Moderators of the Effectiveness of a Mindfulness-Based Stress Reduction Intervention Compared to an Active Control for Solid Organ Transplant Patients

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Dedication

For the two men in my life –

For Zachary Clinton Sherr
My beloved son, I am grateful for your smiles, laughter, and daring.
You are teaching me much about joy.
I am lucky to be your mom.

For Greg

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Introduction

Due to advances in medical technology over the past several decades, transplant patients are living longer, more productive lives and, as a result, are becoming an increasingly larger population. There have been more than 400,000 transplant patients since the 1960s and currently over 100,000 patients are on wait-lists to receive an organ (Scientific Registry of Transplant Recipients, 2008). One of the downsides of organ transplantation is that patients are forced to manage a chronic condition for the rest of their lives and must take immunosuppressant drugs that have significant side effects. Nevertheless, there is a strong body of evidence suggesting that, across organ type, levels of psychological distress and sleep dysfunction generally improve after transplantation (Goetzmann, et al., 2006; Jofre et al.,1998; Karam et al., 2003; Kugler, Strueber, Tegtbur, Jiedermeyer, & Axel, 2004; Limbos, Chan, & Kesten, 2000). For example, in a review of research on lung transplant patients, psychological disorders were common among those waiting for transplants, with prevalence rates substantially above those in the general population (Fusar Poli et al., 2007). After surgery, recipients had significantly less psychological distress compared to those awaiting transplantation. In another study, kidney recipients were found to have significantly less insomnia than those on a wait-list for transplants. Their post-transplant rates of insomnia were similar to those in the general population (Novak et al., 2006).

Despite these promising figures, rates of psychological distress and sleep disturbance remain high after transplantation for many patients. In one study, depression and anxiety prevalence and symptom severity significantly decreased after lung transplantation; however, levels were still high with 24% of post-transplant

patients reporting moderate to severe depression and 21% reporting moderate to severe anxiety (Russell & Feurer, 2008). Whereas sleep disturbance in kidney recipients generally improves from pre to post transplant, rates remain elevated after surgery and are higher than those in the general population (Sabbatini et al., 2008). Another study of kidney recipients found that 14% were depressed (BDI $\geq$ 17), and severity of depression was strongly associated with poorer sleep quality (Erylimaz, Ozdemir, Yurtman, Cilli, & Karaman, 2005). Nearly a quarter of liver recipients were found to have clinically significant depression and anxiety scores (Nickel, Wunsch, Egle, Lohse, & Otto, 2002). Lung recipients' subjective sleep disturbance scores were positively associated with anxiety and psychological distress (Cohen, Littlefield, Kelly, Maurer, & Abbey, 1998). Additionally, sleep disturbance mediated the relationship between pre-transplant anxiety and post-transplant adjustment and quality of life.

In their prospective cluster analysis of data from organ transplant recipients (heart, lung, liver, kidney, and bone marrow), Goetzmann et al. (2008) argued that, despite a large body of evidence suggesting that transplant recipients improve in psychosocial and physical functioning after surgery, analysis of the means in these studies may mask significantly differing trajectories. They followed patients prior to surgery as well as 6, 12, and 24 months after transplantation and identified two groups of patients. Cluster A included patients with good-to-optimal psychosocial profiles both before and after transplantation. Cluster B accounted for 41% of the sample and included patients with higher rates of psychological distress prior to surgery. Mental health continued to decline for this group following surgery. These results were evident across transplant type and were not related to patients' age or sex. These findings

suggest that, whereas the majority of transplant patients have optimal pre-and post-transplant psychosocial functioning, a significant minority deteriorate after transplantation.

Of particular concern is evidence suggesting that, for some patients, these rates of psychological distress and sleep disturbance appear to remain high for months or even years following surgery. At three months post-transplant, 53% of heart transplant recipients reported being bothered by symptoms of insomnia, 52% reported anxiety, and 39% reported depression (Jalowiez et al., 1997). A longitudinal study examining prevalence rates for major diagnostic categories in heart transplant patients for the first year following transplantation found that major depression was the most prevalent disorder with a one-year rate of 17% (Dew et al., 2001). Furthermore, nearly 40% of heart recipients met criteria for depression or anxiety at some point during the first three years following surgery.

