Cognitive Therapy, WL/TAU = Waitlist Treatment as Usual

Table 2

Study Variables by Treatment Group

Study Variables	**Total (N = 60) M (SD)**	**MBCT (N = 31) M (SD)**	**WL/TAU (N = 29) M (SD)**	**Significance**
HMSE	116.5 (19.1)	118.1 (16.7)	115.0 (21.5)	.392
FFMQ	129.4 (17.7)	128.0 (17.57)	132.2 (18.34)	.935
MIDAS	53.3 (43.5)	43.4 (33.8)	63.9 (50.3)	.487
HDI[†]	51.4 (18.9)	52.5 (21.2)	[††]50.2 (16.2)	.664

Note. Note. MBCT = Mindfulness-Based Cognitive Therapy, WL/TAU = Waitlist Treatment as Usual; HMSE = Headache Management Self-Efficacy Scale; FFMQ = Five Facet Mindfulness Questionnaire; MIDAS = Migraine Disability Assessment; HDI = Henry Ford Hospital Headache Disability Inventory

[†]N = 57

[††]N = 26

Table 3
Month 1 HMSE with Demographic Variables for Total and Randomized Groups

	HMSE (Total N=60)		HMSE (MBCT N = 31)		HMSE WL/TAU N=29)	
	M (SD)	**Sig.**	**M (SD)**	**Sig.**	**M (SD)**	**Sig.**
Demographics						
Gender		.867		.372		.471
Male	115.2 (18.6)		128.5 (16.3)		106.3 (16.3)	
Female	116.7 (19.3)		117.4 (16.8)		115.9 (22.0)	
Ethnicity		.650		.924		.656
Hispanic/Latino	114.2 (20.5)		117.4 (21.7)		111.0 (21.7)	
Non- Hispanic /Latino	117.1 (18.9)		118.2 (16.3)		115.8 (21.8)	
Race		.156		.325		.346
White	188.2 (19.1)		119.4 (16.8)		116.9 (21.7)	
All Else	109.1 (17.9)		111.2 (16.5)		107.5 (20.4)	
Education		.739		.104		.409
College degree or less	115.6 (18.5)		113.0 (14.6)		119.0 (22.7)	
Graduate degree	117.3 (19.7)		123.0 (17.3)		112.1 (20.8)	
Employment		.104		.359		.219
Full-Time	119.6 (18.5)		120.0 (17.1)		119.1 (20.8)	
Not full-time	111.3 (19.2)		114.0 (16.1)		109.1 (21.9)	
Marital Status		.552		.478		.839
Single	115.2 (19.4)		116.2 (18.1)		114.2 (21.2)	
Married/Living with a domestic partner	118.2 (18.9)		120.4 (14.9)		115.9 (22.5)	

Migraine Status		.116		.423		.182
Chronic	112.8 (18.1)		115.7 (17.6)		109.8 (18.6)	
Episodic	120.6 (19.6)		120.6 (15.9)		120.6 (23.6)	

Note. Note. MBCT = Mindfulness-Based Cognitive Therapy; WL/TAU = Waitlist Treatment as Usual; HMSE = Headache Management Self-Efficacy Scale

Table 4

Month 1 HMSE Correlations with Month 1 FFMQ (Total and Subscales)

	HMSE	**Significance**
	r	
FFMQ Total	.197	.132
FFMQ Observe	.027	. 387
FFMQ Describe	.226	.082
FFMQ Aware	.138	.201
FFMQ Non Judgment	.143	.277
FFMQ Non React	.097	.460

Note. N = 60; HMSE = Headache Management Self-Efficacy Scale; FFMQ = Five Factor Mindfulness Questionnaire

Table 5

Linear Mixed Effects Model Changes in Self-efficacy

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	112.68	3.82	<.001
Group	3.51	5.30	.509
Month			
2 vs 1	0.94	2.63	.722
4 vs 1	5.29	3.02	.086
Month*Group			
Month 2 vs 1	9.72	3.58	.008
Month 4 vs 1	7.02	4.29	.108

N = 60

Table 6

Linear Mixed Effects Model Changes in Self-efficacy with Age

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	98.70	10.66	<.001
Group	5.82	5.61	.303
Month			
2 vs 1	0.87	2.53	.089
4 vs 1	5.25	3.03	.303
Age	0.32	.23	.166
Month*Group			
Month 2 vs 1	10.10	3.54	.005
Month 4 vs 1	6.23	4.34	.157

N = 60

Table 7.

