Mindfulness
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A Brief Mindfulness Intervention Is Associated with Negative Outcomes in a Randomised Controlled Trial Among Chemotherapy Patients

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Abstract Emotional distress is common during chemotherapy, and supportive interventions during this time are often required. Mindfulness-based interventions appear promising amongst cancer survivors, but scant research has been conducted amongst patients undergoing acute treatment. This trial compared the efficacy of a brief mindfulness-based intervention (bMBT) with relaxation therapy on reducing distress amongst chemotherapy patients. Sixty-eight people receiving first-line chemotherapy at Auckland City Hospital were randomised to bMBT (n = 32) or relaxation training groups (n = 36). In both conditions, participants attended three 90-min weekly sessions. Overall distress (distress thermometer (DT); impact thermometer (IT)), cancer-related stress (Impact Events Scale–Cancer (IES-C)), cancer symptom distress (Memorial Symptom Assessment Scale–Short Form (MSAS-SF)) and social avoidance (SA) were assessed at enrolment, post-intervention and at 3-month follow-up. Both groups reported reductions in overall and cancer-related stress over time. Immediately post-intervention, however, bMBT (but not relaxation training) participants reported *increased* symptom distress, marginally increased social avoidance and *decreased* quality of life. So whilst overall distress and cancer distress declined in both groups, the mindfulness intervention was associated with increased symptom distress and social avoidance and reduced quality of life. This report presents a randomised controlled trial of a mindfulness-based intervention during chemotherapy and suggests that care is needed in employing mindfulness-based interventions in acute health treatment contexts.

Keywords Mindfulness · Relaxation · Emotion · Chemotherapy · Cancer

Introduction

Facing chemotherapy can be daunting—fear of what lies ahead, the threat to mortality, physical and emotional pain, grief and loss, can all combine to create a volatile emotional mix. Unsurprisingly, high levels of distress and diminished quality of life are commonplace (Iconomou et al. 2004). Psychological distress can have serious correlates, including greater reported side effects like nausea and fatigue (Higgins et al. 2007, 2008), non-adherence to medical regimens (Hohneker et al. 2011) and social withdrawal (Manne et al. 2010).

Despite widespread suggestion that psychosocial support be available as people undertake cancer treatment (National Comprehensive Cancer Network 2003), practical barriers limit the feasibility of many interventions during this time. Many chemotherapy patients experience significant symptom load and burden from multiple medical appointments and hospital commitments across their treatment (Eakin and Strycker 2001; Henry et al. 2008); finding the emotional resources and time for further commitments (even if potentially beneficial) can be difficult. Low participation and high attrition is common in this context (Rawl et al. 2002), meaning that

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psychosocial interventions during chemotherapy need to be brief, pragmatic and accessible (Eakin and Strycker 2001).

Psychosocial interventions with chemotherapy patients have shown mixed results (Lotfi-Jam et al. 2008). Physical relaxation training (e.g. progressive muscle relaxation)—which aims to reduce distress by encouraging the release of bodily tension (Yoo et al. 2005)—shows promise. An early meta-analysis found that relaxation-based interventions predicted modest reductions in treatment-related physical symptoms (nausea, pain) and larger reductions in depression, anxiety and hostility (Luebbert et al. 2001). However, whilst relaxation training has few contraindications and is generally suitable for cancer patients, it does not directly address the underlying causes of distress like ruminative worry.

In contrast, another widely used supportive intervention—mindfulness-based training (MBT)—does not specifically encourage physical relaxation but, rather, teaches a shift from worrying thoughts about the past or the future to non-judgmental engagement with the present moment (Baer et al. 2006). Rather than consciously attempting to reduce mental and physical tension as with progressive muscle relaxation, MBT cultivates a “letting go” of desired outcomes and an acceptance of the current moment (Kabat-Zinn 1990). Mindful approaches thus seem well suited to chemotherapy, where worrying thoughts and unpleasant experiences are common. Emerging work suggests that MBTs promote benefits including better coping and lower depression and anxiety amongst cancer survivors (Foley et al. 2010).

However, other than one recent study (Carlson et al. 2013), designs have compared MBT to treatment as usual or waitlist controls and have not investigated how MBT compares to other therapies. Furthermore, research has almost entirely focussed on the post-treatment phase. A recent review found only one study of mindfulness during acute treatment (a pilot study during stem cell transplantation), and studies during chemotherapy are entirely absent (Shennan et al. 2011). To a large extent, the absence of studies at the time when support is most needed almost certainly reflects the complexity of running studies during this period. During treatment, patients commonly deal with the existential distress associated with diagnosis and the treatment’s physical and psychological demands (Carlson et al. 2004). In contrast, post-treatment demands tend to focus around coping with chronic effects, managing fears of recurrence and depression, finding meaning and dealing with re-entry into “normal life” (Stanton 2006). As such, the benefits of MBT in post-treatment cancer groups may not replicate in persons undergoing acute treatment.

As noted, the relative absence of validated interventions conducted during chemotherapy likely reflects the practical challenges involved in recruiting and retaining participants during treatment. The time commitments of standard MBTs (6–8 × 2-h sessions, plus homework; Bartley 2012; Carlson and Speca 2010) are considerable and offering brief MBT may be more appropriate to patient resources and practicalities. Flexibility in training and simplified interventions during intensive cancer treatment have already been called for (Shennan et al. 2011). Shortened versions of MBSR may be no less effective in reducing distress than standard formats (Carmody and Baer 2009), and lower dose, less intensive MBTs can reduce perceived stress (Klatt et al. 2008); brief (three to four sessions) MBTs with gynaecological cancer patients (Brotto et al. 2012) and in a non-clinical sample (Jain et al. 2007) have also shown reductions in distress. Although it has yet to be tested, similar benefits might also be available during acute treatments such as chemotherapy.