Psychological distress can have deleterious consequences on the health and well-being of transplant patients. For example, one study found that anxiety and depression were correlated with poorer health status and interpersonal relationships in post-transplanted kidney patients (Noohi et al., 2007). Anxiety was also significantly associated with greater sleep disturbance. Post-transplant anxiety has been shown to negatively impact the long-term mental health of liver, kidney, and heart transplant patients and to lead to impaired social, emotional, and financial functioning (Pérez-San Gregorio, Martin-Rodriguez, Diaz-Dominguez, & Pérez-Bernal, 2006). More troubling is the association between distress and medication compliance, which in transplant recipients is necessary to prevent rejection of the transplanted organ and possible death.

In one study, higher levels of depression were positively correlated with nonadherence to medication regimens in kidney transplant patients (Cukor, Newville, & Jindal, 2008). Furthermore, in kidney recipients, depression was associated with a greater risk of graft failure, return to dialysis therapy, and death with a functioning graft (Dobbels et al., 2008).

Complementary and Alternative Medicine (CAM) as a Viable Adjunctive Treatment

Complementary and alternative medicine (CAM) may provide solid organ transplant patients with effective adjunctive therapies to their allopathic treatment, and can decrease psychological distress and improve sleep functioning without interfering with required immunosuppressant medication. CAM is defined as "a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine" as they have not yet demonstrated safety and efficacy (National Center for Complementary and Alternative Medicine, 2010, p. 1). Complementary therapies are those that are done in conjunction with conventional treatments whereas alternative interventions are used instead of conventional treatments. Some of the therapies that fall under the CAM umbrella include acupuncture, biofeedback, deep breathing exercises, Tai chi, hypnosis, yoga, and meditation.

CAM appears to be growing in use among the general population of the United States as well as among those with chronic illness. A national survey conducted on trends in complementary and alternative medicine use found that, in 2002, 36% of Americans adults had used at least one form of CAM (Barnes & Bloom, 2008). This figure increased to 38.3% of American adults by 2007. At both time points, CAM was

used most frequently by those with chronic conditions, including chronic pain, anxiety, depression and insomnia. Another national survey of CAM use found that mind-body therapies such as meditation, imagery, and yoga were the most commonly used therapies and were often used to treat medical conditions (Wolsko, Eisenberg, Davis, & Phillips, 2004). Those utilizing CAM appear to be doing so in conjunction with conventional medical care. For example, 90% of those using a mind-body treatment had seen their physician and use of mind-body therapies was discussed with physicians 80% of the time (Wolsko et al., 2004). A review of CAM usage among lung transplant patients found that 88% of patients had used at least one type of complementary therapy and 70% had used more than one modality (Matthees et al., 2001). Patients using mind-body therapies were seeking relief from anxiety, stress, depression, and/or fatigue, and were doing so in conjunction with their prescribed medications.

Transplant patients need safe and effective methods to manage sleep dysfunction and psychological distress that are unlikely to interfere with a demanding drug regimen. Mindfulness-Based Stress Reduction (MBSR) is one CAM modality that has the potential to be an effective adjunctive treatment for transplant patients. The MBSR program was originally designed for, and has demonstrated efficacy in, those managing chronic illness (Kabat-Zinn, 1990). In its standardized form, MBSR is an 8-week group intervention that consists of relaxation, formal and informal meditation, and body awareness in conjunction with daily individual mindfulness practice. Being mindful is defined as moment-to-moment awareness (Brown & Ryan, 2003). Practitioners of MBSR learn to engage in the present moment rather than be consumed by habitual patterns of anxiety, rumination, or depressive thinking. A number of outcome studies of

MBSR have shown promising results in a variety of clinical and community samples (Baer, 2003; Bishop, 2002) among individuals with a variety of problems, including chronic pain (Kabat-Zinn, 1985), anxiety and panic disorder (Kabat-Zinn et al., 1992; Miller, Fletcher, & Kabat-Zinn, 1995; Surawy, Roberts & Silver, 2005), depression (Teasdale et al., 2000), sleep disturbance (Carlson et al., 2004, 2005; Kreitzer et al., 2005) and eating disorders (Kristeller & Hallett, 1999).

