Mediators of Mindfulness-Based Stress Reduction (MBSR): Assessing the Timing and Sequence of Change in Cancer Patients

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Objectives: This waitlist-controlled study examined the timing of changes during Mindfulness-Based Cancer Recovery (MBCR), and explored sequential mediated effects through enhanced mindfulness and emotion regulation (ER) in a cancer population. **Method:** Patients were recruited from the MBCR program waitlist and were either registered for immediate participation ($n = 135$) or waiting for the next program to begin ($n = 76$). Participants completed self-report measures of stress symptoms, mood disturbance, mindfulness, and ER (rumination, worry, and experiential avoidance) pre-, mid- and post-MBCR or waiting period. **Results:** There was a relatively early effect of MBCR on observing, nonjudging, rumination, and worry. All other measures changed later. Early changes in present-focused nonjudgmental awareness, rumination, and worry mediated the effect of MBCR on mindfulness skills such as nonreactivity later on. **Conclusion:** The constructs of mindfulness and ER may overlap and changes may be mutually facilitative during MBCR. The study informs our understanding of mindfulness and ER as mechanisms of mindfulness-based interventions. © 2014 Wiley Periodicals, Inc. J. Clin. Psychol. 00:1–20, 2014.

Keywords: mindfulness; meditation; emotion regulation; mechanisms; cancer

Many cancer patients continue to have high levels of anxiety, depression, fatigue, pain, and sleep difficulties after completion of primary treatments (Carlson et al., 2004). The potential health benefits of mindfulness meditation in oncology and other medical settings are becoming clear (Sedlmeier et al., 2012), largely because of the development and widespread application of the Mindfulness-Based Stress Reduction (MBSR) program of Jon Kabat-Zinn and colleagues (1990) and other mindfulness-based interventions (MBIs), including our adaptation called Mindfulness-Based Cancer Recovery (MBCR; Carlson & Speca, 2010). The crux of MBIs comprises learning mindfulness meditation, a technique involving moment-to-moment nonjudgmental awareness of internal and external experience.

In cancer settings, results from nine randomized controlled trials (RCTs) indicate a beneficial effect of MBIs on symptoms of stress, mood disturbance, depression, anxiety, perceived stress, quality of life, physical functioning, sleep, fatigue, energy, spirituality, meaning, and positive states of mind (Branstrom, Kvillemo, & Moskowitz, 2011; Carlson et al., 2013; Garland et al., 2014; Henderson et al., 2012; Hoffman et al., 2012; Lengacher et al., 2009; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003; Speca, Carlson, Goodey, & Angen, 2000; Wurtzen et al., 2013). It is not yet known what program elements bring about change and whether

This research was funded by a Mind and Life Francisco J. Varela Research Award and Alberta Innovates Health Solutions.

Dr. Linda E. Carlson holds the Enbridge Research Chair in Psychosocial Oncology, co-funded by the Alberta Cancer Foundation and the Canadian Cancer Society Alberta/NWT Division. She is also an Alberta Innovates-Health Solutions Health Scholar. Results have been presented at the Centre for Mindfulness in Medicine, Health Care and Society 10th Annual International Scientific Conference for Clinicians, Researchers and Educators (March 2012).

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Published online in Wiley Online Library (wileyonlinelibrary.com/journal/jclp). DOI: 10.1002/jclp.22117

targeted constructs such as the cultivation of mindfulness are critical in changing outcomes (Moyer et al., 2012).

Clinical researchers from many fields emphasize the importance of understanding how interventions work (i.e., identifying mechanisms of action) to advance treatment research (Kazdin, 2006; Moyer et al., 2012). Mediation analyses may help determine whether program components need to be modified and whether targeted constructs lead to observed benefits. Tailoring programs accordingly (i.e., ensuring adequate levels of the mediating component and excluding unnecessary components) can render such programs more effective and efficient, allowing benefits to be more accessible (Laurenceau, Hayes, & Feldman, 2007). Amalgamating information about mediators across several studies can help distill the mechanisms of change that cut across populations and MBIs (Hayes, Villatte, Levin, & Hildebrandt, 2011).

The foundational premise of MBIs is that the techniques practiced (i.e., mindfulness meditation) cultivate mindfulness as a quality of consciousness (Kabat-Zinn, 1990), but this construct is difficult to measure. Self-report measures contain anywhere from one to five facets, reflecting disagreement in how the construct is defined (e.g., Brown, Ryan, & Creswell, 2007; Grossman & Van Dam, 2011). Two of the most thoroughly validated measures of mindfulness are the Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) and the Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

The MAAS produces a single score representing the presence or absence of attention to and awareness of what is occurring in the present in daily activities (i.e., one's tendency to "act mindfully"; Brown & Ryan, 2003). The FFMQ assesses "mindfulness skills": attending to present-moment experience (Observe), accepting/allowing experience without judgment (Nonjudge), labeling internal experiences with words (Describe), acting with awareness in daily life (Act), and nonreactivity to inner experience (Nonreact; Baer et al., 2006). Both the MAAS and FFMQ correlate in expected directions with measures of psychological functioning and well-being. However, it is unclear whether these questionnaires assess aspects of functioning consistent with mindfulness per se, or its antecedents or effects (Brown et al., 2007). Examining change in mindfulness subscales relative to change in "outcomes" through MBCR will illuminate dialogue regarding the definition and measurement of mindfulness.

Theories regarding the mechanisms of MBIs posit that the cultivation of mindfulness triggers emotion regulatory processes that optimize psychological functioning and alleviate psychological distress (Figure 1; Chambers, Gullone, & Allen, 2009; Hayes & Feldman, 2004; Holzel et al., 2011; Shapiro, Carlson, Astin, & Freedman, 2006). There is accumulating evidence that MBIs improve psychological outcomes through increased mindfulness in normal, distressed community, and cancer samples (Branstrom, Kvillemo, Brandberg, & Moskowitz, 2010; Carmody & Baer, 2008; Garland et al., 2013; Nyklicek & Kuijpers, 2008; Shapiro, Oman, Thoresen, Plante, & Flinders, 2008). Findings also suggest that decreased perseverative thinking mediates beneficial outcomes of MBIs (Jain et al., 2007; Labelle, Campbell, & Carlson, 2010). However, Carmody, Baer, Lykins, and Olendzki (2009) found that during MBSR, self-regulation of emotions and thoughts did not mediate the association between trait mindfulness and psychological symptom reduction. They called for future refinements in the definition and measurement of mindfulness and its purported effects, including whether these constructs develop simultaneously or sequentially through a regular mindfulness practice.