Chemotherapy can be a challenging time for cancer patients; heightened distress, lowered quality of life and withdrawal from support networks are all common (Iconomou et al. 2004). Given that mindfulness training has shown benefit in chronic cancer and survivorship contexts (Shennan et al. 2011), this study was designed to assess whether these positive findings might translate to the acute treatment context. Given evidence that brief MBTs can still provide benefit and to minimise demands on patients during chemotherapy, the intervention was adapted to be shorter than traditional formats. In line with guidelines suggesting psychological support should be standard practice for distressed cancer patients (National Comprehensive Cancer Network 2003) and the need for active controls in mindfulness research, the study assessed a brief MBT in relation to an established “active” control (rather than a waitlist). Relaxation training—recommended as a therapeutic intervention in this context (Luebbert et al. 2001)—was used for this purpose. Thus, our primary research question regarded assessing how a brief, mindfulness-based intervention compared to relaxation training in reducing distress in cancer patients undertaking chemotherapy for the first time. Specific hypotheses were that (1) mindfulness would increase over time for participants in the bMBT intervention and (2) that whilst all participants would report reductions over time in overall distress, cancer-related stress, problems with cancer symptoms and avoidance of their social networks (as well as increases in quality of life), benefits would be more pronounced in the bMBT intervention relative to the relaxation intervention.

Method

Participants

This randomised controlled trial (RCT) compared two interventions - a brief mindfulness-based program (bMBT) and an active control (relaxation training). Assessments occurred immediately prior (baseline) and post-intervention, and at follow-up (3 months later). Ethics approval was granted by the New Zealand Northern B Health and Disability Ethics

Committee, and the protocol was approved by the Auckland District Health Board (ADHB). Inclusion criteria for this study were intentionally broad to facilitate access. Patients with a non-metastatic diagnosis scheduled to initiate or currently undergoing adjuvant chemotherapy were eligible, as were patients scheduled for/undergoing first-line treatment for metastatic disease. Exclusions were non-English-speaking patients, persons aged less than 18 years, prior chemotherapy treatment and prior enrolment in another clinical trial. Based on prior intervention studies of mindfulness training in cancer contexts, an a priori power analysis using an α error of 0.05 and effect size of 0.30 suggested that 58 participants would provide approximately 80% power to detect within-between interactions in repeated-measures ANOVA analyses. Allowing for attrition in this demanding time, we thus recruited 68 participants at baseline.

After baseline assessment and consent, participants were randomised to bMBT or relaxation training groups by an assistant not involved in delivering the intervention or data analysis in blocks of 8 to a 4:4 ratio using a random sequence. Randomisation was completed after enrolment (concealing group allocation), and participants were only told that they would be randomised to one of two stress management programs. The psychologist conducting the manualised intervention groups was not blinded.

Procedure

Eligible patients were identified from the ADHB chemotherapy waitlist. Research assistants attempted to contact patients three times by telephone. To maximise recruitment, information was disseminated in chemotherapy orientation packs, flyers posted in clinic waiting rooms, and by medical staff and support services. The facilitator attended chemotherapy orientations so patients could ask questions. Those interested were given study information, a consent form and, depending on preference, an online or written questionnaire with a prepaid return envelope. Within 2 days of receiving the completed questionnaire and consent form, participants were contacted and invited to attend the next week's group. To minimise waiting and maximise retention, sessions were designed to be attended in any order. In both conditions, participants attended three 90-min group sessions on consecutive weeks. They were given a $10 voucher for each session to cover travel. When transport was unavailable, volunteer drivers and/or taxis were provided. Recruitment was conducted between March and August 2013, with data continued to be collected until January 2014.

Interventions Both interventions were conducted at the premises of the Auckland Division of the Cancer Society and combined psycho-education with experiential exercises (Table 1). All participants were given handouts reinforcing teaching points and an audio CD and were encouraged to practice for 20 min daily. Exercises for the bMBT were sourced and adapted primarily from a validated program (Segal et al. 2002) modified for cancer patients (MBCT-Ca; Bartley 2012). Exercises that expanded Segal's suggestion to "soften" difficult thoughts and feelings (soften-soothe-allow; Germer and Neff 2013) and a meditation (tree visualisation) designed for cancer patients (Rosenbaum and Kabat-Zinn 2007) were also utilised. To encourage mindful reflection on exercises and home-based practice, ca. 15% of session time were spent on facilitator-led inquiry. The relaxation training intervention was based on standard physically focused relaxation techniques (e.g. PMR; Davis et al. 2008). Given the commonalities between the interventions, we elected to have both interventions conducted by the same therapist which ensured greater control over differentiation of teaching points and also minimised therapist effects (expertise, therapeutic alliance, etc.) across the groups, albeit at the expense of potential allegiance bias (Luborsky et al. 1975).

To ensure treatment fidelity, interventions for both groups followed standardised manuals created for the study. Content was reviewed by experts in both experimental design and mindfulness to ensure that curricula encapsulated the active ingredients of relaxation (i.e. induction of a state of physical calm) and mindfulness (i.e. non-judgmental engagement in present-moment experience). The therapist had over 5 years' experience with cancer patients, had completed mindfulness-based practitioner training (MBSR, MBCR and MiCBT) and was supervised throughout by a clinical psychologist with 10+ years' of mindfulness practice who had taught 20+ MBSR courses.

Measures

Demographics and Medical Status A baseline questionnaire assessed age, sex, marital status and ethnicity. Chart audits determined diagnosis, disease stage, date of diagnosis, type of chemotherapy and whether any toxicity problems had occurred during the study.

Questionnaires at the three time points assessed mindfulness and distress management activities; primary outcomes were focused on various aspects of distress—overall distress, stress reactions to cancer and symptom distress; and secondary outcomes focused on broader aspects of life—quality of life and social avoidance.

Mindfulness The Five Facet Mindfulness Questionnaire (FFMQ) measures five components, including observing, describing, acting with awareness, non-judging and non-reacting (Baer et al. 2006) using a 0 (never or very rarely true) to 4 (very often or always true) point scale. Negatively worded items were reverse-coded, and the mean of all items provided an overall score. In previous work, the FFMQ has been found

Table 1 Session outlines for bMBT and relaxation interventions

	bMBT intervention	Relaxation intervention
Session A	• Introduction to mindfulness and grounding exercise • Teaching: increasing awareness • Raisin meditation • Mindful movement • Body scan meditation • Mindful pause • Wrap-up, homework and close	• Introduction to relaxation • Short breathing and tension release exercise • Teaching: stress response • Break • Controlled breathing exercise • Progressive muscle relaxation exercise • Wrap-up, homework and close
Session B	• Introduction to mindfulness and grounding exercise • Teaching: dealing with difficult experiences • Soften-soothe-allow exercise • Mindful movement • Tree visualisation • Mindful pause • Wrap-up, homework and close	• Introduction to relaxation • Short breathing and tension release exercise • Teaching: over-breathing and hyperventilation • Break • Controlled breathing exercise • Progressive muscle relaxation exercise • Wrap-up, homework and close
Session C	• Introduction to mindfulness and grounding exercise • Teaching: thoughts are not facts • Mindful touch exercise • Mindful movement • Awareness of breath and "letting go of thoughts" meditation • Mindful pause • Wrap-up, homework and close	• Introduction to relaxation • Short breathing and tension release exercise • Teaching: self-care • Break • Controlled breathing exercise • Progressive muscle relaxation exercise • Wrap-up, homework and close

to have good internal consistency, correlates with meditation experience and psychological well-being (Baer et al. 2008) and is widely used (Veehof et al. 2011). It had adequate reliability in the current study (subscale α 0.69 to 0.92).

