



## Workplace based mindfulness practice and inflammation: A randomized trial

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### ABSTRACT

We have developed a low dose Mindfulness-Based Intervention (MBI-Ild) that reduces the time committed to meetings and formal mindfulness practice, while conducting the sessions during the workday. This reduced the barriers commonly mentioned for non-participation in mindfulness programs. In a controlled randomized trial we studied university faculty and staff ( $n = 186$ ) who were found to have an elevated CRP level,  $>3.0$  mg/ml, and who either had, or were at risk for cardiovascular disease. This study was designed to evaluate if MBI-Ild could produce a greater decrease in CRP, IL-6 and cortisol than an active control group receiving a lifestyle education program when measured at the end of the 2 month interventions. We found that MBI-Ild significantly enhanced mindfulness by 2-months and it was maintained for up to a year when compared to the education control. No significant changes were noted between interventions in cortisol, IL-6 levels or self-reported measures of perceived stress, depression and sleep quality at 2-months. Although not statistically significant ( $p = .08$ ), the CRP level at 2-months was one mg/ml lower in the MBI-Ild group than in the education control group, a change which may have clinical significance (Ridker et al., 2000; Wassel et al., 2010). A larger MBI-Ild effect on CRP (as compared to control) occurred among participants who had a baseline BMI  $<30$  ( $-2.67$  mg/ml) than for those with BMI  $>30$  ( $-0.18$  mg/ml). We conclude that MBI-Ild should be more fully investigated as a low-cost self-directed complementary strategy for decreasing inflammation, and it seems most promising for non-obese subjects.

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### 1. Introduction

Current research suggests that chronic stress in our society is a contributing factor to the behaviors and physiology that have accelerated the increase in chronic disease states. Hence low-cost self-directed stress reduction programs could be of great assistance in managing this epidemic. One such candidate is mindfulness-based stress reduction (MBSR), which is a structured group program that utilizes mindfulness meditation to help manage a variety of adverse health issues (Ludwig and Kabat-Zinn, 2008).

Mindfulness is characterized by non-judgmental, moment-to-moment awareness of physical sensations, perceptions, affective states, thoughts and imagery. It involves sustained awareness of mental phenomena which arise during waking consciousness. As a form of receptive awareness, mindfulness may create an interval of time where one is able to view one's mental landscape, including one's behavioral options. One goal of mindfulness practice is to enable the individual to make conscious life choices, allowing for a

greater appreciation of possible responses to life events. Mindfulness practice may create a resilience resource for enhancing health, and recovery from illness by exposing the self induced stress caused by the framing of internal and external events. Improvements have been noted in standardized mental health measures including quality of life scales, depression, anxiety, coping style, and other affective dimensions of disability following mindfulness training (Ludwig and Kabat-Zinn, 2008). For chronic disease, meditative practices that cultivate and enhance awareness (exposing thoughts as narratives of our thinking and not as reality) may modulate the experience of pain and/or improve the capacity to deal with pain (Morone et al., 2008; Zautra et al., 2008), enhance the management of type 2 diabetes (Hartmann et al., 2012) and improve psoriasis (Kabat-Zinn et al., 1998).

It has been suggested that mindfulness practice may engage several biological pathways, including immune and endocrine changes evidenced by an increase in antibody titers to influenza vaccine (Davidson et al., 2003), higher salivary IgA levels and lower salivary cortisol levels following an acute stressor (Tang et al., 2007). Furthermore, only 5 days of body-mind training improved regulation of the autonomic nervous system (heart rate variability and blood pressure) and it was associated with EEG activation in the frontal cortex (Tang et al., 2009).

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Functional MRI imaging demonstrate that individual disposition toward mindfulness is associated with extensive prefrontal cortical activation and diminished bilateral amygdala activity (Creswell et al., 2007) indicating thoughtful response patterns rather than hyperemotional reaction to life events. Both effects are associated with more controlled regulation of inflammation via the hypothalamic-pituitary-adrenal axis, the autonomic nervous system and immune system (Cerqueira et al., 2008).

Research over the past two decades has established chronic inflammation as a pathophysiologic component of numerous disease processes including various cardiovascular disorders. Levels of the inflammatory peptide CRP, that are in the highest tertile of the normal range increase the risk two-fold for a myocardial infarction over the following three years (Ridker et al., 2000).

CRP not only predicts adverse cardiovascular events but it also appears to induce a variety of pro-inflammatory processes in the vascular endothelium (Paffen and DeMaat, 2006). Furthermore, in a longitudinal study of aging, higher CRP and IL-6 levels predicted decreased survival (Wassel et al., 2010). Psychological and behavioral factors have been shown to predict CRP levels in middle aged and older adults (Suarez, 2004), and waist circumference, latency to sleep, smoking, and perceived stress were independently associated with increased CRP levels (McDade et al., 2006).

A recent review of published clinical studies have pointed to the shortcomings of clinical MBSR investigations that we have attempted to address. These problems include small numbers of participants, lack of an active control group, the inclusion of only subjective endpoints, lack of details of participant characteristics that allow generalization of findings, insufficient details of treatment methods, inadequate documentation of protocol adherence by the participants, and infrequent use of biologic measures (Ludwig and Kabat-Zinn, 2008).