For change in a particular variable to be a mediator, change in that variable must precede *and* predict change in outcomes through the intervention (Kraemer, Wilson, Fairburn, & Agras, 2002). However, the vast majority of MBI studies have collected proposed mediator and outcome variable data at only two time points (pre- and postprogram), and therefore could not assess temporal precedence of change in mediators. Without evidence of temporal sequence of change, alternative models (e.g., that improved psychological functioning accounts for the association between MBI participation and increased mindfulness) cannot be ruled out (Baer, 2011). Lack of evidence of sequential change also contributes to ambiguity in distinguishing the construct of mindfulness from its antecedents and effects (Brown et al., 2007). Understanding the timing and sequence of change through MBIs informs debates regarding the conceptualization and measurement of mindfulness and strengthens conclusions regarding mechanisms of action.

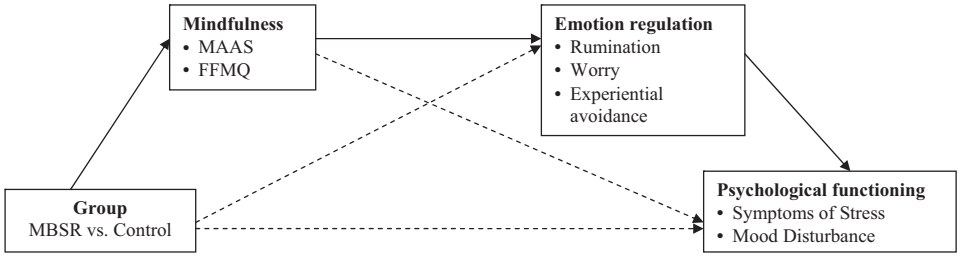


Figure 1. Proposed mediation model: Increased mindfulness through MBSR leads to enhanced emotion regulation, which in turn leads to decreased symptoms of stress and mood disturbance.

This longitudinal waitlist-controlled study explored the timing and sequence of change in outcome variables in the context of MBCR. The objectives of the study were to (a) replicate previous research demonstrating a beneficial effect of MBIs on psychological outcomes (symptoms of stress and mood disturbance) and hypothesized mediators (mindfulness, rumination, worry, and experiential avoidance) in cancer patients; (b) address the timing of MBCR-related changes by testing the effect of participation within the first and second halves of this 8-week program (including an assessment exactly midway through the intervention was theoretically arbitrary given the absence of research addressing this question, but was the most straightforward approach to begin exploring timing of change); and (c) test whether earlier changes in mindfulness and emotion regulation (in the first half of the program) mediate the effect of MBCR participation on benefits observed later (in the second half of the program). Figure 1 depicts a theoretical framework for exploring mediators of change through the program. Given limited empirical knowledge regarding the timing and sequence of changes during MBIs, and ambiguity in the literature in distinguishing the construct of mindfulness from its proximal antecedents and effects, we did not limit our analyses to tests consistent with the theoretical model. That is, we sought to identify any "upstream" changes in mindfulness or ER variables that mediated any "downstream" changes through the program, including those inconsistent with the model, and (d) examine correlations with adherence (program attendance and home meditation practice).

Method

As described by Carlson and Speca (2010), the program offered through the Tom Baker Cancer Centre (TBCC) provides an opportunity to become aware of one's personal responses to stress and to learn and practice techniques that will bring about healthier stress responses. This 8-week group intervention is offered three times per year and comprises two to three separate groups of approximately 15 to 25 participants per group. The intervention comprises weekly, 90-minute group sessions, and one 6-hour intensive session on a Saturday between weeks 6 and 7. Two psychologists and a nurse who have been delivering the intervention for over 15 years facilitate the groups. Group sessions include mindfulness meditation techniques (e.g., sitting with full awareness of breathing, "open awareness" meditation, walking meditation) and gentle Hatha yoga, as well as discussions to facilitate feedback and support regarding experiences and challenges encountered through the practice. Participants are expected to practice the prescribed meditation and yoga techniques daily, for 45 minutes.

Recruitment and Study Design

Data collection began in October 2007 and included eight consecutive 8-week MBCR programs spaced 4 months apart, and eight "waiting periods" between programs. All patients were recruited consecutively from the waitlist, and were placed in either the MBCR or waitlist control

group depending on timing of their entry to the waitlist. Specifically, patients were recruited for the waitlist control group if there were more than 8 weeks before the start of the next MBCR program (hence they would be waiting that long anyway), and the treatment group if there were fewer than 8 weeks before the start of the next program. This design allowed for a natural waitlist control group, such that patients were not self-selecting into the MBCR or control condition. Waitlist control participants also completed questionnaire assessments when they later participated in the MBCR program, however those data are not presented here.

Patients were self- or health care professional-referred, and they were eligible for the study if they met the following inclusion criteria: (a) age 18 years or older, (b) a diagnosis of any type of cancer, at any time in the past, (c) speak and read English sufficiently to complete questionnaires, and (d) had not previously participated in an MBSR group.

A power analysis was conducted according to recommendations for determining sample size required to test intervention and mediated effects (Fritz & Mackinnon, 2007; MacKinnon, Lockwood, & Williams, 2004). Data from two comparable trials (Speca et al., 2000; Van Wielingen, Carlson, & Campbell, 2007) were used to estimate the standardized coefficients required to determine sample size.

To obtain an adequate sample size ($n = 122$ with complete data), 324 cancer patients were screened for eligibility (refer to flowchart, Figure 2). Participants completed a questionnaire package three times: prior to, halfway through, and after the MBCR program (MBCR group participants), or the 8-week waiting period (control group participants). Participants recorded the number of minutes spent in home practice (meditation and yoga) using forms provided, which were collected each week during class. The study was approved by the Conjoint Health Research Ethics Board of the University of Calgary Faculty of Medicine.

