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# Mindfulness-Based Cognitive Therapy for Headache Pain:

# An Evaluation of the Long-Term Maintenance of Effects

Running Head: LONG-TERM EFFICACY OF MBCT FOR HEADACHE

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## Highlights

- This study is the first to examine the durability of gains following Mindfulness-Based Cognitive Therapy (MBCT) for headache.

- Treatment related gains made at post-treatment were maintained at 6-months follow-up for key pain outcomes and process variables.
- Current results add to a growing body of literature supporting the durability of MBCT for painful conditions.

**Abstract**

*Objectives.* This study aimed to examine the durability of gain patterns following an 8-week Mindfulness-Based Cognitive Therapy (MBCT) for headache pain program.

*Design.* A secondary analysis of a randomized controlled trial was conducted. Participants (N=19) were individuals with headache pain who completed both the MBCT program as well as a 6-month follow-up assessment at a headache clinic or a university psychology clinic. Standardized measures of the primary outcomes (pain intensity and pain interference) and secondary outcomes (pain catastrophizing, mindfulness, activity engagement, pain willingness, and self-efficacy) were administered. Paired-samples *t* tests and effect sizes were examined.

*Results.* Significant (uncorrected *p*s<.05) pre- to post-treatment gains were found for pain intensity, pain interference, pain catastrophizing, activity engagement and self-efficacy, and these gains were maintained at 6-months post-treatment. Effect sizes for the significant changes from pre- to post-treatment, and from pre-treatment to follow-up were mostly consistent across epochs ($.62 \leq d\text{s} \leq -1.40$), indicating steady maintenance of effects. Improvement in mindfulness and pain willingness was non-significant immediately post-treatment and at follow-up, with small effects observed.

*Conclusions.* This study adds to a growing body of literature supporting the durability of MBCT for painful conditions. Results indicated a consistent pattern of maintenance of treatment-related gains across a number of key pain-related outcomes. Future research with a

larger sample is needed to investigate the mechanisms underlying these continued gains in order to optimize targeted relapse-prevention.

**Key Words:** Mindfulness-Based Cognitive Therapy; Long-term Efficacy; Maintenance of Gains; Headache

## Introduction

Headache pain, and specifically migraine, was classified by the World Health Organization as the sixth most common cause of disability worldwide.(1) In the US alone, 45-million individuals are affected by headache pain which substantially contributes to massive annual healthcare expenditures.(2) Notably, the most frequently identified headache trigger is stress, and the role of biopsychosocial factors in the experience of headache is well recognized.(3) Thus, effective treatment requires targeting the full, multidimensional nature of headache pain.(4)

The current "gold standard" psychosocial intervention for headache is cognitive-behavioral therapy (CBT), and this approach is endorsed as a first-line treatment in combination with pharmacotherapy by leading headache organizations.(4) The CBT approach is designed to be an empowering intervention that teaches specific skills that patients can continue to use to manage headache pain long after completion of treatment. However, while benefits following CBT for headache pain on average tend to be maintained at long-term follow-up, within this average are also a number of individuals who do not respond or who relapse following CBT.(5-7)

A recent innovative approach to the management of pain, including headache, is Mindfulness-Based Cognitive Therapy (MBCT).(8) Unlike CBT for pain, which targets changing specific cognitive and behavioral responses to pain, MBCT more globally targets a

shift in patients' *relationship* to cognitions, emotions, and behaviors and to the pain itself, to cultivate a decentered, mindful acceptance of the entirety of experience, including the pain.(9) It is possible that targeting this more global shift – through training in the combined MBCT cognitive-behavioral and mindfulness-based skillset – might better equip patients to manage and more adaptively respond to a range of potential relapse triggers, thereby potentially leading to improved long-term maintenance of gains.

Although research has examined Mindfulness-Based Stress Reduction for headache pain,(e.g., 10) to our knowledge, only two prior studies have examined the durability of outcomes following MBCT for pain. Parra-Delgado and Latorre-Postigo examined MBCT within a fibromyalgia sample and found that treatment-related benefits were maintained at the 3-month follow-up.(11) Further, Dowd and colleagues examined internet-delivered MBCT within a heterogeneous chronic pain sample and found that most of the MBCT-related improvements across a range of outcomes were maintained at 6-month follow-up.(12)

No prior research has examined the maintenance patterns of benefits obtained during MBCT for headache. Thus, the aim of the present study was to conduct a secondary analysis of a prior trial of MBCT for headache, factoring in 6-month follow-up data on individuals who completed treatment to examine long-term efficacy and maintenance of gains patterns.(8) Results of the pre- to post-treatment findings of the original trial showed that those participants who completed treatment reported significant and clinically meaningful improvements in primary headache-related outcomes (pain interference, pain intensity) and important secondary outcomes (pain catastrophizing, headache management self-efficacy, pain acceptance); mindfulness (an additional secondary outcome) did not show meaningful improvement.(8) Based on past research,(11, 12) it was hypothesized that these pre- to post-treatment benefits would be maintained at 6-months post-treatment.

