

**COMPARISON OF AN ONLINE MINDFULNESS-BASED COGNITIVE THERAPY
INTERVENTION WITH ONLINE PAIN MANAGEMENT PSYCHOEDUCATION: A
RANDOMIZED CONTROLLED STUDY.**

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Haulie Dowd DPsych Sc^{1,2}, Michael J Hogan PhD¹, Brian E McGuire PhD^{1,2}, Mary C Davis PhD³, Kiran M Sarma PhD¹, Rosemary A Fish PhD^{1,2}, Alex J Zautra PhD³.

¹School of Psychology, National University of Ireland Galway, Ireland

²Centre for Pain Research, National University of Ireland Galway, Ireland

³Department of Psychology, Arizona State University, US

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Author to whom correspondence should be sent:

Dr. Michael Hogan, School of Psychology, National University of Ireland Galway, Ireland.

Telephone: +353 91 493455; email: michael.hogan@nuigalway.ie

Comparison of an online mindfulness-based cognitive therapy intervention with online pain management psychoeducation: A randomized controlled study.

Abstract

Background: This study tested the effectiveness of a computerised mindfulness-based cognitive therapy intervention compared to computerized pain management psychoeducation in a randomized study.

Methods: Using an intention to treat (ITT) approach, 124 adult participants who reported experiencing pain that was unrelated to cancer and of at least 6 months duration were randomly assigned to computerized mindfulness-based cognitive therapy (“Mindfulness in Action” [MIA]) or pain management psychoeducation (PE) programmes. Data were collected before and after the intervention and at six-month follow-up.

Results: Participants in both groups showed equivalent change and significant improvements on measures of pain interference, pain acceptance and catastrophizing from pre-treatment to post-treatment and the improvements were maintained at follow-up. Average pain intensity also reduced from baseline to post-treatment for both groups, but was not maintained at follow-up. Participants in both groups reported increases in subjective well-being, and these were more pronounced in the MIA than the PE group. Participants in the MIA group also reported a greater reduction in pain ‘right now’, and increases in their ability to manage emotions, manage stress and enjoy pleasant events on completion of the intervention. The changes in ability to manage emotions and stressful events were maintained at follow-up.

Conclusions: The results of the study provide evidence that while there were equivalent changes across outcomes of interest for participants in both conditions over time the MIA program showed a number of unique benefits. However, the level of participant attrition in the study highlighted a need for further attention to participant engagement with online chronic pain programmes.

Comparison of an online mindfulness-based cognitive therapy intervention with online pain management psychoeducation: A randomized controlled study.

Introduction.

Cognitive behavioural therapy (CBT) has the strongest evidence base as a psychological approach to chronic pain¹⁻³. However, there is also an emerging body of evidence for other therapies such as acceptance and mindfulness-based approaches⁴⁻⁷. There is also evidence that some patients prefer an acceptance-based approach over traditional CBT⁷.

While these research findings point to the value of psychological interventions for chronic pain, access to effective pain management programmes is often limited, due to a scarcity of services³. This is the case in Ireland, where there is a relative shortage of pain management services⁸, despite the fact that chronic pain affects up to one third of patients surveyed via General Practice lists⁹ and in economic terms costs 2.5% of GDP¹⁰. As well as a shortage of services, there are other barriers to treatment which can include physical symptoms that limit mobility, distance from a clinic, transportation requirements and cost constraints¹¹. In response to these barriers to service delivery, alternative ways of delivering psychological pain management programmes need to be considered.

Internet-based interventions have emerged as a potential response to the barriers to clinic-based pain management¹². Indeed, the public demand for online health resources is increasing¹². In many instances, existing efficacious face-to-face interventions are adapted for use on the internet as a means of addressing these barriers to care. Such adapted therapies frequently report effect-sizes rivalling those of the original interventions¹³⁻¹⁵ with the added benefits of convenience, privacy, and providing clinicians with the ability to provide care to a broader spectrum of patients,

including those in remote areas^{16,17}.

CBT has been delivered successfully in an online format to chronic pain populations¹⁷ and large effect sizes have been achieved from relatively brief interventions¹⁸. However, aside from CBT, few other forms of psychological therapy have been evaluated in online formats. Recent exceptions include Buhrman et al¹⁹ who evaluated an online Acceptance and Commitment Therapy (ACT) programme including mindfulness compared with an online discussion forum in 76 chronic pain patients and found benefits for the treatment group in pain acceptance and reductions in pain-related distress, anxiety and depressive symptoms. A six month follow-up showed maintenance of improvements. Another recent study showed beneficial effects for an acceptance and mindfulness program in 79 patients with fibromyalgia, compared with a control condition (healthy lifestyle tips)²⁰.

A recent Cochrane review pointed out that most of the evidence for psychological treatments arises in studies where an active therapy such as CBT has been compared with usual care or a waiting list control². There is, therefore, a basis for comparison between active treatments. We are not aware of any randomised controlled trial of an online mindfulness program for chronic pain compared with another active psychological treatment. We evaluated the feasibility and effectiveness of a computerised and modified version of an existing mindfulness-based cognitive therapy program^{20,21}, which we called Mindfulness in Action (MIA) and compared it to an active comparator treatment, an online version of a pain management psychoeducation programme (PE)²² for chronic non-cancer pain patients. While online or distance education programmes for pain have produced small to moderate effect sizes (e.g., $d = .2 - .4$)²³, mindfulness interventions have suggested potential for moderate to large effect sizes for primary outcomes (e.g., $d = .48 - 1.1$)⁶. Furthermore, studies comparing mindfulness and education programmes directly have demonstrated larger effects for mindfulness, with differences in the order of $0.35 - 0.67$ for primary outcomes²⁴. While

psychoeducation programs are often considered as “attention control” conditions, there is now ample evidence that education is itself an active intervention^{23,25-28}. Having said that, the psychoeducation programme used in the current study primarily focused on the provision of information in relation to chronic pain and did not have a strong cognitive or behavior change component. Conversely, the mindfulness intervention included both a psychoeducation component, a mindfulness practice focus, and a cognitive and behavioral change component^{20,21}. Therefore, we predicted that the mindfulness programme would be superior to the education programme for primary outcomes of pain interference and distress, but also for other outcomes including self-reported pain, catastrophizing, pain acceptance, subjective wellbeing, and self-reported mindfulness.