Although there is promising evidence from outcome studies, qualitative reviews of the efficacy of MBSR for reducing stress and psychological symptoms are mixed. Although several reviews of both controlled and uncontrolled studies have found that MBSR was effective for decreasing psychological distress (Ott et al., 2006, Praissman, 2008, Smith et al., 2005, Teixeira, 2008), a review of 15 controlled studies found no reliable effects of MBSR on depression and anxiety in participants with mood disorders or medical conditions, or in non-clinical community and undergraduate samples (Toneatto & Nguyen, 2007). The authors noted that few studies included an active control group and, in those that did, no evidence was found for the efficacy of MBSR. Additionally, a recent state of the research review of meditation practices for health concluded that the therapeutic effects of meditation practices cannot be established based on the current literature (Ospina et al., 2008). The authors concluded that it is imperative that future studies be rigorous in design, execution, analysis, and reporting of the results.

Several meta-analyses have offered more promising results. The results of five meta-analyses show that MBSR has a small to medium effect in improving depression and anxiety in a variety of clinical, medical, and community samples, and these effect

sizes were consistent whether the analyses were pre- to post intervention (Hoffmann et al., 2010), MBSR compared to controls (Bohlmeijer et al., 2010, Ledesma & Kumano, 2008) or a combination of the two (Baer, 2003; Grossman et al., 2004).

Despite these promising results, a significant problem in MBSR research is that the proliferation of outcome studies has occurred without concurrent evaluation of why MBSR is effective and what components of the intervention most contribute to its effectiveness. Although treatment outcome studies are important in their own right, there is a significant gap in our knowledge about how MBSR works, and for whom it is most effective.

Another troubling problem in MBSR research is that there is a lack of methodological rigor. As Bishop (2002) noted, there is a lack of controlled studies of MBSR. This is particularly the case in studies investigating MBSR in samples of individuals with chronic illness as the majority of these studies are uncontrolled. Other methodological problems include inappropriate use of statistics, small sample sizes, and failure to control for concurrent treatment, instructor attention, and group support, all of which may affect outcome. Although preliminary findings are encouraging, for MBSR to be deemed an effective and efficacious intervention, stronger study designs and analyses are required.

One way to advance understanding in this field and introduce more methodologically rigorous research design is to move beyond the simple question of "does this intervention work?" to analyze moderators that explain *for whom* an intervention may be effective (Frazier, Barron, & Tix, 2004). A moderator is defined as a qualitative or quantitative variable that affects the direction and/or strength of the

relation between an independent and a dependent variable (Baron & Kenny, 1986). Moderators can be helpful in determining which intervention may be most effective for which patient.

Only one article was located that investigated moderators of an MBSR intervention. Cordon, Brown and Gibson (2009) conducted an uncontrolled study of 185 participants enrolled in MBSR programs in 14 U.S. states to determine if attachment style moderated the relationship between the intervention and perceived stress. The authors hypothesized that insecurely attached adults may benefit more from an MBSR program than those with a secure attachment style because they may have more initial stress and therefore more room for improvement. They noted that the inverse may also be true such that insecurely attached participants may benefit less than securely attached adults given the social nature of the intervention. Participants were given the Experiences in Close Relationships-Revised Questionnaire to assess whether their pre-intervention adult attachment style was secure (n = 85) or insecure (n = 98). Perceived stress was measured with the Perception of Stress Scale.

Results indicated that there was a main effect of attachment style on stress such that those in the secure group reported significantly less stress than the insecure group at both pre- and post-intervention assessments. Those in the insecure group experienced a larger reduction in perceived stress over time compared to the secure group, although the interaction was only marginally significant (p = .06). Limitations of this study include the lack of a control group, a demographically homogeneous sample, and no follow-up on the durability of the intervention on perceived stress. No study was located

that empirically investigated moderators of a mindfulness intervention in a sample of individuals with chronic illness.

The Present Study

The purpose of the present study was to assess potential moderators of the effectiveness of an MBSR intervention for reducing depression, anxiety, and sleep dysfunction in comparison to an active control group in a sample of solid organ transplant patients. In other words, this study assessed whether there are individuals who respond better to MBSR or to the active control intervention. The six moderators that were tested include baseline levels of depression, anxiety, sleep quality, mindfulness, self-efficacy, and transplant-related stress. The rationale for assessing these moderators will be presented after a description of the primary study outcomes and a review of treatment outcome studies that assess moderators of treatment effectiveness among individuals with chronic illnesses. See Appendix A for a comprehensive review of research on the effectiveness of MBSR on the proposed outcome variables of interest (depression, anxiety, and sleep quality).