Distress Management Activities Participants indicated how often they had used prescribed activities to manage stress or emotions in the past 4 weeks, including meditation and breathing exercises. Possible responses were "daily/almost daily", "2–4 times a week", "about once a week", "less than once a week" or "not applicable". Items were coded such that higher scores indicated a greater use.

Cancer Distress The distress thermometer (DT) is a widely used, one-item measure that has been recommended as a tool to detect distress in cancer patients (Donovan et al. 2014; Larouche and Edgar 2004). Participants rated their past week's distress on a 0 to 10 scale. Most studies suggest that scores over 4 indicate clinically significant distress (Donovan et al. 2014). Construct validity for this brief measure has been established in numerous studies that show good correlations with established, but lengthier, measures of distress such as the Hospital Anxiety and Depression Scale (Donovan et al. 2014). The impact thermometer (IT) compliments the DT by assessing the impact of distress (also rated from 0 to 10) and improves accuracy (Baken and Woolley 2011).

Stress Reactions to Cancer Diagnosis The Impact of Events Scale–Cancer (IES-C) was adapted from the IES-R and assesses thoughts, feelings and behaviours during the past 7 days, including avoidance, intrusion and hyper-arousal (Weiss 2007). It has been found to be valid and reliable in cancer patients (Thewes et al. 2001) and has predicted reduced stress in patients after mindfulness training (Bränström et al. 2010). It included statements such as "I tried not to talk about cancer" and "I stayed away from reminders of cancer". The total IES-C score had good reliability (α = 0.96 at all time points).

Symptom Distress The Memorial Symptom Assessment Scale–Short Form (MSAS-SF) measures the distress associated with 32 physical (e.g. nausea, difficulty sleeping) and psychological (e.g. feeling sad, worrying) symptoms in cancer patients (Chang et al. 2000). Distress is rated on a five-point scale and weighted to provide a total, with higher scores indicating greater distress. Scores >1 indicate clinical significance (Chang et al. 2000), but significant changes have not been defined. In previous work, Cronbach alpha coefficients have ranged from 0.76 to 0.87, test-retest correlations have been adequate and convergent validity with extent of disease and cancer-related functioning was established (Chang et al. 2000). Internal reliability in our study was good (alphas ranged from 0.89 to 0.94).

Quality of Life Cancer-related quality of life was measured with the widely used 28-item Functional Assessment of Cancer Therapy–General (FACT-G; Cella et al. 1993). Items relate to functional, emotional, social and physical well-being with higher scores indicating better quality of life. A five-point difference in the FACT-G total over time indicates clinically meaningful change (Brucker et al. 2005). A recent review found good evidence of internal consistency, test-retest reliability and strong support for its convergent and discriminant validity in cancer settings (Luckett et al. 2011). The FACT-G had good reliability in the current study with alphas between 0.88 and 0.91.

Social Avoidance Socially avoidant thoughts and feelings were assessed with a specifically developed seven-item scale that listed reasons why people with cancer might withdraw from and/or avoid others. Participants rated from 0 to 4 how true statements such as "I was embarrassed by the way I look" and "I didn't want to talk about unpleasant aspects of my cancer and treatment" are for them. Higher scores on the social avoidance (SA) indicated greater social avoidance. Principal component analysis suggested a single, reliable component (alphas 0.93 to 0.94).

Data Analyses

First, analyses were conducted to assess participation and verify randomisation. Next, to assess time and group main effects as well as interaction effects, intent to treat (ITT) analyses began with a series of 3 time (baseline vs. post-intervention vs. 3 months later) × 2 condition (bMBT vs. relaxation training) repeated-measures MANOVAs on the FFMQ subscales and distress management activities. Where significant, post hoc *t* test and ANOVA analyses were conducted to investigate where the groups differed. This was followed by 3 time × 2 condition repeated-measures ANOVAs on each of the outcome variables, which, again, were followed up with post hoc *t* tests and ANOVAs when significant differences were obtained. In the case of baseline differences in dependent variables, supplementary ANCOVA analyses were conducted with baseline variables used as covariates.

Results

Participants

Sixty-eight cancer patients were randomised (CONSORT diagram; Fig. 1). Participant ages ranged between 26 and 79 years (median = 55 years) with the majority being female (72%). Most participants identified as NZ European (n = 49; 72%), seven as Maori (10%), two as both Maori and NZ European (3%), four Pacific (6%), five Asian (7%) and one of other ethnicity. Participants had a range of primary cancer diagnoses with the majority having either breast (n = 27; 40%), colorectal/anal (n = 15; 22%), lung (n = 7; 10%) or gynaecological (n = 7; 40%). Most were having adjuvant chemotherapy (n = 27, 40%), with 12 (18%) having neo-adjuvant chemotherapy and 17 (25%) being treated for metastatic disease. Of those eligible, 19% took part. Randomisation checks (Table 2) confirmed that demographic, medical characteristics and outcome variables did not vary between the treatment groups at baseline.