Methods

Design

The design was a randomized-controlled pilot study with 6-month follow-up. The study had a mixed factorial 2 (Group) x 3 (Time) design utilising an ‘intention to treat’ analysis (ITT) based on a mixed linear modelling analytical approach for the primary analysis²⁷. The between-subjects variable (Group) had two levels – Mindfulness in Action (MIA) and Pain Management Psychoeducation (PE). The within-subjects variable (Time) had three levels – Before Intervention (T1), After Intervention (T2), and 6-months post-intervention (T3). The research sought to test the effect of the pain management programmes on both primary (Pain Interference and Distress) and secondary outcome measures (Self-reported Pain, Catastrophising, Pain Acceptance, Self-reported Mindfulness, Satisfaction with Life and Patient Self-reported Impression of Change). Outcome variables were selected based on the IMMPACT recommendations for chronic pain clinical trials²⁸. The full study protocol is available from the corresponding author.

Participants

A total of 534 volunteers with self-reported chronic pain listed on a research database based at National University of Ireland, Galway, were informed by email about the intervention. Those who were interested to participate ($N = 192$) completed an on-line screening questionnaire, hosted by the on-line survey provider SurveyMonkey (www.surveymonkey.com). Participants were excluded if they (a) had less than 6 months of pain (b) reported experiencing chronic pain due to cancer (c) reported possible symptoms of psychosis (Health Problems Questionnaire [HPQ])²⁹ (d) were under the age of 18 years and (e) were unable to complete the required questionnaires due to insufficient English language or cognitive ability. Sixty eight participants were excluded for not meeting the inclusion criteria. The remaining 124 were randomly allocated to one of two treatment conditions (MIA $n=62$ and PE $n=62$). There were 112 females (90.3%) and 12 males with a mean age of 44.53 years ($SD=12.25$; Range 19-76). Fifty participants (40.3%) reported living in Ireland, 41 (33.1%) in the UK, 26 (21%) in North America and 7 (5.6%) in other countries.

Completion rates and attrition trends are presented in the consort diagram in Figure 1, but in summary, 28 participants completed the MIA intervention to Time 2 (45%) and 23 to Time 3 (37%). For the PE intervention, 37 completed the programme to Time 2 (60%) and 27 to Time 3 (43%).

- Insert Figure 1 around here -

Sample Size and Power Analysis

Previous similar mindfulness intervention research has shown medium to large effect sizes ($d = .5 - 1.1$) for primary outcome variables including depression, anxiety, and pain interference in comparison with waitlist and treatment as usual control conditions^{6,7,30}. Online or distance education programmes for pain have produced small to moderate effect sizes (e.g., $d = .2 -$

.4)²³. We characterized the current study as a superiority trial (MIA superior to PE) and given that our education condition did not involve active CBT elements of hypothesis testing and behavioural change, we estimated effect size differences between conditions for primary outcomes to be in the range .3 – .5. Sample size calculations assumed a medium effect size of .5 for primary outcomes probed individually and a power value of .8. Sample estimates suggested that 51 respondents per group were required to test the hypotheses. To allow for attrition between end-of-trial and follow-up, we aimed to recruit 65 per group.

Measures Rationale

Drawing on the IMMPACT recommendations³¹ and domains considered by Cochrane Reviews^{2,32}, data were collected on physical functioning and disability, psychological distress, pain intensity, participant ratings of improvement and satisfaction with treatment, catastrophic thinking, and adherence to the treatment regimen. In addition to reducing the negative effects of pain on mood, thinking, and functioning, we also predicted positive effects of mindfulness on subjective wellbeing, pain acceptance, and self-reported mindfulness. We chose pain interference and psychological distress as primary measures as these were specific targets of the MIA intervention. We chose to measure *pain on average* as our main pain experience measure but due to the focus of mindfulness on experience in the present moment⁵ we also measured *pain right now*. The full set of primary and secondary outcomes are presented below.

Primary Measures

Pain Interference

The Brief Pain Inventory (BPI)³⁴ was initially developed for assessing cancer-related pain, but has since been validated in a sample with chronic non-malignant pain³⁵. The BPI captures the extent to which pain interferes with general activity, mood, walking ability, normal work,

relations with other people, sleep and enjoyment of life. Tan and colleagues³⁵ reported good internal consistency for the interference scale ($\alpha = .88$) and found expected relationships between these subscales and a measure of disability. Cronbach's α for the current sample of study completers were acceptable for pain interference (before $\alpha = .86$; after $\alpha = .93$; follow-up = .90).

Psychological Distress

The Hospital Anxiety and Depression Scale (HADS)³⁶ is a 14-item scale which assesses both anxiety and depression and was designed for use in medical outpatient clinics. This measure captures severity of anxiety and depression and has been shown to be suitable for a chronic pain population^{37,38} without contamination of scores by reports of physical symptomatology. Higher scores indicate greater psychological distress³⁹. Cronbach's α values for completers in the current sample were good (before $\alpha = .87$; after $\alpha = .82$; follow-up = .88).

Secondary Measures

Pain Intensity

Two numerical rating scales (NRS) from the Brief Pain Inventory³⁴ were used to measure level of pain intensity *right now* and *on average*. Respondents rated their pain intensity on a scale of 0 to 10 anchored at 0 “*No Pain*” and 10 “*Pain as bad as you can imagine*”.

Catastrophizing

The Pain Catastrophizing Scale (PCS)⁴⁰ is a 13 item scale with a 0 (‘not at all’) to 4 (‘all the time’) point response format. The scale is a predictor of pain intensity and disability⁴⁰. Cronbach's α values for the current sample were good (before $\alpha = .95$; after $\alpha = .93$; follow-up = .93).

Pain Acceptance

A brief 8-item version of the Chronic Pain Acceptance Questionnaire (CPAQ-8)⁴¹ was used. Participants rated items on a scale of 0 (never true) to 6 (always true). Studies suggest satisfactory reliability ($\alpha = .78-.82$) and validity suggested by high correlations with measures of avoidance, distress, and daily functioning. The CPAQ-8 has been validated in online chronic pain studies^{41,42}. Cronbach's α values for the current sample were acceptable (before $\alpha = .71$; after $\alpha = .80$; follow-up = $.67$).