**Methods**

*Research Design*

This is a secondary analysis of data obtained from a parallel group, un-blinded, randomized controlled trial (RCT) that compared MBCT to a delayed treatment control (DT) within a headache population.(8) In this trial, the DT group crossed over following the wait-list period to then complete treatment (DT-MBCT). This trial was pre-registered on clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT01213056). The MBCT intervention took place at the Kilgo Headache Clinic, or the University of Alabama Psychology Clinic. Several manuscripts have been published from data obtained in this trial, including the primary outcome paper,(8) two mechanisms papers,(13, 14) and a qualitative paper.(15) Both the MBCT group and the DT-MBCT group were invited to complete a 6-month follow-up assessment, and the follow-up data collapsed across these two groups is the focus of this current study; this 6-month follow-up data has not been previously analyzed or reported in previous research. This research was approved by the Institutional Review Board at the University of Alabama, and informed consent was obtained with all patients prior to participation. For additional details, see the original trial.(8)

*Participants*

Participants were adults with headache pain. As reported in the original trial, the study inclusion criteria were: (1) ≥19 years of age; (2) ≥3 pain days per month (for the past ≥3 months) due to a primary headache pain type (i.e., migraine, tension type headache, cluster, or other) as defined by the international classification of headache disorders (16); (3) Primary pain source was headache pain; (4) If currently using psychotropic or headache medications, use of these medications must have begun at least 4-weeks prior to baseline assessment; and (5) Reading ability was sufficient to comprehend self-monitoring forms. The study exclusion criteria were: (1) HIV-related pain and cancer pain because these are associated with malignant disease (17); (2) History of seizure or facial neuralgia, as these conditions might

preclude the accurate diagnosis of headache; (3) Significant cognitive impairment as evidenced on the Mini-cog (18); (4) Current participation in other psychological treatments for any pain condition; and (5) Schizophrenia, bipolar affective disorder, seizure disorder not adequately controlled by medication, or current substance abuse. To address the aims of this study, an additional inclusion criterion was completion of both the 8-week MBCT program (either immediately or following the DT period) and the 6-month follow-up assessment. A total of N=19 participants were included in all analyses. The CONSORT flow diagram and a detailed description of the sample characteristics can be found in the original report.(8)

*MBCT Intervention Protocol*

In the original trial,(8) an existing 8-week MBCT for depression protocol was adapted for headache pain.(19) The adapted protocol incorporated knowledge about the specific issues of relevance and importance to a headache pain population.(20) The MBCT manual consists of eight, weekly 2-hour sessions and was delivered in a group setting. Participants were encouraged to practice cognitive-behavioral exercises and meditation daily in between group sessions. See the original trial for protocol details.(8)

*Primary Outcome Measures*[1]

The Wisconsin Brief Pain Inventory (BPI) assessed pain intensity and pain interference.(21) The BPI scales have demonstrated adequate internal consistency in a variety of pain populations and concurrent validity with other pain instruments.(21)

*Secondary Outcome Measures*

The Pain Catastrophizing Scale (PCS) was used to assess catastrophic thinking.(22) The PCS has been shown to have strong internal consistency, concurrent and discriminant validity.(22) The Mindful Attention and Awareness Scale (MAAS) was used to assess the

[1] Although daily headache diaries were included as an additional primary outcome measure in the original trial, due to ethical concerns regarding participant burden, daily diaries were not collected for an additional 6-months following treatment. Hence, survey data obtained at pre- and post-treatment and 6-month follow-up is examined as the primary outcome of the current study.

participant's tendency to attend to present-moment experiences.(23) The MAAS has exhibited reliable internal consistency and excellent test-retest reliability.(23) The Chronic Pain Acceptance Questionnaire (CPAQ) subscales of activity engagement and pain willingness were used.(24) As described in Vowles et al., the CPAQ demonstrates adequate reliability.(25) Self-efficacy for the prevention and reduction of headache was assessed using the Headache Management Self-Efficacy scale (HMSE), which has been shown to be reliable and valid.(26)