Linear Mixed Effects Model Changes in Self-efficacy and Changes in Mindfulness over time

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	110.05	4.13	<.001
Group	7.93	6.14	.201
Month			
2 vs 1	1.90	2.92	.516
4 vs 1	5.33	3.19	.102
ΔFFMQ	1.28	0.60	.038
Group*Month			
Month 2 vs 1	5.87	4.13	.160
Month 4 vs 1	3.10	4.74	.517
Month*ΔFFMQ			
Month 2 vs 1*Δ FFMQ	-0.15	0.42	.707
Month 4 vs 1*Δ FFMQ	0.06	0.46	.890
Group*ΔFFMQ	-1.09	0.66	.105
Month*Group*Δ FFMQ			
Month 2 vs 1*Group*ΔFFMQ	0.42	0.46	.363
Month 4 vs 1*Group*ΔFFMQ	0.30	0.51	.599

N = 51

Table 8

Linear Mixed Effects Model Changes in Self-efficacy and Changes in Mindfulness with Age

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	100.41	11.16	<.001
Group	9.73	6.47	.137
Month			
2 vs 1	1.83	2.81	.516
4 vs 1	5.33	3.44	.124
Change in FFMQ	1.23	0.60	.046
Age	0.22	0.24	.357
Group by Month			
2 vs 1*Group	6.14	4.01	.130
4 vs 1*Group	2.83	5.12	.582
Month by Change in FFMQ			
2 vs 1*Change in FFMQ	-0.13	0.40	.736
4 vs 1*Change in FFMQ	0.06	0.50	.898
Group*Change in FFMQ	-1.10	0.67	.106
Month by Group by Change in FFMQ			
2 vs 1*Group*Changes in FFMQ	0.44	0.45	.329
4 vs 1*Group*Changes in FFMQ	0.26	0.56	.648

N = 51

Table 9

Linear Mixed Effects Model Changes in Self-efficacy and Mindfulness Practice

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	97.39	8.77	<.001
Proportion days meditated	28.91	12.42	.024
Month			
2 vs 1	18.03	7.38	.018
4 vs 1	2.70	11.72	.818
Month*Proportion of days meditated			
Month 2 vs 1*Proportion of days meditated	-10.97	10.17	.445
Month 4 vs 1*Proportion of days meditated	12.07	15.71	.669

N = 31

Table 10

Sensitivity Analysis of Linear Mixed Effects Model Changes in Self-efficacy and Mindfulness Practice

Fixed Effects	**Estimate**	**SE**	**Significance**
Intercept	97.39	18.86	<.001
Proportion days meditated	28.91	11.21	.014
Month			
2 vs 1	10.51	2.71	<.001
4 vs 1	11.96	3.64	.002