Mindfulness

The construct of mindfulness has been operationalized in dispositional terms by the Mindful Attention Awareness Scale (MAAS)³³, a 15-item self-report instrument. Initially, the scale has been validated in college, working adult, and cancer patient populations and was found to have a single factor structure. However, more recently the MAAS has been reported for a chronic pain population⁴³, and the authors found the measure to be both valid and reliable. Cronbach's α for the current sample were good (before $\alpha = .93$; after $\alpha = .93$; follow-up = $.94$). Higher scores on the scale indicate higher levels of dispositional mindfulness.

Life satisfaction

The Satisfaction with Life Scale⁴⁴ is a 5-item scale designed to measure global cognitive judgments of one's life satisfaction. Participants indicate how much they agree or disagree with each of the 5 items using a 7-point scale that ranges from 7 (strongly agree) to 1 (strongly disagree). The possible range of scores is 5-35, with a score of 20 representing a neutral point on the scale. Higher scores on the scale indicate higher levels of satisfaction. Cronbach's α for the scale ranged from $.79$ to $.89$, indicating that the scale has high internal consistency. The scale was also found to have good test-retest correlations ($.84$, $.80$ over a month interval)⁴⁵. Cronbach's α for the current sample were good (before $\alpha = .87$; after $\alpha = .90$; follow-up = $.93$).

Patient impression of change

The Patient Global Impression of Change scale (PGIC)⁴⁶ is recommended for use with chronic pain interventions as a core indicator of improvement²⁸. It uses a seven-point scale that ranges from ‘very much improved’ to ‘very much worse’ with ‘no change’ in the middle. There has been widespread use of the PGIC in chronic pain research and it has been found to be a responsive and readily interpretable measure of participants’ assessment of the value of an intervention²⁸. Rather than assessing only the global value of the interventions, the current study used a modified version of the PGIC, asking participants to rate change in a number of targeted domains (1) *Ability to manage your emotions* (2) *Dealing with stressful situations* (3) *Ability to enjoy pleasant events*. Cronbach’s α in the current sample was acceptable (after = .80; follow-up = .84).

Randomisation procedure

Participants were randomly assigned to condition using an independent, computerized randomization programme. The randomisation allocation was generated by an independent researcher who also enrolled the participants and group assignment was given to both the participant and study staff only after completion of the baseline assessments. Due to the nature of the treatments, blinding of participants was not possible although neither was described as a ‘control’ condition.

Treatment regimens

Participants in each condition received 12 sessions of treatment, twice per week for 6 weeks. The MIA intervention was based on an established mindfulness meditation and emotional regulation programme shown to be effective for chronic pain²⁰. The intervention drew on mindfulness meditation aspects of the mindfulness-based stress reduction (MBSR) approach developed by Kabat-Zinn⁴⁹ integrated within cognitive therapy⁴⁷. An audio-visual version of

the programme was developed for this study. Each session included a pre-recorded presentation designed to build skills associated with mindfulness and instructions on how to cultivate and sustain positive emotional experiences, particularly within social relationships (see Table 1). Individual sessions were approximately 20 minutes duration and each session also included a recommended audio-recorded meditation component that participants were asked to access daily. Participants in the MIA group received twice-weekly emails inviting them to visit the Mindfulness in Action website and to view the session material and to practice the suggested mindfulness meditation.

The psychoeducation programme (PE) was based on many of the common elements found within pain management programmes such as explaining pain within a biopsychosocial model, information about activity pacing, encouragement to be active, and cognitive behavioural skills such as problem solving and the role of unhelpful thoughts. Some of the materials were drawn from a self-management chronic pain handbook²². This programme was presented in a series of emails containing written information about chronic pain self-management (see Table 1). The purpose of the PE programme was to have an active comparator treatment based on established pain education material. Participants in the PE group received twice-weekly emails with psychoeducational material related to chronic pain.

After the 6 weeks of the programme, participants in the MIA and PE groups were asked to complete a battery of self-report measures on www.surveymonkey.com and the same battery again 6-months later.

- Insert Table 1 around here --

Analytic Strategy

The initial data analytic steps were to determine whether 1) completers (i.e., those providing follow-up data) differed from non-completers and 2) MIA participants differed from PE participants in demographic variables or health-related measures at pre-treatment by conducting a series of chi-square analyses for categorical variables, Mann Whitney U tests for ordinal variables, and t-tests for normally distributed variables.

Intervention effects were evaluated using multilevel modeling (MLM). MLM is well-suited to the evaluation of data that have a hierarchical structure (i.e., pre, post, and 6-month follow-up reports nested within each of the 124 participants) because it is able to account for variation both within and between individuals. All multilevel analyses were conducted using SAS PROC MIXED⁵⁰, estimating the variance components using restricted maximum likelihood. The MIXED procedure is particularly useful because it includes all available data; as a result, all 124 participants were included in multilevel analyses (i.e., intent-to-treat). Models included the predictors Time (T1, T2, and T3), Treatment group (MIA versus PE), and the Time X Treatment group interaction. The model specifications followed the recommendations of Singer⁵¹ to identify the best fitting model of the variances and covariances of the variables under study. The dependent variables were modeled as random variables. Post hoc evaluations of Time and Time X Group interactions were accomplished with analyses for simple effects. Estimates of means and standard errors for groups over time were calculated with LSMEANS in SAS PROC MIXED. Omnibus effect sizes (i.e., d_s)⁵² for each outcome based on multilevel modeling were computed according to the recommendations of Feingold⁵³, incorporating the coefficients of the length of study (time) and of the slope difference between groups. Based on commonly used guidelines, effect sizes of 0.2, 0.5, and 0.8 are interpreted to reflect small, moderate, and large effects⁵². As participants' impression of change data were only available for T2 and T3, independent-

samples t-tests were conducted to examine differences between groups in the participants' impression of change.