**Results**

SPSS version 23.0 was used in all analyses.(27) Differences between pre-treatment to post-treatment, and between both pre-treatment and post-treatment to 6-month follow-up were examined using paired-samples t-tests. Bonferroni adjusted *p* values are reported on the basis of 21 comparisons, thus the critical adjusted significance value for each individual test was set at .05/21=.002. However, this method has been criticized for its emphasis on the general null hypothesis and for being overly conservative, and it has been recommended that uncorrected *p* values also be reported in conjunction with the associated confidence interval and effect sizes.(28-30) Therefore, uncorrected *p* values, confidence intervals and within-subject effect sizes were also calculated and Cohen's *d*s are reported. See Table 1 for a summary of the primary and secondary outcomes at pre- and post-treatment, and at 6-months follow-up. BPI pain intensity significantly improved from pre- to post-treatment (Confidence Interval [CI]: .26 to 1.67; $p$=.01; Bonferroni adjusted $p$>.05) and from pre-treatment to 6-months follow-up (CI: .20 to 1.54; $p$=.01; Bonferroni adjusted $p$>.05); the change from post-treatment to 6-months follow-up was non-significant (CI: -.56 to .38; $p$=.69; Bonferroni adjusted $p$>.05), thus improvement in pain intensity was maintained long-term. The medium effect size for these relations was similar from pre- to post-treatment ($d$=.65), as from pre-treatment to follow-up ($d$=.62), suggesting maintenance of gains.

Significant improvement in BPI pain interference was observed from pre- to post-treatment (CI: .84 to 2.75; $p$=.001; Bonferroni adjusted $p$<.05) and from pre-treatment to 6-months follow-up (CI: .37 to 2.14; $p$=.008; Bonferroni adjusted $p$>.05); change in pain interference from post-treatment to 6-months follow-up was non-significant (CI: -1.32 to .24; $p$=.16; Bonferroni adjusted $p$>.05), indicating long-term maintenance. The effect size for change in pain interference from pre- to post-treatment was large ($d$=.93), while the effect size from pre-treatment to follow-up was medium ($d$=.68), indicating a relatively stable maintenance pattern.

Secondary outcomes were also examined. PCS pain catastrophizing was significantly improved from pre- to post-treatment (CI: 5.03 to 14.86; $p$<.001; Bonferroni adjusted $p$<.05) and from pre-treatment to 6-months follow-up (CI: 5.43 to 14.25; $p$<.001; Bonferroni adjusted $p$<.05); this improvement was maintained at 6-months follow-up, as indicated by the non-significant change in pain catastrophizing change from post-treatment to 6-months follow-up (CI: -2.81 to 2.60; $p$=.94; Bonferroni adjusted $p$>.05). The large effect size from pre- to post-treatment ($d$=1.02), was similar for the pre-treatment to follow-up period ($d$=1.12), suggesting stable treatment-related gains in pain catastrophizing.

Change in MAAS mindfulness was non-significant from both pre- to post-treatment (CI: -.65 to .11; $p$=.15; Bonferroni adjusted $p$>.05) and from pre-treatment to 6-months follow-up (CI: -.86 to .01; $p$=.06; Bonferroni adjusted $p$>.05). Change in mindfulness was also non-significant from post-treatment to 6-months follow-up (CI: -.45 to .14; $p$=.28; Bonferroni adjusted $p$>.05), suggesting no significant post-treatment gains in mindfulness. The effect size for change in mindfulness from pre- to post-treatment was small ($d$=-.35), as was the effect size from pre-treatment to follow-up ($d$=-.47).

The CPAQ subscales of activity engagement and pain willingness were examined. Although activity engagement significantly improved from pre- to post-treatment (CI: -11.48