N = 31

Figures

Figure 1

Mean Predicted Headache Management Self-efficacy by Group

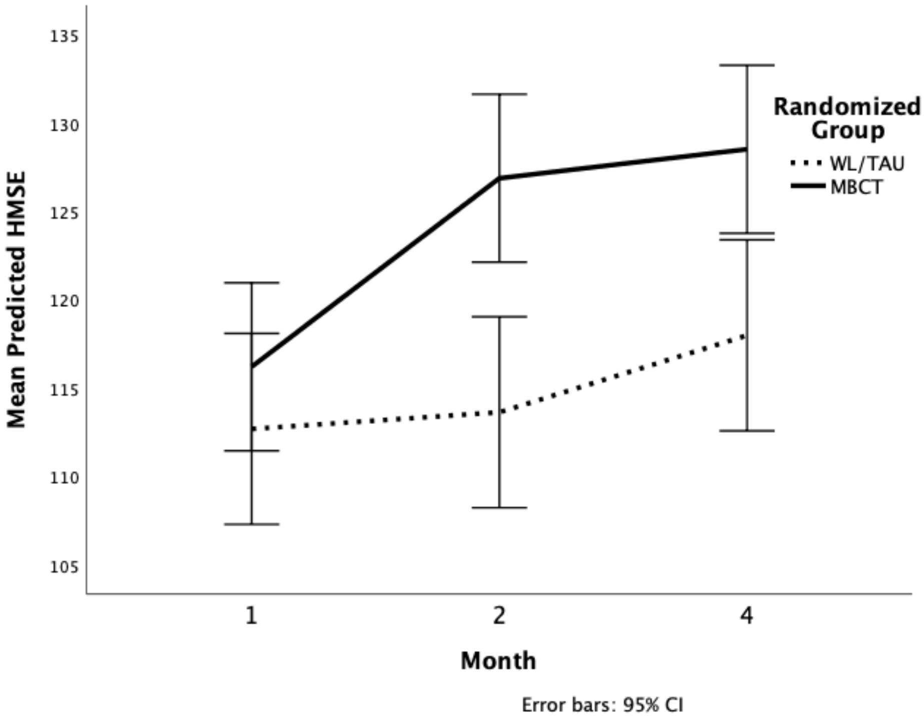
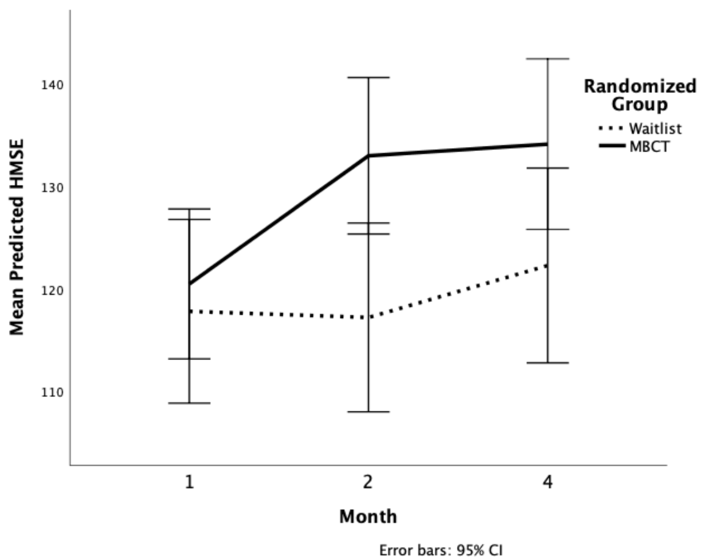