Results

Pain Profile

Participants reported a mean duration of pain of 10.8 years (Median 8.6 years; range 6 months to 50 years; $SD = 9$ years). One-hundred and eighteen (95%) reported experiencing pain on the day of completing the survey. When asked 'How often do you experience pain', 60 (48%) reported experiencing pain 'all the time', 52 (42%) said 'Daily'. A breakdown of pain profile data by group is included in Table 2.

When asked to identify 'Areas where you feel pain', 45 (36.3%) reported pain in their lower or upper back and the remainder reported pain affecting a range of other body areas. However, only twelve people (16%) reported a single site of pain with sixty-five people (52%) reporting five or more sites. When asked to indicate the primary cause of their pain, the greatest number reported fibromyalgia (33; 27%). A more detailed list of reported pain locations and causes of pain are included in Table 2. One hundred and sixteen of the 124 original randomised participants (94%) reported medication as a treatment. A breakdown of treatments by group is included in Table 2.

----Insert Table 2 about here----

Completer versus non-completer baseline comparisons

Treatment completers and non-completers did not differ on how long they had experienced pain ('pain duration'), time since most recent experience of pain ('last experience of pain'), how often they experienced pain ('frequency of pain'), where on their body they primarily experienced pain ('pain location') or 'primary cause of pain'. There also were no significant

differences between completers and non-completers on age, pain interference, pain ‘right now’, pain ‘on average’, or psychological distress (all p values $>.05$).

MIA versus PE baseline comparisons

Participants in the MIA and PE conditions did not differ in terms of demographics, ‘pain duration’, ‘last experience of pain’, ‘frequency of pain’, ‘pain location’ or ‘primary cause of pain’. There also were no baseline differences between participants in MIA and PE groups on primary or secondary variables. The estimated means and standard error for each outcome measure of MIA, PE, and combined groups at each time point are provided in Table 3.

- Insert Table 3 about here -

Treatment Adherence

For those who provided data at follow-up by self-report, reported treatment adherence was high in both groups (based on self-report at T2). The mean number of sessions reportedly viewed by participants in the MIA group was 11.22 sessions ($SD = 1.68$; range = 6-12) with 17 of the 23 participants (74%) reporting viewing all of the sessions. Respondents reported meditating an average of 5.74 days per week ($SD = 1.32$; range = 2-7) with 10 (43.5%) reporting meditating 7 days. When asked about duration of meditation each day, one engaged in less than five minutes meditation, eight did between six and ten minutes, nine did 10 - 20 minutes and five did more than 20 minutes. The mean number of sessions reported as read by participants in the PE group was 11.59 sessions ($SD = 1.22$; range = 8-12) with 23 participants (85.2%) reporting reading all of the sessions. Automated recording of the number of sessions accessed was not a feature of the software.

MLM Analysis - Primary and Secondary Outcome Measures

Table 4 displays the results of models testing whether there were intervention effects on outcomes, and whether groups differed in the magnitude of change over time.

Primary Outcomes

Pain interference. Pain interference improved over time (Time $F = 26.87, p < .0001$), and the magnitude of change was similar between groups (Time X Group $F(119,104) = 0.02, ns$). Post hoc comparisons probing the Time effect indicated that in the sample as a whole, pain interference declined significantly from T1 to T2 (Time slope estimate = $-12.34, t = -6.57, p < .0001$), and remained stable from T2 to T3 (Time slope estimate = $3.85, t = -1.29, ns$), and was significantly lower at T3 relative to T1 (Time slope estimate = $-5.00, t = -3.30, p < .002$).

Psychological distress. The other primary outcome, psychological distress as assessed by the HADS, did not change over time, nor did the magnitude of change vary by group (Time and Time X Group $F_s < 1.95, ns$).

Secondary Outcomes

Satisfaction with life. Satisfaction with life improved over time (Time $F = 71.13, p < .0001$). However, the MIA group showed more substantial improvements than did the PE group (Time X Group $F = 4.37, p = .04$). Post hoc comparisons of the interaction effect indicated that from T1 to T2, the magnitude of the change was different between groups (Time X Group $F = 4.14, p < .05$). Satisfaction with life increased from T1 to T2 in the MIA group (Time slope estimate = $1.58, t = 2.68, p < .02$), but not in the PE group (Time slope estimate = $-0.15, t = -0.23, ns$). The magnitude of change from T2 to T3 did not vary between groups (Time X Group $F = 0.31, ns$), reflecting that satisfaction with life continued to improve in the MIA group (Time slope estimate = $5.79, t = 5.55, p < .0001$) and that the PE group also showed improvements (Time slope estimate = $4.98, t = 5.14, p < .0001$). Finally, satisfaction with life was significantly higher at T3 relative to T1 for both the MIA

(Time slope estimate = 3.90, $t = 7.48$, $p < .0001$) and the PE groups (Time slope estimate = 2.56, $t = 4.19$, $p < .0003$), with a similar magnitude of change across groups (Time X Group $F = 3.08$, $p = .09$).

Average pain intensity. Ratings of average pain did not change significantly over time nor was there a difference between groups in the lack of change over time (Time and Time X Group effects $F_s < 0.83$, *ns*).

Pain right now. Ratings of pain right now showed a marginal downward trend over time (Time $F = 5.98$, $p < .02$; Time slope estimate = -0.36, $t = -1.90$, $p = .07$) that did not vary by group (Time X Group $F = 0$, *ns*).

Pain acceptance. On the CPAQ-8, pain acceptance ratings increased over time (Time $F = 26.42$, $p < .0001$), and the magnitude of the change was similar across groups (Time X Group $F = 0.52$, *ns*). Post hoc probes including both groups indicated that acceptance increased from T1 to T2 (Time slope estimate = 2.18, $t = 3.40$, $p = .002$), and remained stable from T2 to T3 (Time slope estimate = 1.75, $t = 1.59$, *ns*), such that T3 levels of acceptance were significantly higher than those at T1 (Time slope estimate = 1.96, $t = 3.59$, $p = .001$).