Measures

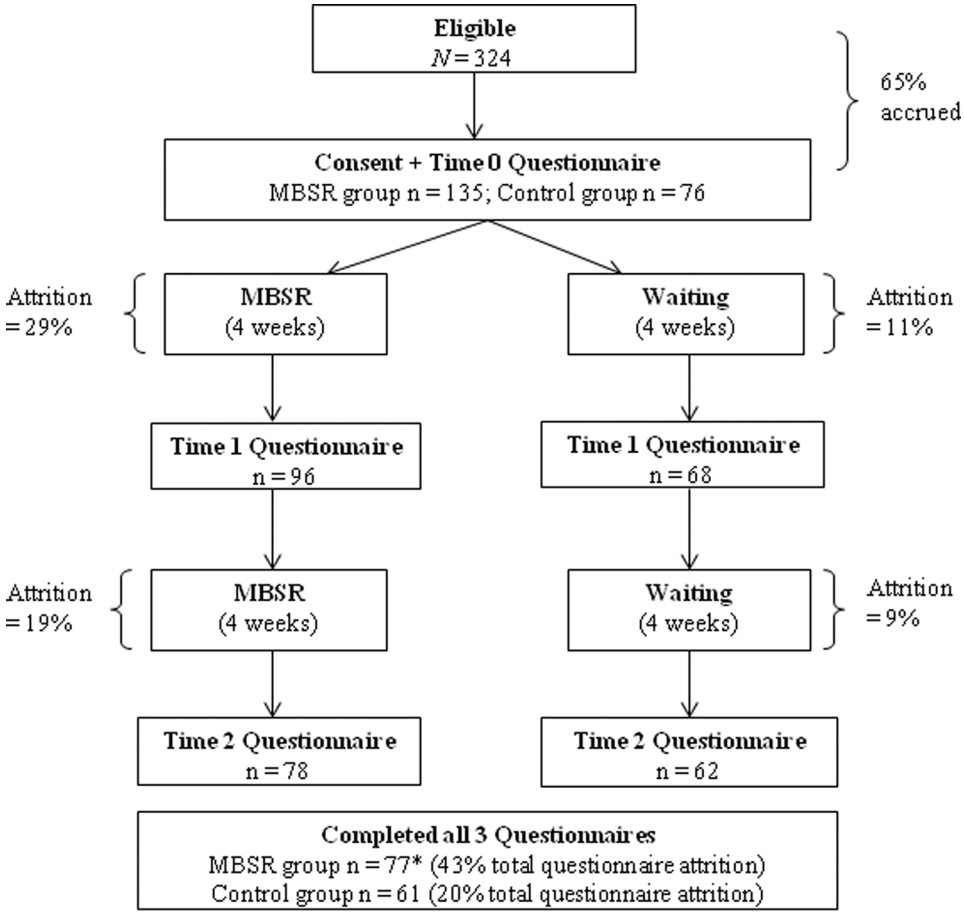
Calgary Symptoms of Stress Inventory (CSOSI; Carlson & Thomas, 2007). The CSOSI is a 56-item scale, a revision of the 95-item Symptom of Stress Inventory (SOSI; Leckie & Thompson, 1979); both scales were designed to capture multiple domains of stress symptoms, including physical and psychological manifestations of stress. In the current sample, internal consistency of the CSOSI was excellent (total score Cronbach's alpha $\alpha = .95$).

Profile of Mood States (POMS; McNair, Lorr, & Droppelman, 1971). The POMS is a 65-item scale that assesses six affective dimensions and provides a Total Mood Disturbance score. The POMS is frequently used to measure psychological adaptation to cancer and its treatment, including psychosocial interventions. Internal consistency of the POMS was excellent in the current sample (total score $\alpha = .95$).

Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003). The MAAS was developed to measure present-centered attention-awareness, that is, the presence or absence of attention to and awareness of what is occurring in the present. A thorough validation process has demonstrated the reliability and validity of the MAAS (Brown & Ryan, 2003; Carlson & Brown, 2005). In the current study, internal consistency was .86.

Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006). Baer and colleagues determined that the combined pool of 112 items from five different mindfulness questionnaires contains five clear, interpretable facets of mindfulness. In the current sample, the FFMQ facets demonstrated acceptable to excellent internal consistency (Cronbach's alphas): Observe (.78), Describe (.91), Act (.88), Nonjudge (.89), and Nonreact (.80).

Rumination-Reflection Questionnaire (RRQ; Trapnell & Campbell, 1999). The Rumination subscale of the RRQ assesses recurrent, primarily past-oriented thinking about the self, which is prompted by threats, losses, or injustices to the self. The scale correlates with mindfulness in expected directions (e.g., Brown & Ryan, 2003; Trapnell & Campbell, 1999). In the current study, internal consistency was .92.



* Two MBSR participants who completed all 3 questionnaires attended fewer than 5 MBSR classes, and therefore are considered drop-outs. The final mediation sample: MBSR group $n = 75$ and Control group $n = 61$.

Figure 2. Flow chart of eligibility, accrual, and questionnaire attrition.

Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990). The PSWQ is a 16-item scale designed to assess trait worry, capturing the excessiveness, pervasiveness, and uncontrollability of clinically significant worry (Meyer et al., 1990). This validated scale appears to measure a construct that is independent of anxiety and depression (Meyer et al., 1990). Internal consistency in the current study was .94.

Acceptance and Action Questionnaire (AAQ; Hayes et al., 2004). The AAQ was developed to measure experiential avoidance, the tendency to negatively evaluate internal experiences (e.g., emotions, body sensations), unwillingness to be in contact with such experiences, and the need to control or alter them or the contexts that engender them (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). The psychometric properties of versions of the AAQ have been well established in clinical (e.g., anxiety disorder) and nonclinical samples (e.g., Hayes et al., 2004). The 16-item version of the AAQ used in the present study produces a single factor. Internal consistency was acceptable ($\alpha = .77$).

Data Analyses

Total intervention effects and timing of change. For all psychological variables, distribution residuals were tested for normality. When psychological test data were not normally distributed, transformations were applied and these transformed scores were used.

Two-level hierarchical linear modeling (HLM) was employed to assess potential changes over time as a function of condition (MBCR vs. control) for the Time 0, Time 1 and Time 2 data obtained for mediator and outcome variables, using the intent-to-treat sample. HLMs testing treatment effects were conducted using the entire (intent-to-treat) sample. HLM 6 statistical software (Raudenbush, Bryk, & Congdon, 2004) was used. Compared with more conventional (e.g., analysis of variance) approaches, HLM procedures provide a more precise characterization of individual growth and allow improved handling of unbalanced designs and missing data (Raudenbush & Bryk, 2002). HLM allows for inclusion of all available data in making estimates. For each HLM, at Level 1 (unconditional growth model), each participant's scores over time was represented by an individual growth trajectory and at Level 2 (conditional model), intercepts and slopes as outcomes were modeled with Group (MBCR vs. control, dummy coded as 1 and 0) added as a predictor. The fixed effect of Group on individual growth rates (i.e., the Group X Time interaction) was examined to ascertain whether MBCR group participants changed more over time, relative to controls.

To assess timing of change (i.e., whether MBCR-related changes occurred during the first and/or second half of the intervention), piecewise HLM models were applied. Piecewise HLMs enable estimation of the effect of Group on mean rate of growth within each time segment (i.e., from Time 0 to 1, and from Time 1 to 2).

Effect sizes were computed for each outcome variable based on the recommended formula, $d = \beta_{11}(\text{Time})/SD_{\text{raw}}$ (Feingold, 2009). Specifically, β_{11} was the difference between the groups in mean growth rates, Time was a value of "2" as the linear weight for Time differed by one unit between waves (i.e., 0 to 1 and 1 to 2), and SD_{raw} was the standard deviation of raw scores at baseline (Time 0). This formula produces effect sizes that are comparable to those for between-groups designs (Feingold, 2009).