Figure 2

Mean Predicted Headache Management Self-efficacy and FFMQ Change Score by Group

FFMQ Change Score > 0, N = 34



FFMQ Change Score ≤ 0, N = 17

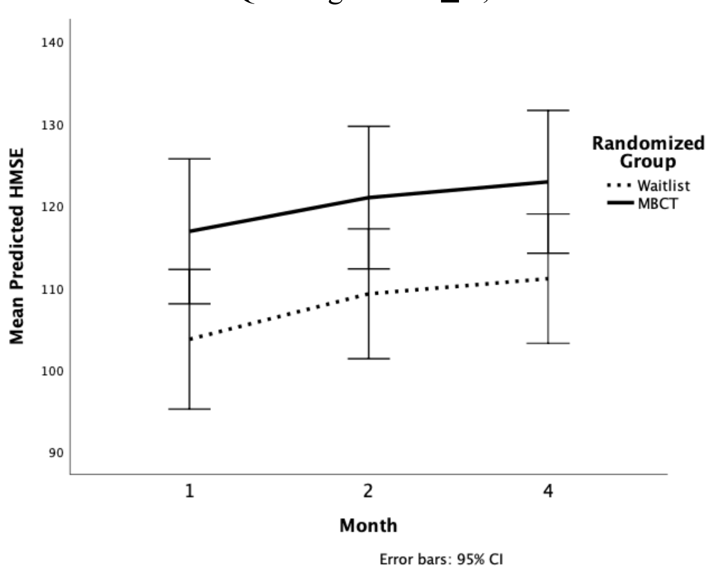


Figure 3

Mean Predicted Headache Management Self-efficacy and Proportion of Mindfulness Meditation Practice

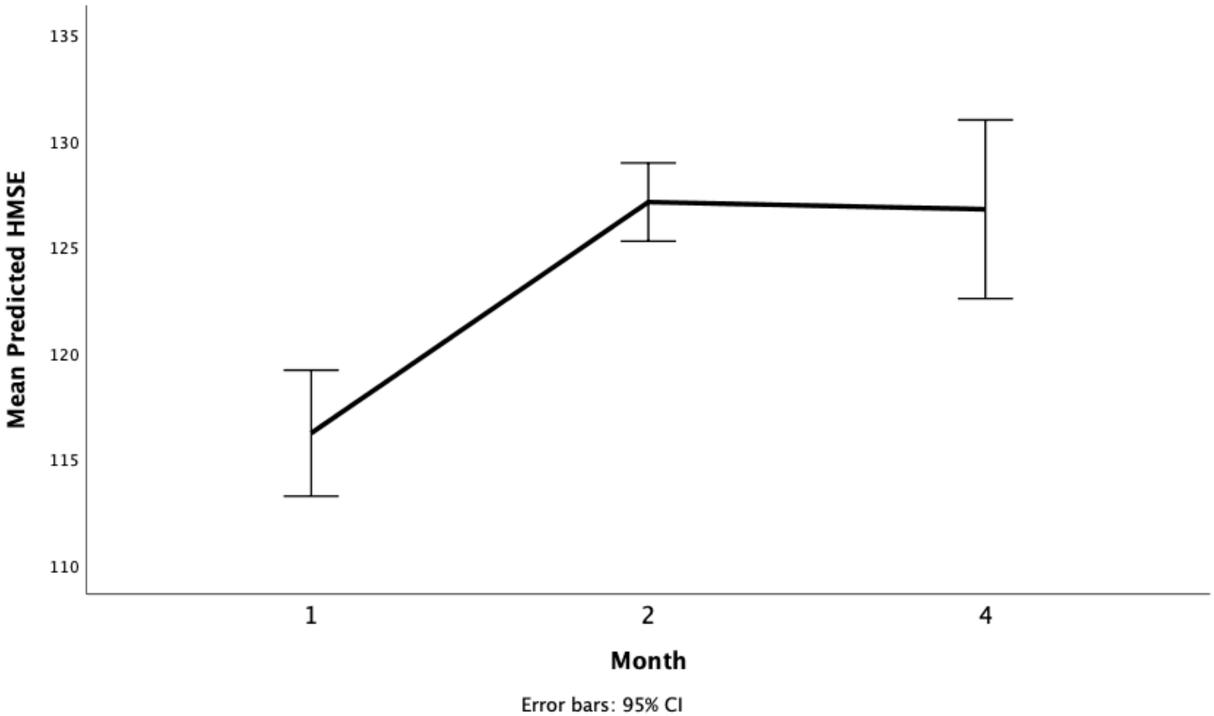
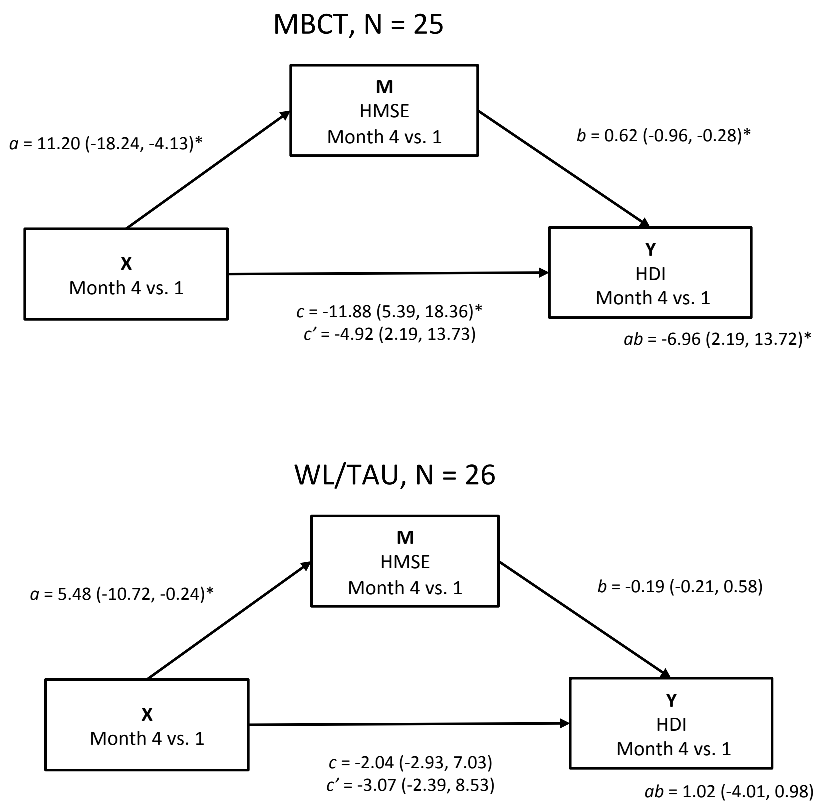