Wellness Intervention after Transplant Study

This thesis is based on an existing data set from the 5-year, NIH funded Wellness Intervention After Transplant study (WIAT study; National Institute of Nursing Research grant no. R01 NR008585 ClinicalTrials.gov, NCT00367809) conducted through the University of Minnesota's College of Pharmacy, Departments of Nursing and Psychology, and the Center for Spirituality and Healing. The objective of the main outcomes study (Gross, Kreitzer, Thomas, Reilly-Spong, Cramer-Bornemann, Nyman, Frazier, & Ibrahim, in press) was to determine if MBSR was more effective

than both wait-list and active control groups in reducing psychological and sleep symptoms and improving quality of life in a sample of solid organ transplant patients.

Participants were initially stratified by type of transplant, type 1 diabetes, and whether they had taken medication in the past year for depression, anxiety, or sleep disturbances. They were then randomized equally within strata to the MBSR group; an active control, referred to as Health Education (HE); or a passive control delayed–intervention group (DI). The DI waitlist group was then re-randomized to either the MBSR or HE group after 26 weeks (for more detail about the study design and use of a recycled waitlist, please refer to Gross, Kreitzer, Reilly-Spong, Winbush, Schomaker & Thomas, 2009). The demographic characteristics of the sample will be fully described in the Results section.

Main outcomes included depression, anxiety, and sleep quality. Depression was measured using the Center for Epidemiological Studies – Depression Scale (CES-D); anxiety was measured using the State Trait Anxiety Inventory (STAI) – State Version; and sleep quality was measured with the Pittsburgh Sleep Quality Index (PSQI). Secondary outcomes measured quality of life and perceived health and consisted of the SF-12 (mental and physical health summary subscales), the SF-36 (bodily pain and vitality subscales) and visual analogue scales (VAS) for health and quality of life. Measurements were taken at baseline, post-intervention (8 weeks), 26 weeks, and 52 weeks post-baseline. Assessments consisted of self-report surveys that were mailed to participants at all time points.

The MBSR group was based on the standardized intervention (Kabat-Zinn, 1990) and consisted of eight weekly 2-½ hour classes with instruction in three forms of

meditation (sitting, standing, and supine) as well as Hatha yoga. Participants were provided with a series of audio practice tapes and encouraged to cultivate their own home practice during the 8-week course of at least one form of meditation for 45 minutes per day 6 days a week. A one-day retreat was held between weeks 6 and 7, and a meditation "booster" class was held in month 4. After the 8-week intervention, phone contact was made in a tapering fashion with all participants to promote their continued practice of mindfulness and to assist in identifying obstacles to regular practice. Calls were made weekly during month 3, twice in month 4, and once in months 5 and 6.

The active control group, referred to as the Health Education (HE) group, was based on Stanford University's Chronic Disease Self-Management Program and consisted of an 8-week, manualized, peer-led workshop that focused on action planning and covered areas such as appropriate exercise, medication management, communication with friends and family, nutrition, and cognitive techniques to deal with frustration, fatigue, and pain. The group uses the book *Living a Healthy Life with Chronic Conditions* (Lorig et al., 2000). In the WIAT study, the standardized program was expanded by two weeks to include two additional classes that focused on transplant issues and to match the length of time of the MBSR intervention. Research findings in both randomized and quasi-experimental trials suggest that the self-management program improves health behaviors, increases self-efficacy for disease management, and decreases health care costs (Lorig et al., 1999, 2000, 2001). For example, a community-based, randomized controlled study compared the chronic disease self-management program with wait-list controls in 952 patients with a variety of diagnoses (including heart disease, lung disease, stroke or arthritis). Compared to controls, those

in the self-management group significantly increased healthy behaviors (e.g., exercise time, cognitive symptom management, and communication with physicians); maintained or improved health status; decreased health distress, fatigue, and social/role limitations; and had decreased rates of hospitalization (Lorig et al., 1999). There is also some evidence to suggest that many of these benefits remained long after the intervention was completed. A study comparing participants to their baseline measurements found that hospital visits and health distress were significantly reduced and self-efficacy increased two years post-intervention (Lorig, 2001). In the WIAT study, participants who completed the HE intervention were called on a tapering schedule similar to those in the MBSR group to control for time and attention of the research staff.