Early change in mindfulness and ER as mediators. A cross-lagged difference score approach to longitudinal mediation was used (MacKinnon, Fairchild, & Fritz, 2007). Specifically, separate tests of mediation were conducted with Group (MBCR vs. Control) as the independent variable, early (Time 0 to 1) changes on the MAAS and FFMQ Observe, FFMQ Nonjudge, RRQ, and PSWQ scales as mediator variables, and later (Time 1 to 2) changes in all mediator and outcome variables as dependent variables. Residualized change scores (e.g., the difference between the observed score at Time 1 and the predicted score at Time 1, where the Time 0 measure is used to predict Time 1) were used in lieu of raw change scores (MacKinnon, 2008).

As per current conventions and recommendations for testing mediation, causal steps linear regression was applied (Baron & Kenny, 1986; Kraemer et al., 2002), followed by nonparametric bootstrapping to test the statistical significance of each cross-lagged mediated effect (MacKinnon et al., 2007). In causal steps analyses, a series of linear regressions tested whether the independent variable was associated with change in the mediator, the latter of which was associated with change in the outcome, above and beyond the direct effect of independent variable on outcome (Baron & Kenny, 1986). Tests of the indirect effect (bootstrapping analyses) were used to supplement to the causal steps approach, with interpretations based on results of tests of the indirect effect (Hayes, 2009). Preacher and Hayes' (2004) SPSS syntax was used to derive bias-corrected and accelerated confidence intervals (95%) for indirect effects. Five thousand repeated random samples were taken from the original data to compute the indirect effects. Mediation is said to occur if the derived confidence interval does not contain zero (Preacher & Hayes, 2004). Mediation effects and associations with group attendance were examined using the "completer" sample, as potential pathways of change may be strongest in this subset of participants.

Associations with adherence. Pearson product-moment correlations were conducted to test associations (a) between the number of MBCR sessions attended and pre- to post-MBCR residualized change in proposed mediator and outcome variables, in MBCR participants who completed the study ($n = 75$), and (b) between the minutes of meditation, yoga, and total practice and pre- to postintervention residualized change in proposed mediator and outcome variables, in MBCR participants who completed the study and returned at least 50% of their meditation logs ($n = 53$).

Results

Participant Flow

Participant flow is documented in Figure 2. For the MBCR group, 135 patients were recruited, and 76 for the control group (intent-to-treat $N = 211$). Participants were considered to have dropped out if they attended fewer than 50% of the MBSR classes (i.e., < 5 out of 9, including the Saturday retreat) and/or did not return all three questionnaire packages. The "completer" sample comprised 75 treatment group participants and 61 controls ($N = 136$). Significantly more MBSR group participants ($n = 58$; 43%) than control group participants ($n = 15$; 20%) did not return all three questionnaire packages, $\chi 2(1) = 11.59$, $p < .01$. In addition, relative to study completers, those who dropped out were younger (mean [M] = 49.31 vs. $M = 54.66$ years), $t(1,209) = 3.45$, $p < .01$, and more likely to be male (52.4% of men vs. 31.4% of women dropped out), $\chi 2(1) = 6.49$, $p < .05$. Relative to completers, dropouts also had higher total scores on baseline measures of symptoms of stress and mood disturbance, $t(1,208) = 2.71$, $p < .01$ and $t(1,208) = 3.74$, $p < .001$, respectively.

Sample Characteristics ($N = 211$)

Table 1 presents participant characteristics for the total (intent-to-treat) and completer samples. Groups were equivalent at baseline in the intent-to-treat sample. Among study completers, the MBCR group had significantly more diagnoses of breast cancer (vs. other cancer types; 70.7% vs. 50.8% respectively), $\chi 2(1) = 5.61$, $p < .05$, and a lower mean total mood disturbance score, $t(133) = -2.67$, $p < .01$, relative to the control group. Hence, baseline scores on the POMS were included as covariates in mediation analyses when mood disturbance was an outcome variable. Questionnaire descriptive statistics for study completers at each time point are presented in Table 2.

Program Adherence and Compliance With Home Practice

In calculating MBCR program adherence, class attendance records were missing for 26 of the MBCR participants who did not return all three questionnaire packages. Of those MBCR participants for whom attendance records were available ($n = 109$), the program attendance rate was 70.1%: Participants attended a mean of 6.31 ($SD = 2.41$) out of a possible nine classes, including the Saturday retreat; 22 participants (20.2%) attended fewer than five classes. Hence, the total MBCR program dropout rate is estimated at 20%. Most participants (67%) who dropped out attended one or two MBSCR classes.

Table 3 presents program adherence in the samples used to test (a) intervention effects, (b) mediation and associations with program attendance, and (c) associations with home practice.

Intervention Effects

Results of HLMs are presented in Table 4. Relative to control, MBCR participants demonstrated greater decreases in symptoms of stress and mood disturbance over time. MBCR participation was also associated with greater increases in mindfulness on the MAAS and all five FFMQ facets. Participants in the MBCR group also showed greater decreases in rumination, worry, and experiential avoidance, relative to controls.

Results of piecewise HLMs are presented in Table 5. A significant effect of Group on symptoms of stress and mood disturbance emerged from Time 1 to Time 2 only. Regarding change in

Table 1
Participant Characteristics Within MBSR and Control Groups in Intent-to-Treat and Completer Samples

	Intent-to-treat sample			Completer sample		
	Total $N = 211$	MBSR $n = 135$	Control $n = 76$	Total $n = 136$	MBSR $n = 75$	Control $n = 61$
	M(*SD*)					
Age at first assessment	52.7(11.0)	52.0(*11.0*)	54.0(*10.9*)	54.63(10.04)	54.8(*9.9*)	54.4(*10.3*)
Months since cancer diagnosis	23.4(43.0)	23.8(*37.3*)	23.0(*51.8*)	25.25(49.13)	25.2(*41.9*)	25.3(*57.1*)
Years of education	15.2(2.0)	15.2(*1.9*)	15.2(*2.2*)	15.32(1.86)	15.1(*1.8*)	15.6(*1.9*)
% Female	80.1	82.2	76.3	85.3	89.3	80.3
% White	92.4	93.3	90.8	89.7	89.3	90.2
% Married/living with a partner/spouse	71.1	72.6	68.4	68.4	73.3	62.3
% Employed 20+ hours/week	38.4	39.3	36.8	39.0	40.0	37.7
% Diagnosed with breast cancer	58.8	63.0	51.3	61.8	70.7	50.8*
% Had received surgery	83.4	85.9	78.9	83.8	88.0	78.7
% Had received radiation	44.5	41.0	50.7	49.3	44.6	56.7
% Had received chemotherapy	54.3	56.7	50.0	50.7	49.3	52.5
% Completed primary cancer treatment before first assessment	70.5	74.8	61.8	71.3	78.7	63.3
% Received ongoing primary treatment	16.1	14.1	19.7	16.9	12.0	23.3
% Stopped or started primary treatment during study period	13.2	11.1	17.1	11.0	9.3	13.4

Note. MBSR = Mindfulness-Based Stress Reduction; M = mean; SD = standard deviation.
Among study completers, significantly more patients in the MBSR group (vs. Control group) had a breast cancer diagnosis ($p < .05$).