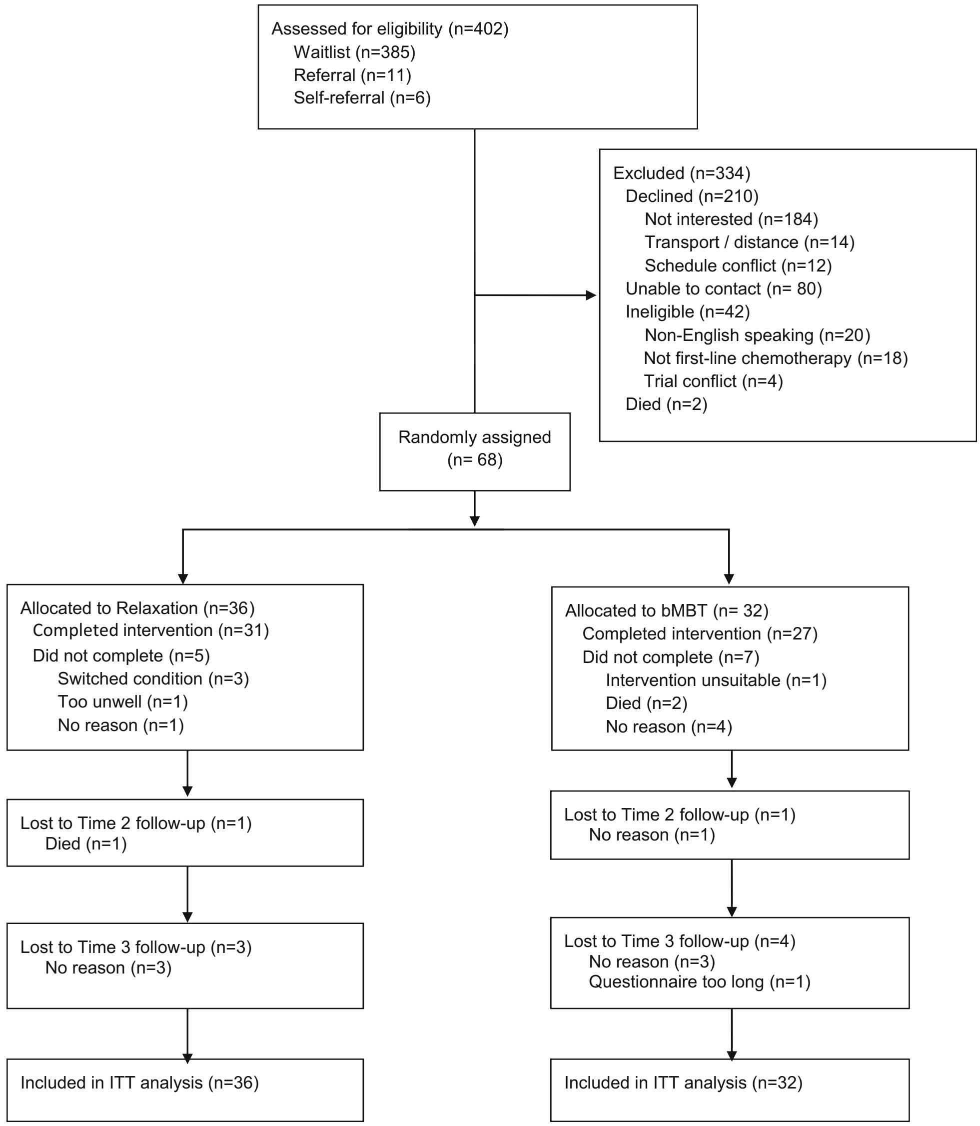
Treatment Completion

Participants were deemed to have received the intervention if they attended all three sessions (n = 58). There were no differences in terms of age, sex, ethnicity or cancer diagnosis in the proportion of patients who completed the study. However, persons with metastatic disease were more likely to drop out, χ^2 (1) = 3.91, p = 0.048. Thirty-one participants (86.1%) completed the relaxation training intervention and 27 (84.4%) completed the bMBT.

Proximal Intervention Outcomes

To assess whether adherence to recommended distress management activities was comparable across groups, repeated-measures ANOVAs were conducted on breathing exercises and meditation practice. Both breathing exercises (Wilks' Λ = 0.59, F(2.65) = 22.55, p = 0.000, η_p^2 = 0.41) and meditation (Wilks' Λ = 0.66, F(2.65) = 17.00, p = 0.000, η_p^2 = 0.34) increased over time (Fig. 2b, c). Whilst no interaction between time and condition was found for breathing (Wilks' Λ = 1.69, F(2.65) = 1.69, p = 0.192, η_p^2 = 0.05), there was a time by condition interaction for meditation (Wilks' Λ = 0.93, F(2.65) = 2.52, p = 0.088, η_p^2 = 0.07). Post hoc ANOVAs revealed that whilst both groups increased meditation between baseline and post-intervention (bMBT, F(1.31) = 28.17, p = 0.000, η_p^2 = 0.48; relaxation, F(1.35) = 8.03, p = 0.008, η_p^2 = 0.19), and both bMBT (F(1.31) = 4.76, p = 0.037, η_p^2 = 0.13) and relaxation (albeit marginally, F(1.35) = 2.70, p = 0.109, η_p^2 = 0.07) decreased meditation by follow-up, it was only in the bMBT group that the amount of meditation practice remained greater at

Fig. 1 CONSORT diagram



3 months than baseline ($F(1.31) = 16.75$, $p = 0.000$, $\eta_p^2 = 0.35$). In the relaxation training group, the amount of meditation at follow-up was no longer different than baseline ($F(1.35) = 1.34$, $p = 0.254$, $\eta_p^2 = 0.04$).

To assess our hypothesis that mindfulness would increase over time in the bMBT intervention, repeated-measures MANOVAs were conducted on each FFMQ subscale. There was an overall time effect (Wilks' $\Lambda = 0.67$, $F(10.57) = 2.86$, $p = 0.006$, $\eta_p^2 = 0.33$). Scores on observe ($F(2.66) = 4.81$, $p = 0.013$, $\eta_p^2 = 0.07$), non-judge ($F(2.66) = 1.17$, $p = 0.003$, $\eta_p^2 = 0.09$) and non-react components ($F(2.66) = 3.75$, $p = 0.028$, $\eta_p^2 = 0.05$) increased with time. There was also an overall group effect (Wilks' $\Lambda = 0.79$, $F(5.62) = 3.28$, $p = 0.011$, $\eta_p^2 = 0.21$), although only the describe component varied between groups ($F(1.66) = 5.25$, $p = 0.025$, $\eta_p^2 = 0.07$). Whilst there was no overall interaction between time and condition (Wilks' $\Lambda = 0.85$, $F(10, 57) = 1.05$, $p = 0.416$, $\eta_p^2 = 0.16$), there was an interaction between time and condition for the non-judge subscale score ($F(2.66) = 3.54$, $p = 0.034$, $\eta_p^2 = 0.05$), with those in the bMBT group reporting more mindfulness at time 3 than those in the relaxation group ($t(2.66) = -1.84$, $p = 0.035$). In the interest of conserving space, only the composite mindfulness score is charted here (Fig. 2a).

