



The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR)

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ABSTRACT

Most of the extant literature investigating the health effects of mindfulness interventions relies on wait-list control comparisons. The current article specifies and validates an active control condition, the Health Enhancement Program (HEP), thus providing the foundation necessary for rigorous investigations of the relative efficacy of Mindfulness Based Stress Reduction (MBSR) and for testing mindfulness as an active ingredient. 63 participants were randomized to either MBSR ($n = 31$) or HEP ($n = 32$). Compared to HEP, MBSR led to reductions in thermal pain ratings in the mindfulness- but not the HEP-related instruction condition ($\eta^2 = .18$). There were significant improvements over time for general distress ($\eta^2 = .09$), anxiety ($\eta^2 = .08$), hostility ($\eta^2 = .07$), and medical symptoms ($\eta^2 = .14$), but no effects of intervention. Practice was not related to change. HEP is an active control condition for MBSR while remaining inert to mindfulness. These claims are supported by results from a pain task. Participant-reported outcomes (PROs) replicate previous improvements to well-being in MBSR, but indicate that MBSR is no more effective than a rigorous active control in improving these indices. These results emphasize the importance of using an active control condition like HEP in studies evaluating the effectiveness of MBSR.

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Mindfulness based interventions, particularly Mindfulness-Based Stress Reduction (MBSR¹; Kabat-Zinn, 1990) are increasingly popular. There is substantial evidence that MBSR improves mental and physical health compared to wait-list controls and treatment as usual, and is of comparable efficacy to other psychological interventions (e.g., Barnhofer et al., 2007; Davidson et al., 2003; Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007; Kabat-Zinn et al., 1998; Ma & Teasdale, 2004; Pradhan et al., 2007; Speca, Carlson, Goodey, & Angen, 2000). However, a complete understanding of the mechanisms by which MBSR is efficacious for these outcomes and a valid test of mindfulness as the presumed active ingredient is not currently possible due to the lack of a suitable control intervention. The validation of such a control is the subject of this article.

A direct test of the efficacy of MBSR's active ingredients requires a comparison of MBSR to an active control that matches MBSR in non-specific factors (e.g., structure) but does not contain mindfulness as an active ingredient (Grunbaum, 1986; Kirsch, 2005). There are only two studies involving MBSR-like interventions that use control conditions that approach this standard (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; McMillan, Robertson, Brock, & Chorlton, 2002)². McMillan and colleagues randomly assigned 145 people with traumatic brain injury either to "Attention Control Training" (based on Kabat-Zinn's work but not MBSR), physical exercise, or a wait-list control and found no differences between the two active groups. Limited descriptions of interventions and providers make it difficult to evaluate if the control was adequate.

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¹ Abbreviations: MBSR = Mindfulness Based Stress Reduction; HEP = Health Enhancement Program.

² A recent study by Raison and colleagues (Pace et al., 2008) also uses an active control condition but focuses on compassion meditation rather than the mindfulness meditation taught in MBSR.

Grossman and colleagues assigned participants with fibromyalgia to MBSR ($n = 43$) or social support/relaxation ($n = 15$). MBSR participants improved relative to the control group on measures of anxiety, depression, quality of life, and pain regulation. However, the study was quasi experimental and the control condition was subject to several limitations that are common in studies evaluating specific components of behavioral interventions (Wampold et al., 1997). Specifically, patients received less contact with providers in the control condition than in the MBSR condition. In addition, the control conditions appeared to be defined more by proscriptions (e.g., “emphasis was placed upon not describing or training mindfulness skills to the control group”), rather than the skillful provision of common therapeutic elements, which may bias tests of intervention effects (Mohr et al., 2009).

An appropriate test of mindfulness as an active ingredient requires a control condition that attends to three major limitations typical of active controls in behavioral intervention research. First, since researcher allegiance to intervention is a strong predictor of differences between two interventions that are directly compared, accounting for up to 10% of the variability in treatment outcomes (Gaffan, Tsaousis, & Kemp-Wheeler, 1995; Luborsky, Diguier, Luborsky, & Schmidt, 1999; Wampold, 2001) and up to 69% of the differences between interventions (Imel, Wampold, Miller, & Fleming, 2008; Luborsky et al., 1999), researchers have recommended balancing allegiance when two psychological interventions are directly compared (Hollon, 1999). Second, active and control interventions should be structurally equivalent. Structural variables include number and duration of sessions, therapist training and qualifications, format of the therapy (e.g., group or individual), and the ability of participants to discuss their particular problems. If interventions are unequal in these ways, differences between interventions may be a result of structural non-equivalencies rather than the mechanism of interest. Indeed, when structural differences between interventions and active controls are eliminated, differential efficacy may disappear. In a meta-analysis of 21 psychotherapy studies, the effect of treatment was Cohen's $d = .47$ when the control was not equivalently structured and only $d = .15$ when it was (Baskin, Tierney, Minami, & Wampold, 2003). Finally, the active control should include all non-specific factors present in MBSR. Many active controls that are designed to control for non-specific factors do not contain an accepted rationale or corresponding specific ingredients and would not plausibly be offered as efficacious by providers (Wampold et al., 2010). A well-designed control should include: (a) positive expectation for intervention success by both the therapist and client (Mohr et al., 2009), (b) a therapeutic relationship, (c) provision of a plausible alternative and adaptive explanation for distress (i.e., therapeutic rationale), and (d) some corresponding action for its alleviation (i.e., specific ingredients; Frank & Frank, 1993).