Mindfulness. Mindfulness ratings on the MAAS decreased over time (Time $F = 32.19$, $p < .0001$), and the magnitude of the change was similar across groups (Time X Group $F = 0.05$, *ns*). Post hoc probes indicated that mindfulness decreased from T1 to T2 (Time slope estimate -3.67, $t = -2.70$, $p = .01$), and continued to decrease from T2 to T3 (Time slope estimate -4.62, $t = -2.07$, $p = .05$), such that T3 levels of mindfulness were significantly lower than those at T1 (Time slope estimate -4.19, $t = 3.42$, $p = .002$).

Catastrophizing. Pain catastrophizing ratings decreased over time (Time $F = 11.20$, $p = .002$), and the magnitude of the change was similar across groups (Time X Group $F = 2.30$, *ns*). Post hoc probes indicated that catastrophizing decreased from T1 to T2 (Time slope estimate = -3.34, $t = -3.51$, $p = .001$), and remained stable from T2 to T3 (Time slope

estimate -1.21, $t = -0.83$, *ns*), such that T3 levels of catastrophising were significantly lower than those at T1 (Time slope estimate -2.22, $t = -3.16$, $p = .003$).

Patient impression of change. A series of three independent-samples t-tests were conducted to examine differences in the participants' impression of change (PGIC). The independent variable was Group, with two levels: MIA and PE. The dependent variables were the scores on the PGIC Scales for (1) *Ability to manage your emotions* (2) *Dealing with stressful situations* and (3) *Ability to enjoy pleasant events*. PGIC for *Ability to manage your emotions* was greater for the MIA group than the PE group at T2 ($t(122) = 2.56$, $p = .011$, $d = .46$) and this difference was maintained at T3 ($t(122) = 2.08$, $p = .039$, $d = .36$). Similarly, PGIC for *dealing with stressful situations* was greater for the MIA group than the PE group at T2 ($t(122) = 3.49$, $p = .001$, $d = .62$) and this difference was maintained at T3 ($t(122) = 2.04$, $p = .044$, $d = .36$). PGIC for *ability to enjoy pleasant events* was greater for the MIA group than the PE group at T2 ($t(122) = 2.27$, $p = .025$, $d = .41$) but this difference was not maintained at T3 ($t(122) = 4.82$, $p = .631$).

Discussion

This was the first study to compare online versions of two treatments for chronic pain that have both yielded benefits when delivered face-to-face: mindfulness-based cognitive therapy intervention and pain management psychoeducation. More specifically, the current study examined if online mindfulness-based cognitive therapy intervention is superior to online pain management psychoeducation in influencing primary and secondary pain outcomes. The results showed that participants in both online programmes displayed similar change over time on several post-intervention psychological outcomes of interest. Total pain interference, as well as pain acceptance and catastrophizing, improved for both groups from pre-treatment to post-treatment and the improvements were maintained at follow-up. The magnitudes of these changes ranged from moderate to large ($ds = .42 - .76$). Although HADS

distress scores tended to reduce for both groups from pre-treatment to post-treatment, this trend did not reach statistical significance and was not maintained at follow-up. In contrast to the lack of significant, sustained change for groups in levels of distress, both groups reported increases in satisfaction with life that were large in magnitude ($d = .90$); moreover, improvements were more pronounced in the MIA versus the PE group ($d = .59$). These positive findings are broadly consistent with the results from previous CBT and mindfulness-based efficacy studies delivered face to face^{1-3,5,7,21,49,54,55}. However, equivalent improvements observed in both MIA and PE conditions in the current study need to be interpreted with caution because neither treatment, itself, has been established as efficacious compared to a waitlist control group and the current trial design does not control for time by including a waitlist control group.

In relation to the superiority of online mindfulness-based cognitive therapy in comparison with online pain management psychoeducation, the mindfulness-based programme was associated with greater improvement over time on a small number of outcomes. The MIA group reported significantly greater personal impression of positive change from baseline to post-treatment in their ability to manage their emotions, deal with stress, and enjoy pleasant events, an effect that was maintained at six-month follow-up for emotion and stress management perceptions. The larger improvement in satisfaction with life in the MIA group coupled with the overall impression of greater subjective improvement in the MIA group across three life domains may reflect an improved ability to optimize emotional experience, despite experiencing pain and associated stress.

Interestingly, both groups reported a decrease in mindfulness after the intervention that was moderate in magnitude. This may have resulted from increased reflection and more honest evaluation of mindful awareness abilities in both groups as a result of the intervention. It may also be the case that the mindfulness measure was not a suitably

sensitive measure, since it is described as a measure of *dispositional* mindfulness rather than state mindfulness.

Pain acceptance and catastrophizing improved over time in the sample as a whole. Pain catastrophizing has been identified in many studies as a mediator of disability outcomes and so interventions that reduce catastrophizing are potentially important. Similarly, pain acceptance may be an important process variable in terms of understanding and facilitating improved outcomes in those with chronic pain. However, it is unclear if increases in self-reported mindfulness are necessary for the longer term success of mindfulness interventions. It will be important in future to identify the most responsive components of mindfulness and to target the most problematic thought processes for treatment and sustained benefits of treatment. In particular, the relationship between changes in mindfulness, acceptance and catastrophizing need to be examined more closely in future intervention studies.

While the MIA program may have shown some unique positive effects, there were some differences between the MIA and PE programme that may have accounted for these effects and the results of the current study need to be interpreted with caution. The MIA programme used audiovisual and audio modes of presentation for mindfulness lectures and mindfulness meditations, respectively, whereas the PE programme used only written text presented online, with some visual images, but no “voice-over”. Differences in delivery strategy and style could account in part for the differences between the MIA and PE conditions.

While we did not use a no-treatment or wait list control group in this study, this is becoming more common as many studies are now aiming to evaluate the relative benefit of two or more active psychological treatments. For example, in a recent study, rheumatoid arthritis patients were randomized to cognitive-behaviour therapy, relaxation response training, or arthritis education. There were benefits for each of the three treatments, with no

overall difference between conditions²⁶. Similarly, a randomized controlled trial with a low-SES, rural chronic pain population compared group CBT with a group pain education intervention and found that participants in both conditions reported significant improvement across pain-related outcomes²⁷ although CBT produced greater gains on cognitive and affective variables at post-treatment and 6-month follow-up. A study comparing the effectiveness of telephone-delivered CBT with telephone-delivered pain education in the management of chronic pain with older military veterans found equivalent increases in physical and mental health and reductions in pain and depression in the two treatment groups²³. Similar to the current study, the results of these studies suggest benefits linked with both CBT and education treatments. However, it is important to reiterate that neither treatment in the current trial has been established as efficacious compared to a waitlist control group and the trial design did not control for time. Thus, while it is appropriate to conclude that MIA can be associated with more change than PE, no firm conclusions can be drawn about the interventions producing change using the current research design.