In our mindfulness intervention, we have adhered to core MBSR principles, the 8 week program duration, and inclusion of a retreat, but have reduced the time committed to meetings and formal practice, while conducting the sessions onsite during the workday (Klatt et al., 2009). This has reduced the barriers commonly mentioned for non-participation in MBSR programs. Similar modifications to weekly/daily mindfulness programs based on MBSR have emerged, for example shortened programs for oncology patients (Ott et al., 2006) and those who are at risk or have cardiovascular disease (Olivo et al., 2009). In our trial we studied university faculty and staff who were found to have an elevated CRP level, >3.0 mg/ml, and who either had or were at risk for cardiovascular disease. This study focused on working adults who could benefit from lifestyle intervention strategies. In comparing the mindfulness intervention to the lifestyle education program, we focused on three biologic measures of chronic stress and inflammation (CRP, IL-6 and cortisol).

## 2. Methods

**PARTICIPANTS:** Subjects were recruited from faculty and staff of The Ohio State University. Advertising promoted the trial as a life style intervention program and the types of interventions were not specified, with participants unaware of the intervention type until the first day of the actual intervention.

**Exclusion criteria** focused on conditions that enhance inflammation and included: a psychiatric disorder other than depression within the past year; pregnancy; experiencing a major life stress such as death in the immediate family in the past two months; alcohol intake in excess of 2 drinks per day (two 1.25 oz shots of liquor, two 12 oz containers of beer, or two 6 oz glasses of wine); smoking more than ½ pack of cigarettes per day; recreational drug use; vaccination during the past 2-months; a cold or other illness

in the past month; a BMI of greater than 40; and conditions that could decrease inflammation such as exercising more than ½ h per day and previous practice of mind-body relaxation techniques.

**Inclusion criteria** was a CRP level in the upper tertile of risk for cardiovascular disease, >3.0 mg/ml and less than 10 mg/ml (values over 10 suggest acute inflammation) in a screening value obtained at the OSU Clinical Research Center (CRC).

Medication use was permitted to increase the generalizability of results. Fifty six participants in the education and fifty four in the MBI-Ild group were taking medications. The total number of medications used at baseline in the MBI-Ild group (134) was similar to the number (126) in the education control group. The number of different drug classifications groups and medications known to influence inflammation were similar for both interventions. See Table 4. We asked about medications being started or discontinued before each visit. Two individuals in the education group and one in the MBI-Ild group stopped an anti-depressant during the 2-month intervention. In sensitivity analysis of the MBI-Ild effect, we controlled for both medication use and diagnoses.

**STUDY PROTOCOL:** Based on our inclusion and exclusion criteria we accrued 186 patients with a CRP level greater than 3 mg/ml following their initial screening visit. They were consented and received \$350 for their participation in the study. One week later, at a second visit to the CRC prior to randomization, they returned their salivary cortisol samples which had been obtained 20 min after arising, noon, 5 p.m. and at bedtime over 3 days at 7 days intervals. Cortisol collection time was uniformly 2 weeks pre intervention and the 2 week period immediately after the intervention for all subjects. At this visit baseline blood pressure, pulse rate, BMI, and a blood sample for CRP and IL-6 were obtained between 8 and 11 am to control for diurnal variation.

Thereafter, subjects were randomly assigned, using permuted blocks of size of 6. Within each block the assignment to the MBI-Ild intervention or an education control was randomly ordered and balanced (3 in each group). Assigned subjects began their cohort's intervention within 1 week of completing pre-study measures. All members of the research team were blinded to group assignment, except the instructors of the intervention and active control group. We stratified subjects into 2 BMI categories (< or >32), and randomized within each to ensure balance on this important indicator of inflammation. The median BMI was close to 32, so we had 92 subjects in the BMI <32 and 94 in the BMI >32 strata.

Between the screening visit and the invitation to return for randomization, subjects were asked to fill out a daily diary and questionnaires online using StudyTRAX (ScienceTRAX, Macon, GA, 2006) as well as obtain the salivary samples for cortisol determinations. Subjects were randomized in 6 different cohorts in order to keep the group size under 18 in each intervention, either MBI-Ild or education.

Following the intervention the baseline studies were performed at 2-months. This trial was designed as an 8 week intervention with baseline and post intervention measurements. We asked participants, however, if they would continue to practice their interventions and return to complete questionnaires and a blood draw at 6 and 12 months to better evaluate changes over time, especially sustainability of any effects.

**INTERVENTIONS:** *Mindfulness:* MBI-Ild was designed as a stress reduction program to be delivered onsite that included reflective writing, sharing among participants, mindfulness instruction, yoga, and formal mindfulness meditation, similar to traditional MBSR. MBI-Ild augmented the yoga stretches with gentle background music as compared to traditional MBSR.

In this program we have retained the core components true to typical MBSR, only reducing the time spent on each component. The traditional group meeting time in MBSR is 2.5–3 h per week and approximately 45 min per day in formal mindfulness practice.

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