Figure 4

Mediation Analysis for Headache Management Self-efficacy and Headache Disability



Note: HMSE = Headache Management Self-Efficacy; HDI = Headache Disability Index

Appendix A

Headache Management Self-Efficacy (HMSE)

Instructions: You will find below a number of statements related to headaches. Please read each statement carefully and indicate how much you agree or disagree with the statement by circling a number next to it. Use the following scale as a guide.

Response Options	Strongly Disagree 1	Moderately Disagree 2	Slightly Disagree 3	Neither Agree or Disagree 4	Slightly Agree 5	Moderately Agree 6	Strongly Agree 7
Items							
1. I can keep even a *bad* headache from disrupting my day by changing the way I respond to the pain.							
2. When I'm in some situations, nothing I do will prevent headaches							
3. I can reduce the intensity of a headache by relaxing.							
4. There are things I can do to reduce headache pain.							
5. I can prevent headaches by recognizing headache triggers.							
6. Once I have a headache there is nothing I can do to control it.							
7. When I'm tense, I can prevent headaches by controlling the tension.							
8. Nothing I do reduces the pain of a headache.							
9. If I do certain things every day, I can reduce the number of headaches I will have.							
10. If I can catch a headache before it begins, I often can stop it.							
11. Nothing I do will keep a mild headache from turning into a bad headache.							
12. I can prevent headaches by changing how I respond to stress.							
13. I can do things to control how much my headaches interfere with my life.							
14. I *cannot* control the tension that causes my headaches.							
15. I can do things that will control how long a headache lasts.							
16. Nothing I do will keep a bad headache from disrupting my day.							
17. When I'm not under a lot of stress, I can prevent many headaches.							
18. When I sense a headache is coming, there is nothing I can do to stop it.							

19. I can keep a *mild* headache from disrupting my day by changing the way I respond to the pain.
20. If I am under a lot of stress, there is nothing I can do to prevent headaches.
21. I can do things that make a headache seem not so bad.
22. There are things I can do to prevent headaches.
23. If I am upset, there is nothing I can do to control the pain of a headache.
24. I can control the intensity of headache pain.
25. I can do things to cope with my headaches.