to -4.31; $p<.001$; Bonferroni adjusted $p<.05$) and from pre-treatment to 6-months follow-up (CI: -10.82 to -3.49; $p=.001$; Bonferroni adjusted $p<.05$), change in pain willingness was non-significant in both the pre- to post-treatment epoch (CI: -.35 to 7.50; $p=.07$; Bonferroni adjusted $p>.05$) and the pre-treatment to 6-month follow-up epoch (CI: -5.85 to 10.63; $p=.55$; Bonferroni adjusted $p>.05$). Change from post-treatment to 6-months follow-up was non-significant for both activity engagement (CI: -1.77 to 3.24; $p=.54$; Bonferroni adjusted $p>.05$) and pain willingness (CI: -8.97 to 6.19; $p=.70$; Bonferroni adjusted $p>.05$), indicating long-term maintenance of improvement in activity engagement, and no delayed improvement in pain willingness. Maintenance of the gains made in activity engagement was evident as the effect size for change in activity engagement was large at both pre- to post-treatment ($d=-1.08$), and pre-treatment to 6-month follow-up ($d=-.96$). The effect size for pain willingness from pre- to post-treatment was small-medium, although this effect was in the *opposite* direction than expected, with some worsening in outcome occurring ($d=.46$); however, this pattern was not replicated at 6-month follow-up ($d=.07$).

Improvement in HMSE self-efficacy was significant from pre- to post-treatment (CI: -32.42 to -15.79; $p<.001$; Bonferroni adjusted $p<.05$) and from pre-treatment to 6-months follow-up (CI: -27.69 to -10.73; $p<.001$; Bonferroni adjusted $p<.05$); change in self-efficacy from post-treatment to 6-months follow-up was non-significant (CI: -3.13 to 12.91; $p=.22$; Bonferroni adjusted $p>.05$), indicating maintenance of improvement. Similar large effect sizes were found from pre- to post-treatment ($d=-1.40$), as from pre-treatment to follow-up ($d=-1.23$), suggesting stable treatment-related gains.

[Insert Table 1 about here]

**Discussion**

This is the first study to report long-term outcomes associated with MBCT for headache, and overall, the results support the durability of MBCT-related benefits. Findings

demonstrated that improvements in pain intensity and pain interference were maintained at 6-months follow-up, although the size of these effects was strongest for pain interference. The most robust long-term effects were found for the secondary outcomes of pain catastrophizing, activity engagement, and headache management self-efficacy. Neither mindfulness nor pain willingness changed substantially either during, or following MBCT.

Past researchers(31) have noted that change in pain intensity is not an explicit focus of mindfulness-based interventions for chronic pain (the emphasis is on accepting pain); thus, the recommended primary outcome is pain interference. Current results showed that the large effect size improvement in pain interference reported in the original trial at post-treatment was similarly maintained at 6-months post-treatment.(8) Further, although change in pain intensity was not explicitly targeted in the MBCT protocol, a medium effect size improvement was found on this outcome, which was maintained at 6-months follow-up. Maintenance of these outcomes is likely crucial to the individual experiencing headache pain, which may reinforce their on-going pain self-management efforts.

Pain catastrophizing is a robust and reliable predictor of many worse pain outcomes, (32) and maintaining treatment-related reductions in this maladaptive cognitive process may be a mechanism for on-going maintenance of improved headache pain outcomes.(33) Although the potential long-term maintenance mechanism role of pain catastrophizing could not be examined in this study, findings showed that MBCT resulted in a large effect size improvement in pain catastrophizing that was maintained at follow-up. This is consistent with the size of effects observed for pain catastrophizing during CBT for headache pain, an approach that explicitly targets this construct.(6)

Theoretically, key process variables of the MBCT conceptual model are mindfulness and acceptance.(9) However, in this study, change in mindfulness was non-significant both during treatment and at follow-up. As discussed in the original trial, this may be due to a

measurement issue, with the validity of MAAS's assessment of trait mindfulness under debate.(34) Similarly, the validity of the CPAQ in measuring acceptance has been questioned, with a recent evaluation determining that the item content assessing "pain willingness" reflects a need for pain control.(35) Thus, the current findings that MBCT did not significantly change a "need for pain control" are not surprising, given the emphasis in MBCT is on "letting go" of control *per se*. On the other hand, results did support that MBCT leads to large effects that were maintained long-term for engaging in meaningful activities despite the pain, which is likely to be of central importance to patients' on-going quality of life.