Results of the WIAT study indicated that, at baseline, 38% of the sample had clinically meaningful depression symptoms, 39% met the cutoff for significant anxiety symptoms, and 42% had poor quality sleep. After the intervention, the MBSR group experienced significantly decreased depressive symptoms and sleep disturbance, and increased mental health and vitality compared to the wait-list control group. Effect sizes ranged from Cohen's $d = 0.49$ to 0.65 indicating medium effects for the differences between the MBSR and wait-list control groups. (Appendix C describes the results of analyses examining potential mediators through which the MBSR intervention was more effective than the control group). The HE group reported significantly greater levels of vitality, health, and quality of life compared to the wait list controls. There were no differences between the HE group and wait list control group on depression, anxiety, or sleep quality. Within the MBSR group, there were significant improvements

from pre- to post-intervention in depression, anxiety, and sleep quality; whereas within the HE group, there were significant improvements in depression and sleep quality. On secondary measures, the MBSR group experienced significant improvements in mental health, vitality, and quality of life VAS and in the HE group, significant improvements occurred for mental health, vitality, health VAS, and quality of life VAS. There were no significant between group differences at the 8-week assessment (post-intervention) on any of the primary outcome measures. However, at the one-year follow up, the MBSR group reported significantly less anxiety and improved sleep quality than the HE group, with effect sizes ranging from .56 to .51, respectively.

Proposed Moderation Analyses

Because there were no significant differences between the MBSR and HE groups at 8 weeks, a study of moderators of treatment effectiveness can augment the WIAT study by exploring reasons for these unexpected results and may help to identify for whom each intervention may be more effective.

Ideally, hypotheses about moderators should be drawn from prior research, theory, or both; however, no studies were located that investigated moderators of the effectiveness of the MBSR program in patients with chronic illness. Results from treatment studies in related areas can inform hypotheses made in the current study. Thus, a literature search was performed to locate moderators of psychosocial interventions for adult patients with chronic illness.

A total of nine studies were located that fit the search criteria. Two studies investigated moderators of the effectiveness of the HE program for patients with a variety of chronic illnesses and comorbid depressive symptoms (Jerant, Kravitz, Moore-

Hill, & Franks, 2008; Jerant, Moore, Lorig, & Franks, 2008). Other samples examined other interventions in patients with breast cancer (Antoni, Lehman, Kilbourn, Boyers, Culver, Alferi, Yount, McGregor, Arena, Harris, Price, & Carver, 2001; Goodwin, Leszcz, Ennis, Koopmans, Vincent, Guther, Drysdale, Hundleby, Chochinov, Navarro, Speca, & Hunter, 2001; Helgeson, Cohen, Schulz, Yasko, 2000; Scheier, Helgeson, Schulz, Colvin, Berga, Knapp, & Gerszten, 2007), prostate cancer (Helgeson, Lepore, & Eton, 2006), chronic obstructive pulmonary disease (Nguyen & Carrieri-Kohlman, 2005), and temporomandibular disorder (Turner, Holtzman, & Mancl, 2007). In each of these studies a similar pattern emerged such that those patients with poorer psychosocial resources pre-intervention appeared to benefit more from various interventions than those patients with greater psychosocial resources. The results of these 9 studies are briefly reviewed below. The majority of these studies examined moderators within interventions from pre- to post-assessment (i.e., whether some individuals benefited more from an intervention than did others). One study compared moderators between an intervention and a control group, and two studies compared moderators of treatment effectiveness between two treatments (i.e., whether some individuals responded better to one treatment than to another). Because the main research question in the present study involves treatment matching (i.e., is one intervention more effective for some people than another intervention?), these latter moderator studies will be described first.