Table 2
Questionnaire Descriptive Statistics at Each Time Point in Study Completers

	MBSR group $n = 75$			Control group $n = 61$		
Variable	Time 0 Mean*(SD)*	Time 1 Mean*(SD)*	Time 2 Mean*(SD)*	Time 0 Mean*(SD)*	Time 1 Mean*(SD)*	Time 2 Mean*(SD)*
CSOSI Total	55.48*(29.37)*	46.65*(23.31)*	40.05*(23.40)*	60.98*(26.15)*	55.36*(30.58)*	58.75*(28.77)*
POMS Total	28.91*(30.34)*	21.85*(27.34)*	15.52*(24.76)*	44.02*(35.25)*	40.39*(39.87)*	44.28*(37.26)*
MAAS	3.63 *(.77)*	3.78*(.64)*	4.04*(.62)*	3.57*(.76)*	3.60*(.71)*	3.60*(.76)*
Observe	25.78*(5.22)*	28.47*(4.52)*	29.53*(4.69)*	25.39*(5.45)*	25.53*(4.86)*	25.20*(5.50)*
Describe	25.52*(6.59)*	27.35*(6.50)*	28.44*(6.23)*	26.95*(6.14)*	27.33*(6.51)*	26.66*(6.10)*
Act	26.47*(5.52)*	27.00*(4.75)*	28.76*(4.30)*	25.03*(5.72)*	25.30*(6.23)*	24.85*(5.85)*
Nonjudge	27.65*(6.03)*	29.23*(5.11)*	30.75(5.65)	26.56*(6.00)*	26.51*(6.01)*	26.21*(6.34)*
Nonreact	19.58*(3.40)*	21.01*(3.83)*	22.63*(3.91)*	19.12*(4.41)*	19.98*(4.66)*	19.38*(5.02)*
RRQ	41.76*(9.03)*	37.92*(8.64)*	34.85*(9.08)*	42.10*(9.04)*	40.48*(9.35)*	41.31*(9.68)*
PSWQ	50.65*(13.80)*	46.23*(11.68)*	43.93*(10.40)*	52.66*(12.49)*	51.79*(13.78)*	52.98*(13.86)*
AAQ	60.18*(11.05)*	58.03*(10.68)*	54.76*(10.05)*	63.57*(10.46)*	62.85*(9.50)*	63.39*(10.86)*

Note. M = mean, SD = standard deviation; AAQ = Acceptance and Action Questionnaire; CSOSI = Calgary Symptoms of Stress Inventory; MAAS = Mindful Attention/Awareness Scale; POMS = Profile of Mood States; RRQ = Rumination-Reflection Questionnaire; PSWQ = Penn State Worry Questionnaire.
n = sample size.

Table 3
Program Adherence in Intent-to-Treat, Mediation, and Home Practice Analysis Samples

	Intent-to-treat sample $N = 135$		Mediation sample (study completers) $n = 75$		Home practice sample (study completers who returned > 50% of logs) $n = 53$	
	M(*SD*)	% compliance	M(*SD*)	% compliance	M(*SD*)	% compliance
Number of classes attended	6.31(2.41)[a]	70.1	7.45*(1.35)*	82.8	7.50*(1.41)*	83.3
Number of log sheets returned	3.79(3.43)	47.4	5.75*(3.07)*	71.5	7.56*(.87)*	94.5
Meditation (mins/day)	9.98(13.72)	–	16.78*(15.46)*	–	22.35*(14.94)*	–
Yoga (mins/day)	5.75(8.96)	–	10.52*(12.13)*	–	14.07*(12.61)*	–
Total home practice (mins/day)	15.72(20.76)	34.9	27.30*(25.32)*	60.7	36.43*(24.54)*	81.0

Note. M = mean; SD = standard deviation.
[a]Includes Mindfulness-Based Stress Reduction program participants for whom class attendance records were available ($n = 109$). Primary reasons for dropping out of the program and study were "being too busy to continue" or "no longer able to meet the program times." Other less frequently endorsed reasons included "feeling too unwell due to treatment" and "the program isn't a good fit for me."

Table 4
Intercept, Group, Time, and Interaction (Group X Time) Effects in HLMs (N = 211)

Variable	Intercept[a] Est.(*SE*)	Group effect Est.(*SE*)	Time effect (*SE*)	Group × Time interaction Est.(*SE*)	*t*	ES
CSOSI Total[b]	7.62(0.23)	−0.05(0.28)	−0.15(0.09)	−0.53(0.12)	−4.25***	0.53
POMS Total[b]	8.45(0.24)	−0.24(0.30)	−0.03(0.11)	−0.57(0.14)	−3.95***	0.52
MAAS	3.54(0.08)	0.005(0.10)	0.03(0.03)	0.21(0.04)	4.70***	0.56
FFMQ-Observe	25.31(0.58)	0.46(0.73)	−0.04(0.24)	2.05(0.32)	6.34***	0.79
FFMQ-Describe	26.52(0.74)	−0.31(0.93)	−0.10(0.24)	1.37(0.31)	4.58***	0.42
FFMQ-Act	24.97(0.61)	0.69(0.77)	−0.02(0.25)	1.24(0.34)	3.80***	0.46
FFMQ-Nonjudge	26.56(0.70)	0.21(0.88)	−0.10(0.32)	1.84(0.42)	4.37***	0.59
FFMQ-Nonreact	19.29(0.47)	0.20(0.58)	0.09(0.23)	1.42(0.31)	4.67***	0.68
RRQ	42.09(1.02)	−0.31(1.29)	−0.51(0.46)	−3.10(0.61)	−5.02***	0.68
PSWQ	52.50(1.50)	−0.68(1.88)	0.10(0.55)	−3.83(0.72)	−5.28***	0.57
AAQ	63.23(1.26)	−1.67(1.58)	−0.06(0.56)	−2.76(0.74)	−3.91***	0.49

Note. HLM = hierarchical linear modeling; AAQ = Acceptance and Action Questionnaire; CSOSI = Calgary Symptoms of Stress Inventory; MAAS = Mindful Attention/Awareness Scale; POMS = Profile of Mood States; RRQ = Rumination-Reflection Questionnaire; PSWQ = Penn State Worry Questionnaire; Group = MBSR (1) vs. Control (0); Est. = change estimates; SE = standard error; ES = effect sizes for Group x Time interactions.
[a]All intercepts are significantly different from 0 (*p*s<.001).
[b]The distributions of residuals for CSOSI and POMS total scores were moderately positively skewed. Square root transformations resolved skewedness and were used in HLM and piecewise HLM analyses.
*$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

mindfulness, MBCR participants showed greater increases than controls on the MAAS, Observe, and Nonjudge scales from Time 0 to 1 and Time 1 to 2. Describe, Act, and Nonreact scores increased in the MBCR group, relative to the control group, from Time 1 to Time 2 only. MBCR group participants demonstrated significant decreases in rumination and worry from Time 0 to 1 and Time 1 to 2. For experiential avoidance, an effect of MBCR participation on individual rates of change was significant during the second half of the program only.