In relation to feasibility, 30% of the population invited to participate in the study showed an interest in taking part and of those assigned to both programmes, 52% completed and 40% provided follow-up data six months later. Completion rates in the current study were low but similar to some other published studies of online interventions⁵⁶. However, the level of attrition raises questions about feasibility and how best to engage participants. Intervention studies that involve face-to-face therapeutic exchanges may benefit from greater commitment on the part of participants and the participants may thus be more likely to complete⁵⁷. However, a recent online study¹⁸ achieved exceptionally high completion rates (over 90%) and this was probably due to their strategy of ensuring weekly telephone contact with participants, making completion of one session a pre-requisite for progression to the next, and possibly elements of the interface and the content. Further research in this area may

benefit from inclusion of online face-to-face exchanges (e.g. using Skype), which may serve to enhance both CBT and mindfulness-based CBT programmes. The question of “what works” – not only in terms of outcomes, but also adherence and completion – is probably the most important question for researchers and developers of online interventions, since a balance must be found between making the interventions cost effective in terms of therapist time and keeping patients engaged.

The study has a number of limitations. First, the remote accessing of the interventions makes it difficult to identify when participants dropped out as this could only be captured at the data collection points. Future research using other technologies could capture data on times logged-on and quality of engagement with the system, thus providing data on adherence and facilitating more timely follow-up with participants who may be contemplating dropping out. This latter data could also provide an opportunity to gather more information on participant satisfaction with the programmes. Another limitation pertains to the assessment of home practice of the skills taught in the programmes. In common with other MBCT interventions⁴, the collection of “homework” data relies on self-report methods which may lead to biased estimates. A significant limitation of the study is the level of attrition which was a problem for both interventions. While attrition is not uncommon either in clinical research or in clinical practice the current low response rates suggest significant caution is required when interpreting and generalising the results of the study. Notably, although mixed linear models were employed to analyse effects, these effects need to be interpreted with caution as they include assumptions about effects observed in the context of the full sample of participants, including those who dropped out of the study.

More generally, in relation to attrition, it is important to garner consumer views about the features of treatment programmes that are most likely to engage them and to

identify obstacles to finding, joining and completing online treatment programmes. Day et al²⁷ recently reported the results of a qualitative analysis of patient perceptions of CBT and Education therapies for pain management —such evaluations may provide important information to inform further developments in the area of online therapy delivery.

The study also had a number of strengths. Previous research has identified time and travel commitments as barriers to attendance at typical group programmes¹¹. The current study involved participants from across three continents and the format provided participants access to program materials at times that suited their own routine. Therefore, the flexibility of delivery and the low delivery cost of the online program in terms of therapist time suggests that such programmes may be of value even with lower uptake and completion rates than traditional programmes.

The current study has made a number of contributions to the literature on online interventions by addressing several unanswered questions in the field. It has tested the feasibility of a computerized MBCT intervention (MIA) for a heterogeneous chronic pain population and compared it with a computerized PE intervention. While the interventions showed similar changes on a number of outcome variables, MIA was associated with some unique changes. The main clinical implication of this study is that it supports the feasibility of using computerized interventions as an additional option for chronic pain management. However, the study also highlights the need to optimize engagement and completion in such studies. In the context of growing evidence for the benefits of online therapies, further research in this area is warranted. Future studies should aim to identify (a) the beneficial/effective components of treatment programs so as to allow for greater treatment efficiencies (b) the patients most likely to respond to one treatment over another (c) the most effective balance of “distance” therapy versus personal contact in order to keep patients

engaged both with research studies and with treatment programs (d) participant experience and preferences for the structure, duration, content and interface options.

In conclusion, the results of the current study provide evidence that a computerized mindfulness-based programme brought about greater improvement on measures of life satisfaction, ability to management emotions, and ‘pain right now’ than a computerized pain self-management psychoeducation program. However, the development of on-line interventions is still in its infancy. Although the method shows promise in making treatments widely accessible to the public, enthusiasm must be tempered by many questions concerning whether the delivery methods diminish impact. Discerning differences between treatments delivered in an on-line format may be especially difficult, as acceptability and efficacy expectations may be lowered to the point that the therapies are indistinguishable from one another in improving lives.

Author Contributions

HD, MH, AZ designed the treatment materials. MCD, KS, and RF assisted with methodology and data analysis. BMcG edited the final manuscript. All authors contributed to the study design, discussed the results and commented on the manuscript.

Disclosures

The authors have no conflicts to declare in relation to this study.

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Figures.

Figure 1. CONSORT flow diagram. Diagram includes Intention to Treat (ITT) and actual participant numbers for both Mindfulness in Action (MIA) and Pain Education (PE) Programs.

Tables.

Table 1. Session-by-session summary of the structure of the MIA and PE interventions with associated mindfulness exercises for the MIA intervention.

Table 2. Participant reports of the pain history, previous treatments, primary cause and the main location of their pain.

Table 3. Mean and standard deviation scores for completers (n=50) on each of the measures reported and for MIA and PM groups.

Table 4. Multilevel Model Results of Mindfulness in Action (MIA) and Pain Education (PE) Intervention Group Effects on Changes over Time in Primary and Secondary Outcomes.

Figure 1. CONSORT flow diagram. Diagram includes Intention to Treat (ITT) and actual participant numbers for both Mindfulness in Action (MIA) and Pain Management Psychoeducation (PE) programmes.