Helgeson et al. (2006) investigated whether psychosocial variables moderated the effects of an eight week information-based educational group or an emotion-focused peer discussion in a sample of 230 women with stage I or II breast cancer. Outcomes included quality of life, and mental and physical health. Moderators included a measure

of perceived emotional support from partners, negative interactions with partners, an index of personal resources (which consisted of self esteem, body image, personal control, and uncertainty about illness), and oncologist informational support. Results indicated that partner emotional support was a moderator of the effectiveness of group on physical functioning such that women lacking emotional support were buffered by both interventions from the deterioration seen in physical functioning in the control group. Women with high emotional support were unaffected with regard to physical functioning by the educational group and adversely affected by the emotion-focused group. Negative interactions with partner and oncologist informational support were also moderators of the effect of group on physical functioning and followed a similar pattern as above. Women reporting more negative interactions and less informational support by physicians were buffered by either group whereas women with less negative interactions and more informational support were unaffected in the educational group and negatively affected in the emotion-focused group. Finally, personal resources moderated the effects of the education group on physical functioning in that women who lacked personal resources were buffered by the education interventions from deterioration seen in the control group.

Nguyen et al. (2005) performed a secondary analysis of a randomized controlled trial of 100 patients with chronic obstructive pulmonary disease (COPD) assigned to one of three versions of a dyspnea (shortness of breath) self-management program. The interventions consisted of individual education and strategies for managing dyspnea, along with exercise suggestions and self-monitoring. The three groups varied in number of sessions of supervised exercise including none, four, and 24 sessions. Those

individuals at high risk for developing depression at baseline had greater reductions in dyspnea when they were assigned to the condition with the greatest amount of supervised exercise compared to those assigned to the other two conditions.

Turner et al. (2007) compared moderators of treatment effectiveness between an intervention group and control group. One hundred and fifteen dental patients with temporomandibular disorder and facial pain were randomized into individual cognitive-behavioral sessions biweekly for eight weeks or an attentional control. For those patients with high baseline masticatory disability, those in the CBT group had significantly lower masticatory disability at one year compared to controls. Patients with low baseline masticatory disability in the CBT group did not differ from controls at one year follow up.

The remaining studies explored moderators of treatment effectiveness within interventions. Jerant et al. (2008) randomized 415 patients with a variety of chronic illnesses and depressive symptoms to one of three conditions: six weekly sessions of the Stanford Chronic Disease Self-Management Program (CSDMP) delivered via home visits or telephone calls, or a usual care control group. The aim of the study was to examine the moderating effect of depression on self-efficacy for managing chronic illness. Results suggested that the intervention was more effective in increasing self efficacy for patients with higher baseline levels of depressive symptoms than for those with less depressive symptoms.

Using the same sample as above, Jerant et al. (2008) investigated whether perceived control over self management had a moderating effect on enhancing self-efficacy of chronic-disease management. Only the home-based intervention was

effective at increasing self-efficacy and, within this group, individuals with lower levels of perceived control at baseline were more likely to have increased self-efficacy after the CSDMP intervention than those with higher baseline levels of perceived control.

Schier et al. (2007) investigated moderators of treatment effectiveness of a larger randomized controlled study with 252 women with early stage breast cancer (Scheier et al., 2005). Participants in the main study were assigned to either a control arm or one of two brief psychosocial conditions consisting of either nutritional or educational information for cancer patients. The psychosocial interventions met for two hours once a month for four consecutive months. There were four significant moderators of the effectiveness of the nutritional intervention. Individuals in the nutrition intervention with higher levels of negative social interaction, fewer interpersonal resources, and a more pessimistic outlook at baseline experienced the greatest reductions in depressive symptoms post-intervention. Additionally, those individuals with a higher number of comorbid conditions improved more in physical functioning in the nutritional intervention. Contrary to the pattern evident in the treatment outcome research, those in the educational intervention with less comorbidity improved more in physical functioning.

Helgeson et al. (2006) conducted a moderator analysis based on a previously published study of 250 men with prostate cancer (Lepore, Helgeson, Eton, & Schulz, 2003). In the main outcomes study, participants were randomized into an education intervention, an education plus group discussion intervention, or usual care. Findings indicated that participants in both interventions experienced significant and positive effects on prostate cancer knowledge, health behaviors, and physical functioning. The

aim of the moderator study was to determine if self-esteem, self-efficacy, and depressive symptoms moderated the effects of treatment on general and prostate specific quality of life in the two intervention groups. Men with higher depressive symptoms, lower self-esteem, and lower prostate self-efficacy benefited more from both interventions from pre- to post-intervention than those with lower depression, higher self-esteem, and higher self-efficacy in either intervention pre- to post-intervention.