Mediation Effects

Early MAAS change as a mediator. Path diagrams of significant mediated effects are presented in Figure 3. Satisfying the first step of the causal steps analysis (Baron & Kenny 1986), the effect of Group on late (Time 1 to 2) change in all mediator and outcome variables was significant.

Group did not predict early MAAS change ($\beta = .16$, $p = .06$); therefore, causal steps analyses did not proceed to for this putative mediator. Using bootstrapping procedures, there was no statistical evidence that early MAAS change acted as a mediator of the effect of MBCR on later change in any variable (confidence intervals contained the value 0).

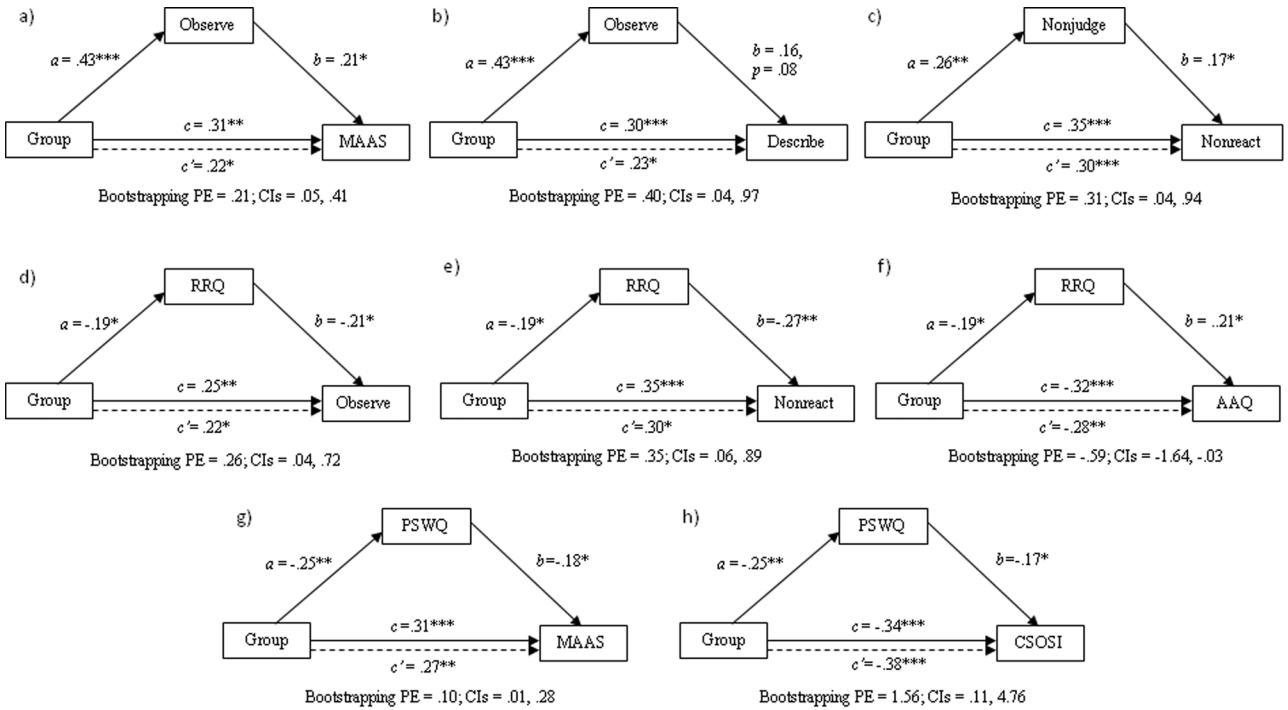
Early Observe change as a mediator. A significant effect of Group on early increases in Observe ($\beta = .43$, $p<.001$) was found. Adjusting for treatment group, early Observe change predicted later MAAS change only ($\beta = .21$, $p < .05$). The coefficient for Group as a predictor of later MAAS change was reduced but remained significant when early Observe change entered the model ($\beta = .22$, $p < .05$), indicating partial mediation. Bootstrapping analyses showed that early Observe change mediated the effect of MBCR participation on late MAAS (95% confidence interval [CI] [.05, .41]) as well as Describe (95% CI [.04, .97]) change.

Early Nonjudge change as a mediator. An effect of Group on early increases in Nonjudge ($\beta = .26$, $p < .01$) was observed. Adjusting for treatment group, early Nonjudge change predicted later Nonreact change ($\beta = .17$, $p < .05$) only. The coefficient for Group as a predictor of later

Table 5
Baseline, Time, and Interaction (Group X Time) Effects in Piecewise HLMs (N = 211)

	Baseline effects		Time effects		Interaction effects					
					Time 0–1			Time 1–2		
Variable	Intercept[a] Est.(*SE*)	Group Est.(*SE*)	Time 0–1 Est.(*SE*)	Time 1–2 Est.(*SE*)	Est.(*SE*)	*t*	ES	Est.(*SE*)	*t*	ES
CSOSI[b]	7.73(0.23)	−0.14(0.29)	−0.54(0.17)**	0.27(0.16)	−0.27(0.23)	n.s.	0.13	−0.80(0.22)	3.63**	0.40
POMS[b]	8.53(0.25)	−0.27(0.31)	−0.32(0.21)	0.27(0.20)	−0.53(0.27)	n.s.	0.24	−0.63(0.27)	2.25*	0.29
MAAS	3.54(0.08)	0.01(0.11)	0.04(0.06)	0.00(0.06)	0.19(0.08)	2.34*	0.26	0.22(0.08)	2.75**	0.30
Observe	25.24(0.60)	0.37(0.75)	0.20(0.43)	−0.30(0.45)	2.39(0.56)	4.22***	0.46	1.66(0.60)	2.78**	0.32
Describe	26.38(0.74)	−0.21(0.93)	0.36(0.46)	−0.61(0.39)	1.04(0.61)	n.s.	0.16	1.69(0.52)	3.22**	0.26
Act	24.87(0.62)	0.87(0.78)	0.33(0.48)	−0.42(0.46)	0.58(0.62)	n.s.	0.11	1.96(0.61)	3.21**	0.36
Nonjudge	26.53(0.72)	0.23(0.90)	0.01(0.56)	−0.24(0.50)	1.81(0.73)	2.47*	0.29	1.86(0.67)	2.77**	0.30
Nonreact	19.12(0.49)	0.39(0.62)	0.66(0.44)	−0.51(0.46)	0.77(0.57)	n.s.	0.18	2.11(0.61)	3.46**	0.50
RRQ	42.42(1.05)	−0.55(1.31)	−1.62(0.85)	0.70(0.77)	−2.40(1.10)	−2.16*	0.26	−3.80(1.03)	−3.67***	0.41
PSWQ	52.78(1.53)	−0.70(1.91)	−0.79(1.03)	1.09(0.88)	−4.03(1.34)	−3.00**	0.30	−3.52(1.17)	−2.98**	0.26
AAQ	63.37(1.28)	−1.88(1.60)	−0.49(0.98)	0.39(0.93)	−2.05(1.28)	n.s.	0.18	−3.48(1.24)	−2.80**	0.31