Primary Outcomes

There was a marginal overall reduction in distress over time as (Wilks' $\Lambda = 0.92$, $F(2.65) = 2.77$, $p = 0.070$, $\eta_p^2 = 0.08$) (Table 3 and Fig. 3), but no time by condition interaction (Wilks' $\Lambda = 0.99$, $F(2.65) = 0.31$, $p = 0.735$, $\eta_p^2 = 0.01$). Equally, the impact of distress was reduced over time (Wilks' $\Lambda = 0.86$, $F(2.65) = 5.47$, $p = 0.006$, $\eta_p^2 = 0.14$). Again, however, there was no time by condition interaction (Wilks' $\Lambda = 1.00$, $F(2.65) = 0.16$, $p = 0.855$, $\eta_p^2 = 0.01$). Because baseline DT scores in the relaxation group were

Table 2 Study measures and demographic characteristics for participants per condition

Measure	Relaxation (n = 36)	Mindfulness (n = 32)	Statistical results
Age, mean (SD)	56.56 (13.00)	55.31 (12.69)	$t = 0.40$
Gender			
Male	9 (25.0%)	10 (31.3%)	$\chi^2 = 0.33$
Female	27 (75.0%)	22 (68.8%)	
Marital status			
Single	8 (22.2%)	5 (15.6%)	$\chi^2 = 3.25$
Married/cohabiting	24 (66.7%)	18 (56.3%)	
Separated/divorced/widowed	4 (11.1%)	9 (28.1%)	
Ethnicity			
NZ European	25 (69.4%)	24 (75.0%)	$\chi^2 = 2.28$
NZ Maori	5 (13.9%)	2 (6.3%)	
NZ Maori/European	1 (2.8%)	1 (3.1%)	
Pacific	2 (5.6%)	2 (6.3%)	
Asian	2 (5.6%)	3 (9.4%)	
Other	1 (2.8%)	0 (0.0%)	
Diagnoses			
Breast	13 (36.1%)	14 (43.8%)	$\chi^2 = 5.17$
Lung	4 (11.1%)	3 (9.4%)	
Colorectal/anal	8 (22.2%)	7 (21.9%)	
Gynaecological	4 (11.1%)	3 (9.4%)	
Upper gastrointestinal	1 (2.8%)	1 (3.1%)	
Head/neck	2 (5.6%)	0 (0.0%)	
Bladder	1 (2.8%)	1 (3.1%)	
Prostate	2 (5.6%)	0 (0.00%)	
Other	1 (2.8%)	3 (9.4%)	
Time since diagnosis, weeks (SD)	11.86 (10.55)	11.24 (13.45)	$t = 0.36$
Chemotherapy			
Adjuvant	19 (52.8%)	20 (62.5%)	
Neo-adjuvant	5 (13.9%)	7 (21.9%)	$\chi^2 = 3.02$
Metastatic	12 (33.3%)	5 (15.6%)	
Chemotherapy toxicity problem	1 (2.8%)	1 (3.1%)	$t = -0.08$
Baseline measures, mean (SD)			
FFMQ	2.53 (0.40)	2.37 (0.51)	$t = 0.22$
Meditation practice	0.81 (1.47)	0.69 (1.47)	$t = 0.54$
Relaxation practice	1.11 (1.70)	1.53 (1.92)	$t = -0.96$
Distress thermometer	4.58 (2.85)	3.32 (3.11)	$t = 1.75$*
Impact thermometer	4.75 (2.91)	4.02 (3.68)	$t = 0.92$
IES-C	3.47 (2.73)	3.48 (2.51)	$t = -0.02$
MSAS-SF	1.18 (0.62)	0.93 (0.50)	$t = 1.77$*
FACT-G	73.47 (14.86)	75.02 (16.35)	$t = -0.41$
SA	1.08 (1.09)	0.90 (0.82)	$t = 0.74$

*$p < 0.10$

marginally greater than the mindfulness group ($p = 0.09$), we also ran a time (post-intervention vs. 3 months later) × condition (bMBT vs. relaxation) repeated-measures ANCOVA controlling for baseline DT scores. Results presented a similar picture with a reduction in overall distress over time (Wilks' $\Lambda = 0.94$, $F(1.65) = 4.13$, $p = 0.046$, $\eta_p^2 = 0.06$) and no interaction between time and condition (Wilks' $\Lambda = 0.99$, $F(1.65) = 0.53$, $p = 0.468$, $\eta_p^2 = 0.01$).

Stress related to cancer (IES-C) declined over time (Wilks' $\Lambda = 0.82$, $F(2.65) = 7.25$, $p = 0.001$, $\eta_p^2 = 0.18$) comparably in both groups (Wilks' $\Lambda = 0.97$, $F(2.65) = 1.03$, $p = 0.363$, $\eta_p^2 = 0.03$). Post hoc ANOVAs indicated that cancer distress

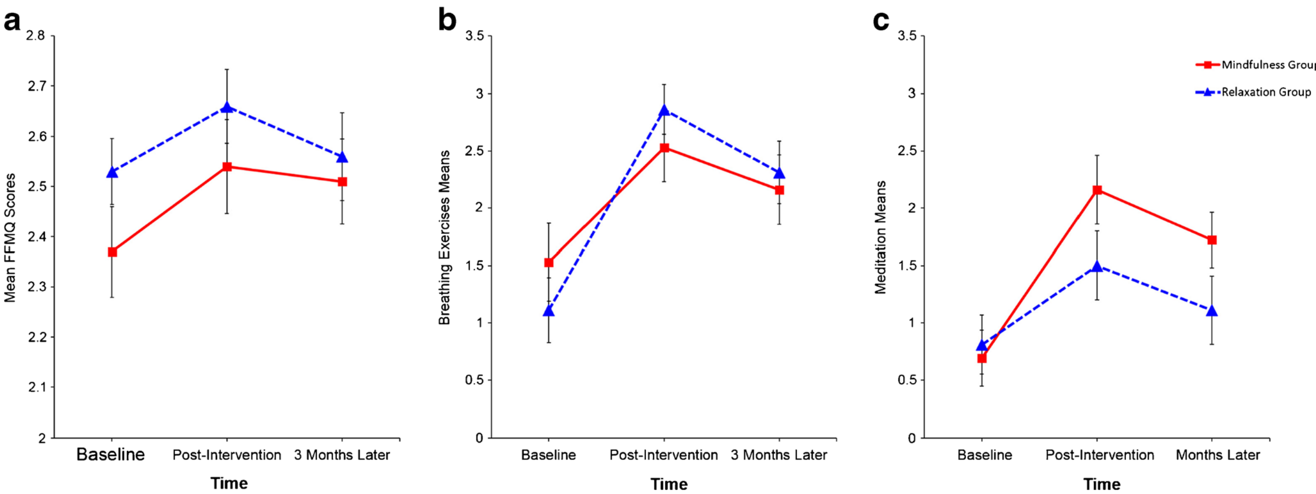


Fig. 2 Mean scores of FFMQ, breathing exercises and meditation over time with standard error bars