Appendix B

Five Facet Mindfulness Questionnaire (FFMQ)

Description:
This instrument is based on a factor analytic study of five independently developed mindfulness questionnaires. The analysis yielded five factors that appear to represent elements of mindfulness as it is currently conceptualized. The five facets are observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

Response Options	Never/very rarely true (1)	Rarely true (2)	Sometimes true (3)	Often true (4)	Very often/always true (5)

Items

1. When I'm walking, I deliberately notice the sensations of my body moving.
2. I'm good at finding words to describe my feelings.
3. I criticize myself for having irrational or inappropriate emotions.
4. I perceive my feelings and emotions without having to react to them.
5. When I do things, my mind wanders off and I'm easily distracted.
6. When I take a shower or bath, I stay alert to the sensations of water on my body.
7. I can easily put my beliefs, opinions, and expectations into words.
8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.
9. I watch my feelings without getting lost in them.
10. I tell myself I shouldn't be feeling the way I'm feeling.
11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.
12. It's hard for me to find the words to describe what I'm thinking.
13. I am easily distracted.
14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.
15. I pay attention to sensations, such as the wind in my hair or sun on my face.
16. I have trouble thinking of the right words to express how I feel about things
17. I make judgments about whether my thoughts are good or bad.
18. I find it difficult to stay focused on what's happening in the present.
19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.
20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.

21. In difficult situations, I can pause without immediately reacting.
22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.
23. It seems I am "running on automatic" without much awareness of what I'm doing.
24. When I have distressing thoughts or images, I feel calm soon after.
25. I tell myself that I shouldn't be thinking the way I'm thinking.
26. I notice the smells and aromas of things.
27. Even when I'm feeling terribly upset, I can find a way to put it into words.
28. I rush through activities without being really attentive to them.
29. When I have distressing thoughts or images I am able just to notice them without reacting.
30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.
31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.
32. My natural tendency is to put my experiences into words.
33. When I have distressing thoughts or images, I just notice them and let them go.
34. I do jobs or tasks automatically without being aware of what I'm doing.
35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.
36. I pay attention to how my emotions affect my thoughts and behavior.
37. I can usually describe how I feel at the moment in considerable detail.
38. I find myself doing things without paying attention.
39. I disapprove of myself when I have irrational ideas.

Appendix C

Headache Disability Index (HDI)

Instructions: ***PLEASE READ CAREFULLY:*** The purpose of the scale is to identify difficulties that you may be experiencing because of your headache. Please check off "YES", "SOMETIMES", or "NO" to eat item. Answer each item as it pertains to your headache only.

Response Options	YES	SOMETIMES	NO
Items			
1. Because of my headaches I feel handicapped.			
2. Because of my headaches I feel restricted in performing my routine daily activities.			
3. No one understands the effect my headaches have on my life.			
4. I restrict my recreational activities (e.g. sports, hobbies) because of my headaches.			
5. My headaches make me angry			
6. Sometimes I feel that I am going to lose control because of my headaches			
7. Because of my headaches I am less likely to socialize			
8. My spouse/significant other, or family and friends have no idea what I am going through because of my headaches.			
9. My headaches are so bad that I feel I am going to go insane.			
10. My outlook on the world is affected by my headaches.			
11. I am afraid to go outside when I feel a headache is starting.			
12. I feel desperate because of my headaches			
13. I am concerned that I am paying penalties at work or at home because of my headaches.			
14. My headaches place stress on my relationships with family or friends.			
15. I avoid being around people when I have a headache			
16. I believe my headaches are making it difficult for me to achieve my goals in life.			
17. I am unable to think clearly because of my headaches.			
18. I get tense (e.g. muscle tension) because of my headaches			
19. I do not enjoy social gatherings because of my headaches			
20. I feel irritable because of my headaches			
21. I avoid traveling because of my headaches			
22. My headaches make me feel confused			
23. My headaches make me feel frustrated			
24. I find it difficult to read because of my headaches			
25. I find it difficult to focus my attention away from my headaches and on other things.			