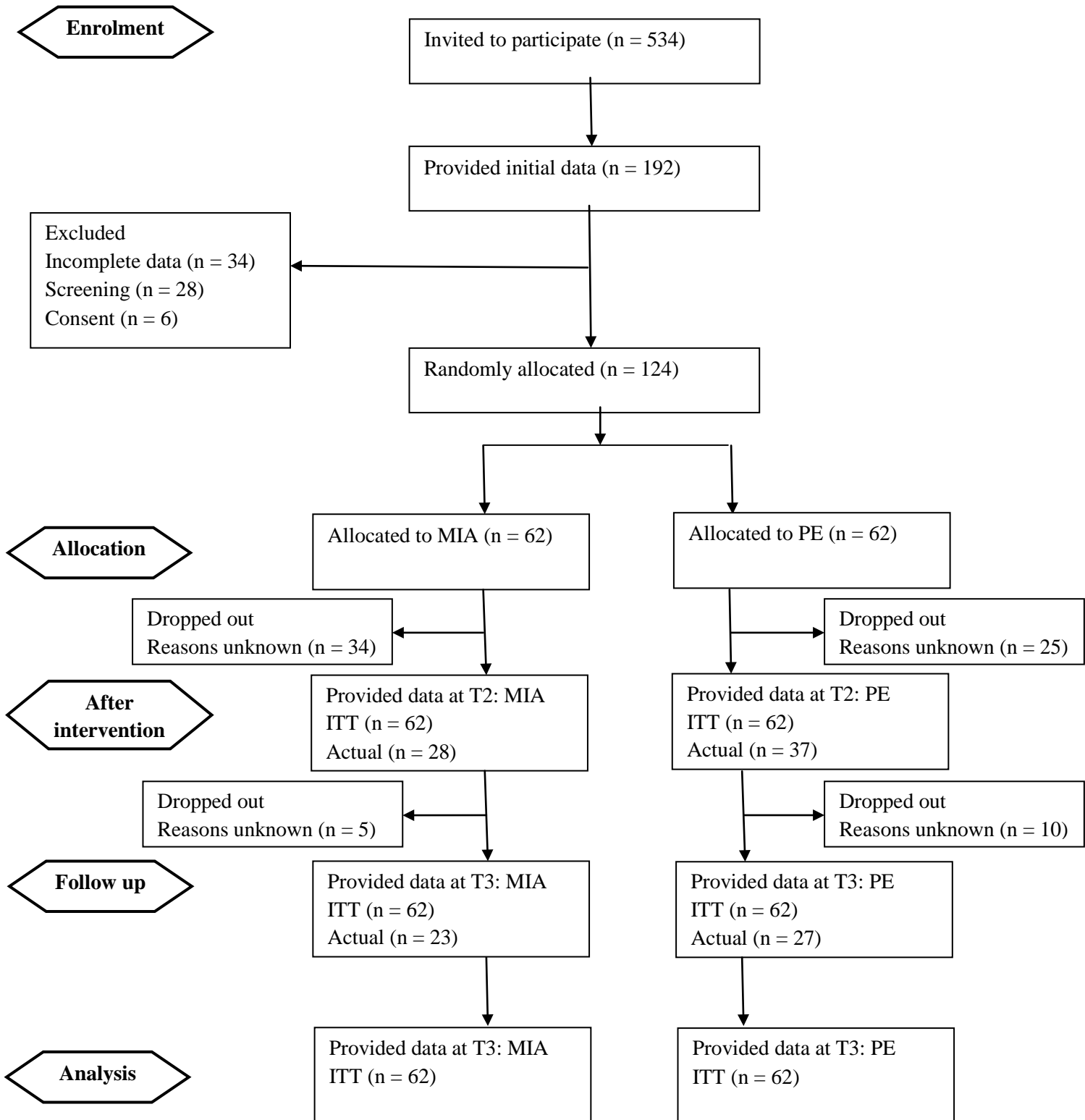


Table 1.

Session-by-session summary of the structure of the MIA and PE interventions with associated mindfulness exercises for the MIA intervention.

Session No	Mindfulness in Action			Pain Education	
	Session Title	Session Content	Meditation	Session Topic	Session Content
1	Introduction	Introduction to Mindfulness. Programme overview	Breathing. Practice Review	What is pain?	Acute pain. Challenges of Chronic Pain: Disability and Suffering
2	Positive and Negative Emotions	Emotional Systems. Letting go of emotions. Two dimensions of emotion.	Breathing	Pain concepts that cause misunderstandings.	The experience of pain. Pain behaviour. Physical injury and damage.
3	Mindfulness	What is Mindfulness? Introduction to Mindfulness. Meditation - Building a daily practice.	3-min breathing-space	Physiology of pain.	Role of the spinal gate. Role of endorphins.
4	Awareness: A crucial skill	Benefits of Awareness. Barriers to Awareness. Ironic Process (Yellow Jeep). Consequences of Mindlessness.	3-min breathing-space	Physical deconditioning.	What is physical deconditioning. Doing too much.
5	Acceptance	Mindfulness, awareness and the management of chronic pain. Role of Acceptance in mindfulness.	Body Scan	Avoiding physical deconditioning	Living within your limitations. Use good pacing procedures. Use Caution during danger times.
6	Living with pain	Living with pain. Acute versus chronic pain. Mindfulness as a response to suffering.	Body Scan	Activity pacing	The Importance of planning ahead and pacing yourself. The Activity-Rest Cycle? Benefits of the Activity – Rest Cycle.
7	Pacing yourself	Rationale for Activity-Rest cycle. Basic steps. Benefits of Activity-Rest cycle. ARC Planner.	Body Scan Standing Walking	Physical fitness	Physical fitness defined. Step to appropriate fitness.
8	Emotional Space	Emotional clarity. Emotional complexity. Relation between thoughts & emotions. Automatic thinking.	Emotions Sensations & Thoughts	Sleep difficulties	Why sleep is important? Developing healthy sleep habit.
9	Thoughts & Beliefs	Reviewing the link between thoughts, emotions, and physical health. Importance of illness beliefs. Role of illness beliefs in adjustment. Changing the context of thoughts.	Seated Thought	Sleep difficulties continued	Tips for when you can't sleep at night.
10	Savouring the positive	Intentional engagement with positive experiences. Savouring positive experiences. Positive emotions as a choice. Scheduling pleasant events.	Pleasant events	Interacting with your medical doctor	The Importance of having a primary care doctor. Doctor - Patient relationship. Problems with being believed or taken seriously.
11	Relationships	Interpersonal relationships. Mindful communication.	Pleasant events	Your relationship with your medical doctor	A Bill of Rights for people with pain. Maintaining reasonable expectations. Communicating with your doctor.
12	Review			Review	

Table 2. Participant reports of the pain history, previous treatments, primary cause and the main location of their pain by group.