in both groups was lower post-intervention relative to baseline (bMBT, $F(1.31) = 4.73$, $p = 0.037$, $\eta_p^2 = 0.13$; relaxation, $F(1.35) = 10.55$, $p = 0.003$, $\eta_p^2 = 0.23$), and this reduction was maintained at 3 months (bMBT, $F(1.31) = 4.42$, $p = 0.044$, $\eta_p^2 = 0.13$; relaxation, $F(1.35) = 3.73$, $p = 0.061$, $\eta_p^2 = 0.10$).

Conversely, there was an increase in distress regarding cancer symptoms over time (Wilks' $\Lambda = 0.90$, $F(2.65) = 3.81$, $p = 0.027$, $\eta_p^2 = 0.11$), although this effect was qualified by a time × condition interaction (Wilks' $\Lambda = 0.84$, $F(2.65) = 6.08$, $p = 0.004$, $\eta_p^2 = 0.16$). Given that MSAS-SF scores in the relaxation training group were marginally greater than the mindfulness group ($p = 0.08$) at baseline, we also ran a time (post-intervention vs. 3 months later) × condition (bMBT vs. relaxation) repeated-measures ANCOVA controlling for baseline MSAS-SF scores. Whilst the difference across time disappeared (Wilks' $\Lambda = 1.00$, $F(1.65) = 0.27$, $p = 0.607$, $\eta_p^2 = 0.004$), the interaction between time and condition remained (Wilks' $\Lambda = 0.93$, $F(1.65) = 4.83$, $p = 0.032$, $\eta_p^2 = 0.07$). In contrast to expectation, post hoc ANOVAs revealed that symptom distress did not increase in the relaxation training group and increased from baseline to post-intervention in the bMBT group ($F(1.31) = 13.31$, $p = 0.000$, $\eta_p^2 = 0.37$). Although it then decreased at follow-

Table 3 Analyses of outcome measures before, after and 3-months post-intervention

Measure	Baseline mean (SD)	Post-intervention mean (SD)	Three-month-later mean (SD)	*P*			Effect size η_p^2	
				Group	Time	Group × time	Time	Group × time
Distress thermometer								
Relaxation	4.58 (2.85)	3.69 (2.72)	3.67 (3.01)	0.088	0.070	0.735	0.08	0.01
Mindfulness	3.32 (3.12)	2.87 (2.72)	2.75 (2.86)					
Impact thermometer								
Relaxation	4.75 (2.92)	3.61 (2.93)	3.99 (3.37)	0.130	0.006	0.855	0.14	0.01
Mindfulness	4.02 (3.68)	2.72 (2.77)	2.78 (2.98)					
IES-C								
Relaxation	3.47 (2.73)	2.53 (2.36)	2.87 (2.42)	0.786	0.001	0.363	0.18	0.03
Mindfulness	3.48 (2.51)	2.96 (2.79)	2.92 (2.73)					
MSAS-SF								
Relaxation	1.18 (0.62)	1.14 (0.74)	1.23 (0.74)	0.873	0.027	0.004	0.11	0.16
Mindfulness	0.93 (0.50)	1.35 (0.66)	1.20 (0.74)					
FACT-G								
Relaxation	73.47 (14.86)	76.55 (12.65)	75.31 (14.87)	0.788	0.560	0.042	0.02	0.09
Mindfulness	75.02 (16.35)	71.58 (17.47)	76.01 (17.44)					
Social avoidance								
Relaxation	1.08 (1.09)	0.88 (0.94)	1.20 (0.99)	0.967	0.019	0.039	0.12	0.10
Mindfulness	0.90 (0.82)	1.11 (1.10)	1.12 (1.03)					