Given that continuing a group MBCT program with a skilled leader as a long-term on-going process is not financially feasible in most contexts, it is critical that patients develop a sense of headache management self-efficacy and belief that they have the personal capacity to self-manage pain. Current results found that MBCT may be especially well-suited to engendering such a sense of self-efficacy, with large effect sizes observed in this domain at both post-treatment and at follow-up. Although it was not possible to explore whether maintained increased self-efficacy corresponded with continued long-term use of the MBCT pain management skill-set in this study, it has been theorized that strong effects on self-efficacy may be critical to continued use of pain coping skills and overall maintenance of gains.(36)

*Limitations*

A limitation of this research is the lack of a comparison condition at follow-up; it was not ethical to require the DT group to wait 6-months to receive a treatment that was expected to be of benefit, thus no long-term data was obtained for the DT control. Subsequently, this limited the current analyses to within-subject, univariate tests. The small sample size is also a limitation as this precluded implementation of advanced statistical modelling aimed towards

uncovering the mechanisms of the observed patterns of maintenance. A further limitation is that the headache outcomes in this study were obtained via retrospective report and not from daily headache activity recordings. Future studies with an active treatment comparison condition designed *a priori* to examine both treatment and long-term maintenance mechanisms using ecological momentary assessment are needed in order to optimize targeted relapse-prevention.

*Conclusions*

This study found that MBCT-related gains across primary and secondary headache-related outcomes were maintained 6-months following treatment, with improvement remaining statistically significant and clinically meaningful long-term. Relapse following psychological approaches for chronic pain is a concern that has been previously emphasized by leaders in the field as a critical problem to address.(5, 33, 36) Current results showed that MBCT may be particularly well-suited to equip patients with the necessary pain coping skill-set to effectively deal with the set-backs and relapse triggers that will inevitably occur in the context of living with headache pain, and to continue to engage in meaningful life activities despite the pain.

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**rences**

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Table 1. *Questionnaire data outcomes at pre- and post-treatment and at 6-months follow-up (N=19)*

| Outcome[1]/Time | Mean(SD) | ΔPre- to Post-Tx[2] | ΔPost- to 6mo Post-Tx[2] | ΔPre- to 6mo Post-Tx[2] |
|---|---|---|---|---|
| BPI[3] Pain Intensity[†] | | 2.86* | -.41 | 2.72* |
| Pre-Treatment | 3.28(1.67) | | | |
| Post-Treatment | 2.32(1.60) | | | |
| 6-Months Post-Treatment | 2.41(1.70) | | | |
| BPI[3] Pain Interference[†] | | 3.94** | -1.46 | 2.98** |
| Pre-Treatment | 2.77(1.72) | | | |
| Post-Treatment | .98(1.03) | | | |
| 6-Months Post-Treatment | 1.52(1.47) | | | |
| PCS[4] Pain Catastrophizing[†] | | 4.25*** | -.08 | 4.69*** |
| Pre-Treatment | 18.79(11.01) | | | |
| Post-Treatment | 8.84(7.57) | | | |
| 6-Months Post-Treatment | 8.95(8.24) | | | |

| | | | | |
|---|---|---|---|---|
| MAAS[5] Mindfulness‡ | | -1.51 | -1.11 | -2.04 |
| Pre-Treatment | 3.92(.93) | | | |
| Post-Treatment | 4.19(.74) | | | |
| 6-Months Post-Treatment | 4.34(.82) | | | |
| CPAQ[6] Activity Engagement‡ | | -4.62*** | .62 | -4.10** |
| Pre-Treatment | 39.16(10.51) | | | |
| Post-Treatment | 47.05(9.36) | | | |
| 6-Months Post-Treatment | 46.32(8.67) | | | |
| CPAQ[7] Pain Willingness‡ | | 1.92 | -.39 | .61 |
| Pre-Treatment | 28.95(10.25) | | | |
| Post-Treatment | 25.36(7.51) | | | |
| 6-Months Post-Treatment | 27.00(8.53) | | | |
| HMSE[8] Self-Efficacy‡ | | -6.09*** | 1.28 | -4.76*** |
| Pre-Treatment | 126.05(14.66) | | | |
| Post-Treatment | 150.16(16.48) | | | |
| 6-Months Post-Treatment | 145.26(23.65) | | | |

[1]Internal consistency for all measures used was at least adequate, $.77 \leq \alpha \leq .91$

[2]Test statistic reported is the paired-samples *t* score

[3] Brief Pain Inventory; score range: 0-10

[4] Pain Catastrophizing Scale; score range: 0-52

[5]Mindful Attention and Awareness Scale; score range: 1-6

[6] Chronic Pain Acceptance Questionnaire, Activity Engagement; score range: 0-66

[7] Chronic Pain Acceptance Questionnaire, Pain Willingness; score range: 0-54

[8] Headache Management Self-Efficacy Scale; score range: 25-175

†Lower scores are indicative of better outcomes on these measures

‡Higher scores are indicative of better outcomes on these measures

Uncorrected *p* values: *=$p<.05$, **=$p<.01$, ***=$p<.001$