Note. HLM = hierarchical linear modeling; AAQ = Acceptance and Action Questionnaire; CSOSI = Calgary Symptoms of Stress Inventory; MAAS = Mindful Attention/Awareness Scale; POMS = Profile of Mood States; RRQ = Rumination-Reflection Questionnaire; PSWQ = Penn State Worry Questionnaire; Group = MBSR (1) vs. Control (0); Est. = change estimates; SE = standard error; ES = effect sizes.
[a]All intercepts are significantly different from 0 (*p*s < .001).
[b]Square-root transformed scores.
*$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.



[1] The indirect effect of Group (MBSR vs. Control) on later change in the dependent variable (DV) through earlier change in the mediator variable (M), where *a* is the estimate of the effect of Group on M, *b* is the estimate of the effect of M on DV adjusted for Group, and *c'* is the estimate of the direct effect of the Group on DV adjusted for M (estimates are standardized coefficients). PE=Point Estimates and CI=95% Confidence Intervals from bootstrapping analyses testing the statistical significance of the indirect effect. MAAS=Mindful Attention/Awareness Scale; RRQ=Rumination-Reflection Questionnaire; PSWQ=Penn State Worry Questionnaire; AAQ=Acceptance and Action Questionnaire; CSOSI=Calgary Symptoms of Stress Inventory. *p<.05 **p<.01 ***p<.001

Figure 3. Path diagrams representing statistically significant mediated effects[1].

Nonreact change was reduced but remained significant when early Nonjudge change entered the model ($\beta = .30$, $p < .001$), demonstrating partial mediation. In bootstrap analyses, early Nonjudge change mediated the effect of MBCR participation on late Nonreact change (95% CI [.04, .94]).

Early rumination change as a mediator. An effect of Group on early increases in RRQ ($\beta = -.19$, $p < .05$) was observed. Adjusting for treatment group, early RRQ change predicted later Observe ($\beta = -.21$, $p < .05$), Nonreact ($\beta = -.27$, $p < .01$), and AAQ change ($\beta = .21$, $p < .05$). The coefficient for Group as a predictor of late Observe, Nonreact, and AAQ change was reduced but remained significant when early RRQ change entered the model (Observe: $\beta = .22$, $p < .05$; Nonreact: $\beta = .30$, $p < .001$; AAQ: $\beta = -.28$, $p < .01$), indicating partial mediation. In bootstrap analyses, early RRQ change mediated the effect of MBCR participation on late Observe (95% CI [.04, .72]), Nonreact (95% CI [.06, .89]), and AAQ change (95% CI [-1.64, -.03]).

Early worry change as a mediator. An effect of Group on early increases in PSWQ ($\beta = .-.25$, $p < .01$) was observed. Adjusting for treatment group, early PSWQ change predicted later MAAS ($\beta = -.18$, $p < .05$) and CSOSI change ($\beta = -.17$, $p < .05$). The coefficient for Group as a predictor of later MAAS and CSOSI change was reduced but remained significant when early PSWQ change entered the model (later MAAS: $\beta = -.27$, $p < .01$; later CSOSI: $\beta = -.38$, $p < 001$), indicating partial mediation. In bootstrap analyses, early PSWQ change mediated the effect of MBCR participation on late MAAS (95% CI [.01, .28]) and CSOSI change (95% CI [.11, 4.76]).

Associations with adherence. Among MBCR participants who completed the study (i.e., the mediation analysis sample, $n = 75$), number of sessions attended was correlated with decreased mood disturbance, $r = -.25$, $p < .05$. No other significant correlations with program attendance were observed. Of the study completers in the MBCR group ($n = 53$), 71% returned at least five out of eight meditation logs and were included in analyses testing associations with amount of home practice. No statistically significant associations were observed between number of minutes of home meditation, yoga, and total practice and pre- to post-MBSR change in any mediator or outcome variable.

Discussion

The first goal of this waitlist-controlled study of MBCR was to replicate intervention effects and explore the timing of changes through the program. MBCR participants reported decreased mood disturbance and a broad spectrum of stress-related symptoms, relative to patients who were waiting for an upcoming group. MBCR participants also demonstrated enhanced mindfulness and improved ER, specifically, decreased rumination, worry, and experiential avoidance, when compared to controls. Effect sizes were medium, consistent with previous research (Branstrom et al., 2010; Campbell, Labelle, Bacon, Faris, & Carlson, 2011; Labelle et al., 2010; Ledesma & Kumano, 2009; Speca et al., 2000). Moreover, results point to a cumulative effect of MBCR on psychological outcomes, symptoms of stress, and mood disturbance, with significant change occurring later in the program. Intensive mindfulness practice (i.e., the full 8-week program in its current format) may be required to improve psychological functioning.

Regarding the timing of change in mindfulness variables, attending to present-moment experience without judgment improved early, while the tendency to label emotions, act with present-focused awareness, and allow thoughts and feelings come and go without getting caught up in them developed later. Observe had the largest effect size during the first 4 weeks, and was the only mindfulness variable with a larger effect size in the first half of the program relative to the second half, suggesting that noticing and attending to present-moment experience was the first mindfulness skill to develop. In an uncontrolled study of the weekly trajectory of change through MBSR, Baer, Carmody, and Hunsinger (2012) similarly found that Observe and Nonjudge increased early in the program, while Describe increased later.

Patterns of rumination and worry decreased early (during the first segment of the program) and continued to decrease during the second segment. While models of change describe rumination as a "secondary" mediator that changes subsequently to increased present-focused nonjudgmental awareness (termed "PNA" to facilitate the current discussion; e.g., Shapiro et al., 2006), results suggest that both increased PNA and reduced perseverative thinking occur relatively early in the program. An effect of MBSR on rumination and worry holds relevance for cancer patients, many of whom continue to struggle with uncontrollable, negative intrusive thoughts about the cancer experience and fear of recurrence after completion of active treatments (Schroevers, Ranchor, & Sanderman, 2006). Rumination and worry are associated with difficulty disengaging from unattainable goals due to cancer and reengaging in attainable and meaningful goals, as well as negative affect and interference in daily life (Schroevers et al., 2006; Whitaker, Watson, & Brewin, 2009).