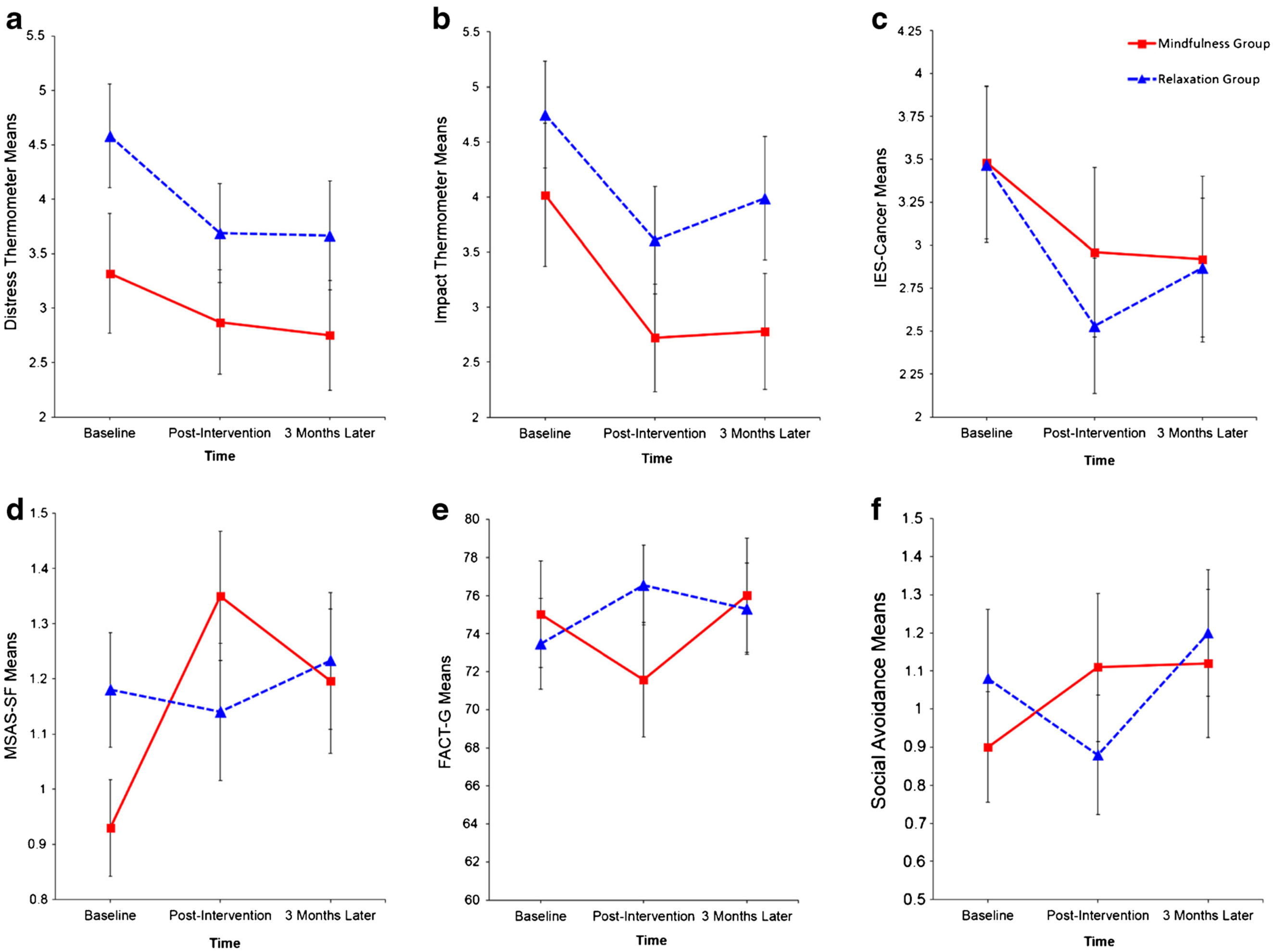


Fig. 3 Changes in outcomes over time with standard error bars

up (F(1.31) = 4.71, p = 0.038, η_p^2 = 0.13), it still remained greater than it was at baseline in this group (F(1.31) = 5.57, p = 0.025, η_p^2 = 0.15).

Secondary Outcomes

Although there was no overall change in quality of life (QOL) scores over time (Wilks' Λ = 0.98, F(2.65) = 0.58, p = ·560, η_p^2 = 0.02), there was an interaction between time and condition (Wilks' Λ = 0.91, F(2.65) = 3.33, p = 0.042, η_p^2 = 0.09). Again, post hoc ANOVAs showed that QOL scores only changed for bMBT participants; quality of life marginally decreased between baseline and post-intervention (F(1.31) = 3.92, p = 0.057, η_p^2 = 0.11) and then increased 3 months later (F(1.31) = 4.36, p = 0.045, η_p^2 = 0.12). There was no difference between baseline and 3-month follow-up quality of life (F(1.31) = 0.18, p = 0.68, η_p^2 = 0.01).

There was an increase in SA scores over time (Wilks' Λ = 0.88, F(2.65) = 4.25, p = 0.019, η_p^2 = 0.12), although this effect was again qualified by a time × condition interaction (Wilks' Λ = 0.91, F(2.65) = 3.42, p = 0.039, η_p^2 = 0.10). Post hoc ANOVAs showed that in the bMBT group, SA scores marginally increased between baseline and post-intervention (F(1.31) = 3.52, p = 0.070, η_p^2 = 0.10) and was greater at 3 months (relative to baseline) (F(1.31) = 6.15, p = 0.019, η_p^2 = 0.17). Conversely, in the relaxation training group, SA scores marginally decreased between baseline and post-intervention (F(1.35) = 2.71, p = 0.109, η_p^2 = 0.07) and then increased again between the intervention and follow-up (F(1.35) = 10.15, p = 0.003, η_p^2 = 0.23).

Discussion

Although other studies have included patients undergoing treatment in broader samples (Carlson and Garland 2005; Speca et al. 2000), this study evaluated a brief MBT in an *acute* cancer treatment. Other than showing the expected reductions in overall distress in both interventions over time, findings were contrary to predictions. Relative to relaxation training group patients, bMBT participants reported *increased* symptom distress and social avoidance, and *decreased* quality of life post-intervention, whilst relaxation training participants either maintained levels on these metrics or improved. Whilst some measures had limitations—the social avoidance measure was not validated and the DT/IT are single-item measures—the well-validated scales (MSAS-SF, FACT-G) revealed large (and similar) patterns of effects. Thus, as assessed by these metrics, bMBT offered less benefit to chemotherapy patients and may have had some (temporary) adverse effects. Given the rapidity with which MBT interventions are being deployed, these findings raise important questions. Below, we interpret these data, describe study limitations and consider the clinical implications for cancer patients and other samples adapting to acute phases of diagnosis, symptomology or treatment.

In the beginning, it is useful to note the interpretative limitation imposed by the absence of a standard-treatment control. Because distress is common during chemotherapy (Iconomou et al. 2004) and relaxation training is sufficiently established as beneficial such that some have suggested that it should be routine (Luebbert et al. 2001), designing a study including randomisation to standard care alone was ethically problematic. This absence does, however, limit our ability to assess whether the increased symptom distress and lowered quality of life seen following the bMBT differ from a "normal" profile where no intervention is given. Whilst relaxation training has been shown to have moderate effects on distress during acute cancer treatment (Luebbert et al. 2001)—a pattern that corresponds with our own findings—it is possible that the bMBT did not have a negative effect compared to standard care but, rather, was simply less effective than relaxation training. This possibility is in line with recent works that found no benefits in the recurrence of anxiety or depression in participants randomised to MBT or active controls (Kuyken et al. 2015; Strauss et al. 2014).