Pain History				Primary cause of pain		
		MIA	PE		MIA	PE
How often do you experience pain?	At all times	29	31	Fibromyalgia	15	18
	Daily	28	24	Nerve Damage/ Pain	10	10
	Several times per week	3	6	Disc problems	5	7
	Once per week	0	1	Arthritis	5	4
	Several times per month	1	0	Traumatic injury	5	3
Last time you experienced pain	Today	60	58	Headaches	1	3
	Last week	2	3	Neuropathy	2	1
	More than 1 week	0	1	Spinal Stenosis	2	1
Duration of pain (months)	Mean	123	138	Other	17	15
	Median	99	105	Main location of pain		
	Range	12 - 480	6 – 600		MIA	PM
Number of visits to doctor in previous 6 months	Mean	10.2	7.6	Back & Lower Back	20	25
	Median	6	6	Leg & Knee	7	5
	Range	0 - 72	0 – 52	Neck	3	6
				Hand/Arm/Wrist	4	4
				Head	3	3
				Abdomen	4	1
				Shoulder	3	2
Previous Treatments						
Medication only		32	36			

Medication + other	24	24	Muscles	2	2
Yoga	1	0	Chest	3	1
Meditation	1	0	Hip	2	1
Psychological	2	1	Other	11	12

Table 3: Estimated Means (SE) for each Outcome Measure of MIA, PE, and Combined Groups at Each Time Point

Variable	Group	Time 1 Estimate (SE)	Time 2 Estimate (SE)	Time 3 Estimate (SE)
Primary Outcomes				
Pain interference	MIA	39.55 (1.96)	24.83 (2.90)	30.71 (3.00)
	PE	44.83 (2.02)	31.50 (2.42)	35.47 (2.69)
	Combined	42.19 (1.41)	28.17 (1.89)	33.09 (2.02)
HADS				
HADS	MIA	14.95 (0.82)	13.50 (1.03)	14.15 (1.10)
	PE	15.34 (0.81)	14.05 (0.92)	14.78 (1.00)
	Combined	15.15 (0.57)	13.77 (0.69)	14.47 (0.74)
Secondary Outcomes				
SWL				
SWL	MIA	13.71 (0.73)	15.52 (1.00)	21.41 (1.07)
	PE	13.86 (0.73)	13.89 (0.86)	18.81 (0.96)
	Combined	13.78 (0.51)	14.70 (0.66)	20.11 (0.72)
Average Pain				
Average Pain	MIA	5.57 (0.24)	5.64 (0.34)	5.97 (0.37)
	PE	5.86 (0.24)	5.17 (0.29)	5.96 (0.33)
	Combined	5.71 (0.17)	5.41 (0.23)	5.96 (0.25)
Pain Right Now				
Pain Right Now	MIA	5.29 (0.28)	3.73 (0.40)	4.81 (0.42)
	PE	5.40 (0.28)	5.10 (0.34)	4.69 (0.38)
	Combined	5.35 (0.20)	4.41 (0.26)	4.75 (0.28)
CPAQ				
CPAQ	MIA	23.31 (0.88)	26.64 (1.15)	26.11 (1.21)
	PE	22.36 (0.88)	24.67 (1.01)	26.40 (1.10)
	Combined	22.83 (0.62)	25.65 (0.77)	26.26 (0.82)
MAAS				
MAAS	MIA	60.90 (2.00)	58.80 (2.53)	51.89 (2.65)

	PE	59.58 (2.00)	55.83 (2.26)	51.46 (2.48)
	Combined	60.24 (1.42)	57.32 (1.70)	51.68 (1.81)
PCS	MIA	14.89 (1.33)	12.93 (1.68)	13.28 (1.76)
	PE	17.64 (1.33)	14.12 (1.50)	13.22 (1.61)
	Combined	16.27 (0.94)	13.53 (1.13)	13.25 (1.19)

Note: Estimates were generated in SAS Proc Mixed with LSMEANS.

Table 4. *Multilevel Model Results of Mindfulness in Action (MIA; n=62) and Pain Management Psychoeducation (PE; n=62) Intervention Group Effects on Changes over Time in Primary and Secondary Outcomes*

Outcomes	Estimate (SE)				<i>d</i> effect size ^a	
	Intercept	Group	Time	Time X Group	Time	Time X Group
Pain interference	48.89 (2.97)	-5.20 (4.22)	-5.78 (1.44)****	0.34 (2.16)	- 0.76	0.04
HADS	15.53 (1.01)	-0.24 (1.44)	-0.39 (0.41)	-0.10 (0.63)	- 0.12	-0.03
SWL	11.17 (1.00)	-1.43 (1.43)	2.24 (0.47)****	1.47 (0.71)*	0.90	0.59
Pain on average	5.76 (0.34)	-0.39 (0.49)	-0.04 (0.16)	0.23 (0.25)	- 0.04	0.25
Pain right now	5.77 (0.39)	-0.32 (0.57)	-0.36 (0.19)+	0.02 (0.29)	-0.32	0.02
CPAQ	20.35 (1.11)	1.66 (1.58)	2.05 (0.46)****	-0.51 (0.70)	0.58	-0.14
MAAS	63.66 (2.44)	1.90 (3.48)	-4.03 (0.98)****	-0.32 (1.48)	- 0.50	-0.04

PCS	19.75 (1.61)	-4.13 (2.31)+	-2.35 (0.63)***	1.47 (0.97)	- 0.42	0.26
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Note. Group is coded MIA = 1 and PE = 2, time is coded Pre = 1, Post = 2, Follow-up = 3. For final model comparing groups, between-subject *dfs* range from 119 to 122, within-subject *dfs* range from 104 to 108. ^a Effect size reflects omnibus test of time slope and the group difference in change over time.

+*p* < .10, * *p* < .05, ***p* < .01, ****p* < .001, *****p* < .0001.