This is the first controlled study to examine whether MBI participation is associated with decreased experiential avoidance. In the MBCR group, experiential avoidance decreased significantly only during the second 4-week segment, suggesting that change in this aspect of ER occurred subsequent to changes in PNA, rumination, and worry. MBSR may counteract experiential avoidance by eliciting psychological contact with private experiences without defence or struggle. Hence, decreased experiential avoidance may be analogous to the process of exposure, which is posited to be a "secondary" mechanism of mindfulness (Shapiro et al., 2006).

The second goal of this study was to test whether earlier changes in mindfulness and emotion regulation mediated the effect of MBSR on later changes, in cancer patients. Results are not consistent with the theory that changes in mindfulness precede and mediate improvements in ER and psychological functioning (Figure 1), when the sequence of change is examined relative to a single mid-program assessment. Interestingly, the early development of present-focused nonjudgmental awareness (PNA) mediated later changes in other mindfulness skills (MAAS, Describe, and Nonreact). A key debate in the mindfulness literature is whether mindfulness questionnaires assess mindfulness per se, conditions that support the unfolding and expression of mindfulness (e.g., attitudes such as nonjudging/acceptance), or antecedents of mindfulness (e.g., improved ER; Brown et al., 2007). In an observational study investigating the facets of the FFMQ in relation to ER and mental health/well-being variables, Coffey Hartman, and Fredrickson (2010) concluded that Observe and Nonjudge appear to be truer measures of mindfulness, consistent with Bishop and colleagues' (2004) maximally parsimonious definition of the construct as nonjudgmental present-focused awareness. Our findings similarly suggest that Describe and Nonreact may be better conceptualized as sequelae of mindfulness, or ER, measuring what mindfulness *does* rather than what it *is* (Brown et al., 2007; Coffey et al., 2010).

Findings also suggest that decreased rumination and worry are pathways through which MBSR enhances present-focused attention and nonreactivity in cancer patients. Even relatively small reductions in rumination and worry early on may have made it easier for participants to apply mindfulness techniques or benefit from those techniques, contributing to improved mindfulness scores over time (Brown et al., 2007). As proposed by Garland, Gaylord, and Fredrickson (2011) and Holzel et al. (2011), the mechanisms of mindfulness may be mutually facilitative in an "upward spiral" process. Theories of change should incorporate factors that influence mindfulness in the context of MBIs (e.g., Grabovac, Lau, & Willett, 2011).

Only one association emerged in a direction consistent with the theoretical model: Early decreases in worry mediated the effect of MBCR on later improvements in symptoms of stress. This finding is pertinent as cancer-related worry is common for patients and is related to psychological symptoms and well-being (e.g., Schroevers et al., 2006). It is also interesting to note that decreased rumination during the first half of the program mediated the effect of MBSR on reduced experiential avoidance later on. During MBSR, reducing *over*engagement with thoughts about losses, threats, and injustices to the self may decrease patterns of *under*engagement with unpleasant thoughts and feelings in an effort to control those experiences.

Of note, assessments taken at three time points (pre-, mid-, and post-MBSR) may not have revealed the complexity of the shape of change and/or relationships among changes in mindfulness, emotion regulation, and psychological outcomes (Laurenceau et al., 2007). Determining

the precise timing of MBSR-related change through more frequent assessments (e.g., weekly) would permit stronger conclusions regarding program mechanisms.

Limitations

Analyses of associations between program adherence and compliance and change in mediator and outcome variables evidenced one significant association: The more MBCR sessions participants attended, the larger the observed decreases in mood disturbance. Contrary to previous RCTs of MBIs in cancer patients (Hoffman et al., 2012; Lengacher et al., 2009; Speca et al., 2000), amount of home meditation and yoga practice was not associated with change in any mediator or outcome variable. This finding is not likely attributable to low amounts of practice given that compliance with home practice in this subgroup of participants was 81% (a mean of 36.4 minutes per day). Unfortunately, the low completion rate of meditation logs (< 50% completion) limits conclusions regarding associations with practice time in the entire sample. Few mindfulness intervention studies report on practice time and findings regarding the association between adherence variables and outcomes are mixed (Carmody & Baer, 2008; Vettese, Toneatto, Stea, Nguyen, & Wang, 2009). A challenge put forth to mindfulness researchers is to develop ways to reliably assess the amount, form, and quality of mindfulness practice (Vettese et al., 2009). Additional research designed to test the mediating role of home practice is needed (e.g., isolating home practice to a separate study arm).

Several other important methodological limitations and related future directions for research merit comment. The current study utilized the naturally occurring waitlist that forms once a program is already underway. It follows that factors other than the intervention itself may have contributed to change in mediator and outcome variables, including preexisting group differences and regression towards the mean. We attempted to mitigate baseline group differences in mood disturbance in the completer sample by including these scores as covariates in mediation analyses. Randomized designs, perhaps designed to test causal mediation models using growth curve or structural equation modeling, will permit stronger conclusions regarding mechanisms of action.

In addition, component-controlled or "dismantling" studies will illuminate the effects of the various components of MBIs (e.g., mindfulness practice, relaxation, leader and group support, didactic learning; Dobkin, 2008). Future studies should also consider potential contamination effects of concurrently receiving other (non-MB) interventions or forms of social support (e.g., exercise classes or peer-support groups). Given that the aims of the study were primarily hypothesis generating, we did not apply a correction for the large number of measures and analyses conducted; the possibility that significant correlations occurred by chance cannot be ruled out.

While the MBCR program dropout rate in the current study (~20%) is comparable to that observed in previous research (Campbell et al., 2011; Speca et al., 2000), the overall study dropout rate (35.6%) was relatively high. Hence, a substantial amount of questionnaire data was missing. Use of HLM allowed improved handling of missing data (Liu & Gould, 2002); however, an effect of missing data on study results cannot be dismissed. In addition, significantly more participants dropped out of the MBCR condition than the control condition (43% vs. 20%, respectively), potentially influencing results. Those who dropped out were also younger, more likely to be male, and had greater mood disturbance and stress symptoms. Future studies could consider whether individual characteristics, such as patient expectancies, distress level, age, gender, personality factors, social support, or interest in spirituality/alternative therapies moderate the impact of MBCR or predict program adherence. It is important to determine not only whether and how MBIs are effective, but also for whom (Kazdin, 2006).

Conclusion

This study contributes to an emerging focus on determining "how" mindfulness-based interventions work in cancer and other populations. In the context of MBCR, the theory that increased mindfulness leads to enhanced emotion regulation, and that changes in these aspects of functioning lead to improved psychological outcomes appears overly simplistic. The constructs of mindfulness and ER may overlap and changes may be mutually facilitative. Testing this

mediation model further in a rigorous manner will inform our understanding of MBIs and may lead to program modifications that will maximize the effectiveness of MBIs in oncology and other settings.

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