However, an alternative, more concerning possibility, is that the bMBT may have *caused* adverse effects on quality of life, symptom distress and social avoidance. Adverse psychological effects (depersonalisation, dysphoria, mania, depression) have been found in meditative practises (Epstein and Lieff 1981; Kuijpers et al. 2007), and mindfulness may exacerbate physical symptoms (Dobkin et al. 2012; Lustyk et al. 2009). Other studies have found possible adverse effects after MBT (Wilson et al. 2015) including greater relapse in adults with recurrent depression when discontinuing medication (Huijbers et al. 2016). In our study, a bMBT participant was hesitant to complete training because he felt "much worse and quite depressed" after his first session. Additionally, there are examples of MBT not working in groups where issues are associated with "life events" rather than long-standing concerns (Ma and Teasdale 2004). Thus, whilst the benefits of MBT in chronic health conditions are well documented (Berghmans et al. 2012; Chiesa and Serretti 2011; Tacon et al. 2003), the symptom-related distress accompanying acute health challenges (such as chemotherapy) may not be optimally addressed by mindfulness-based approaches. Further research investigating the efficacy of mindfulness training across acute vs. chronic health territories could provide insight into situations when MBT might be contraindicated.

Whilst overall distress and stress reactions to cancer diagnosis changed in accordance to our hypotheses, exactly why our bMBT programme was associated with poorer outcomes on the other metrics (at least temporarily) in chemotherapy patients is unclear. It may be that the rolling group format reduced the element of social support that other MBT groups employ, although the fact that the format was used in both conditions should be noted. Alternatively, perhaps the intervention's "dose" of mindfulness was insufficient compared to the traditional, lengthier variants that have returned success in non-acute cancer contexts (Carlson et al. 2013; Shennan et al. 2011). Given that cultivating a different mindset to life experience is challenging, it may be that three 90-min sessions are insufficiently "potent" to enable this shift. As noted, however, time-intensive interventions are impractical during acute treatment (Eakin and Strycker 2001). Nevertheless, despite our lower dose, some validity for this brief approach can be drawn from the fact that trait mindfulness, meditation and the use of breathing exercises increased after the intervention (albeit in both groups)—and only the bMBT group maintained meditation 3 months after the intervention had finished.

Another possibility is that the "present-moment" focus of mindfulness is best not introduced during acute situations. Situations of this kind might be better suited to tools that promote distraction such as Wells' (2005) "detached mindfulness". Indeed, Kabat-Zinn (interviewed by Moyers 1993) noted the importance of practice and warned us not to start "weaving the parachute when you're about to jump out of the plane" (p. 69). Thus, it might be that initiating mindfulness training is more useful before or after acute situations rather than during them. Although analyses did not reveal reductions in intrusive thoughts (as assessed by the IES-C), low participation rates may have impaired the study's ability to detect such an effect.

At the least, these results suggest that regular monitoring of psychological status *during* mindfulness training is warranted—not simply pre- and post-intervention as is common. A comparison of results mid- and post-MBCR in cancer patients suggested that "noticing and attending to present-moment experience was the first mindfulness skill to develop" (Labelle et al. 2015, p. 34). Our intervention may have facilitated developments of this kind or might reflect a "transient period of worsening distress" (Hayes and Feldman 2004). Whilst we have no way of knowing if this is true, our results do serve as a reminder of the need to educate participants about the possibility of temporary negative effects.

Limitations

Although these findings represent an important contribution to the growing evidence about contexts when MBT may or may not be helpful, there are several limitations that should be noted. First, the study had a low participation rate and we have no way of knowing how patients who declined participation might have fared. Low participation rates in patients going through treatment, particularly in men and the recently diagnosed, are well documented and not necessarily a reflection of acceptability (Andrykowski and Manne 2006). Also, given that the same facilitator delivered both interventions, an allegiance bias might be expected. However, given that our hypotheses favoured the MBT intervention, any bias should have been in the opposite direction to the findings. Additionally, the lack of a systematic assessment of treatment fidelity, or any audiotaping or videotaping of group sessions, limits our ability to know the extent to which the facilitator adhered to manualised instructions. Although the increases in FFMQ scores in the relaxation training group and in self-reported meditative practice might be taken as indicating that the facilitator strayed from the prescribed treatment and (inadvertently) taught mindfulness meditation, we believe that it more likely that this result reflects the known overlap between the two techniques (Lehrer and Carrington 2003). The FFMQ measure may be insufficiently nuanced to capture such differences. Dosage assessed in terms of minutes practised per day was not assessed here and may have proved more sensitive. Our a priori power analysis had suggested that 58 persons would provide adequate power to detect effect sizes of 0.30, a reasonable estimate given the prior effects evident in studies of MBIs in cancer patient samples. However, given the possibility that some effect sizes would be smaller than this and the number of dependent variables we measured, a limitation of our study is that it was probably underpowered to detect significance on some metrics and future work would benefit from a larger sample size. The study is also limited by the fact that two of our primary outcomes—the distress thermometer and the impact thermometer—are single item, and as such, we have no way of specifying exactly what aspects of distress are being measured. In future studies, the use of a more comprehensive measure of distress in cancer patients is recommended.

Another limitation of this work is that the diversity of clinical profiles and treatments in our sample means that other factors may have had a role in psychological function; the relaxation training group had marginally more metastatic participants. However, whilst supplementary analyses showed that “time since diagnosis”, “metastatic disease” or “meditation history” all predicted outcomes in their own right, controlling for such factors produced no substantive differences in the pattern of findings other than marginalising a few effects (likely reflecting reduced power). However, further research that is specifically designed to compare different treatment groups could reveal differences.

Despite these limitations, the current work adds to the extant literature by assessing a mindfulness-based intervention in a context that is especially challenging to research—during acute cancer treatment. This work’s core contribution is in providing preliminary evidence that an MBT intervention may not be optimally suited to all cancer settings or populations and suggests that mindfulness training is perhaps best not initiated when other demands (physical or psychological) are high. A more definitive study with a larger sample in an acute cancer treatment setting is warranted, perhaps testing the longer format that has shown efficacy in the survivorship context. The prior decade has seen an exponential increase in the use of MBT interventions in cancer contexts, perhaps suggesting a tendency to deploy the intervention without appropriate consideration. That mindfulness interventions are useful in some contexts is well established. However, this work suggests that a better understanding is needed on its use in acute contexts, where extended time for training cannot be accomplished and where an enhanced focus on the present-moment experience may be detrimental.

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Author’s Contributions LR designed and executed the study, delivered interventions, analysed the data and wrote the paper. IB collaborated with the study design, analyses and editing of manuscript. DB collaborated with the study design, recruitment of participants and editing of the manuscript. NC supervised the design and execution of the study, analyses of data and collaborated in writing paper.

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