The objective of the current study was to isolate mindfulness as a specific ingredient by designing a control condition that meets the criteria above, while not containing any mindfulness training. The Health Enhancement Program (HEP; MacCoon et al., 2011) was

designed to accomplish these goals. Instructors were chosen for their expertise in, and allegiance to, the class content and the mechanisms associated with its efficacy: MBSR instructors were experts in mindfulness and HEP instructors were experts in their areas (see Supplementary materials). Our laboratory's interest in mindfulness is well-known. To help reduce the potential impact of this researcher allegiance, (a) researchers were not part of teaching the classes, (b) instructors played a major role in the design and implementation of their intervention (as previously discussed), and (c) one member of the design team (Z.I.), who played an important role in consultation regarding the rigor of HEP as an active control condition, has primary allegiance to common factor approaches to therapy and little allegiance to mindfulness (for a more detailed discussion, see Supplementary materials).

Both HEP and MBSR were structurally equivalent, having a group format, meeting once a week for 2.5 h (3 h for first and last sessions) for 8 weeks with an “all day” component (9 a.m.–4 p.m.) after week 6, and completing the same amount of home practice (45 min, 6 of 7 days each week).

HEP content met the following criteria: (1) class activities were chosen to match MBSR activities as closely as possible (see Table 1), (2) these activities represented valid, active, therapeutic ingredients in their own right, and (3) these ingredients did not include mindfulness. Thus, the purpose of walking in MBSR is to cultivate awareness in movement, whereas the purpose of walking in HEP is the cardiovascular benefits of the physical activity for cardiovascular training and followed recommendations from the Centers for Disease Control regarding intensity and frequency of physical activity (Haskell et al., 2007). Similarly, the purpose of yoga in MBSR is largely to cultivate nonjudgmental awareness of physical sensations and respecting one's own physical limits as they change over time. In contrast, the purpose of the balance, posture, and agility exercises in HEP's functional movement is to augment one's physical strength, balance, agility and joint mobility resulting in a physically more resilient individual less prone to sustain injury from spontaneous or unpredictable events (e.g., tripping on a curb, slipping on icy ground, lifting a heavy object; e.g., Hu & Woollacott, 1994; McGuine & Keene, 2006). The music therapy component included an exercise that matched the body scan in several ways with a primary difference being the importance of the music as the change agent rather than MBSR's emphasis on awareness of one's own internal states. The nutrition component included didactic material and reading, both modalities used in MBSR but the content was not related to mindfulness.

The rationale for MBSR and HEP reflect these different active ingredients. The following is a summary of the rationale underlying MBSR: Meditative awareness is fundamental to working with problems we may have because recognizing habit patterns of mind, their impact on situations and on the body, and learning to ‘respond’ rather than simply falling into habit patterns is essential in learning skillful means of recognizing ‘problems’ and being open

Table 1
Intervention content comparison.

MBSR		HEP	
In-Class	Homework	In-Class	Homework
Body Scan	Body Scan and light reading	Music Therapy: Relax, listen to music, imagery, and drawing	Relax, listen to music, imagery, and drawing
Sitting Meditation	Body Scan, Sitting Meditation, and light reading	Nutrition Education around Food Guide Pyramid	Planning meals, tracking diet, food labels, journaling
Yoga	Alternate Yoga and Body Scan, and Sitting Meditation	Functional Movement (posture, balance, core movement)	Posture, balance, coordinated movement
Walking Meditation	Walking and other practices	Physical Activity (walk/jog, stretch)	Walking and stretching
All Day (7 h): Work with all practices, Group discussion & exercises	–	“Spa Day” (7 h): Work with all practices, Group discussion & exercises	–

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