Antoni et al. (2001) randomized 100 women with stage I or II breast cancer into a 10-week group cognitive-behavioral stress management intervention or control group. Those in the intervention improved in optimism and had increased reports that cancer had made a positive contribution to their lives; however, these findings were most strongly observed in those women who had low levels of optimism about their futures at baseline.

Finally, Goodwin et al., (2001) investigated women with metastatic breast cancer with a $\geq$ three month survival rate. Participants were randomized to either a weekly supportive-expressive therapy (n = 158) or usual care control (n = 77) group. Women in the treatment group who were initially more distressed experienced significantly greater improvements in psychological symptoms and reported less pain compared to those in the treatment group who were initially less distressed.

Based on these findings from the treatment outcome literature, I hypothesized that a similar pattern would emerge in this sample such that those individuals with greater levels of distress and fewer psychosocial resources would benefit from either intervention more than individuals with less distress and more psychosocial resources. Specifically, I hypothesized that subjects with more baseline depression, anxiety, and

sleep dysfunction, and less mindfulness, less self efficacy, and more stress would derive greater benefit from both interventions. Moreover, I hypothesized that individuals would do better in the intervention that targeted the domain in which they were more lacking (e.g., those with lower baseline levels of mindfulness would do better in MBSR than in HE).

More specifically, in keeping with findings from treatment outcome studies, I hypothesized that more highly distressed individuals and those with poorer sleep quality would derive greater benefit from either intervention compared to less distressed individuals. Therefore, I did not expect a significant interaction effect between group (MBSR vs. HE) and baseline distress and sleep quality.

In accordance with the treatment outcome research, I hypothesized that there would be a main effect for stress such that individuals with higher rates of baseline stress would derive a greater benefit from both treatment programs than those with lower rates of stress. Furthermore, although both MBSR and HE target relaxation and stress reduction, it is a primary focus in MBSR. Therefore, I hypothesized that those with higher amounts of baseline stress would benefit significantly more in the MBSR than in the HE group.

Also in accordance with the treatment outcome research, I hypothesized that the MBSR intervention would be more effective than HE for those with lower baseline levels of mindfulness as the focus of MBSR is to increase mindfulness and this is not one of the targeted skills in HE. Higher levels of mindfulness are related to less psychological distress (Brown & Ryan, 2003) and those with low baseline levels of

mindfulness may have much more to gain from the intervention than those with initially higher levels of mindfulness.

Although there is evidence to suggest that the HE intervention increases chronic illness self-efficacy, it is likely that the MBSR intervention also affects self-efficacy by increasing perceived control among participants (Astin et al., 1997). Thus, I hypothesized that individuals with lower baseline levels of self-efficacy would derive greater benefit from both programs than those with higher baseline levels of self-efficacy. Additionally, as increasing self-efficacy for chronic disease management is an explicit target of HE, I hypothesized that those with lower amounts of baseline self-efficacy would benefit more in the HE group than in MBSR group.

Method

Participants

The sample consisted of 127 solid organ transplant recipients living in the community who were at least six months post-surgery. Fifty-one percent were male; 94% identified as European-American, 3% as American Indian/Alaskan Native, 2% as Asian American, and 1% as African American. The mean age was 53 with the range between 21-75 years old. Transplanted organs included kidney (57%), liver (17%), heart (8%), kidney/pancreas (9%), and lung (6%). Inclusion criteria were having a functioning graft, at least 18 years old, English-speaking, literate, mentally intact, reachable by telephone, on immune suppressant medication, receiving regular medical follow-up care, interested in health promotion and mind-body interventions, and able to attend weekly classes. Patients were excluded if they had serious pre-existing mental health issues (e.g., suicidality or psychosis), were medically unstable, on dialysis, or

regularly practicing mindfulness meditation. The sample used in the current analyses is a subset from the larger WIAT study. It consisted of a per protocol sample (defined as participants having attended at least one class) after the second randomization, contained 67 participants in the MBSR group and 60 in the HE group, and included baseline and post-intervention (8-week) assessments.

Measures

Depression. Center for Epidemiological Studies – Depression Scale *(*CES-D; Radloff, 1977) is a 20-item scale assessing depressive symptoms that demonstrates substantial construct validity, internal consistency (coefficient alpha ranging from .85 to .90) and test-retest reliability ($r > .50$) in community samples (Radloff, 1977). In the current study, Cronbach's alphas for baseline and time 2 data were .91 and .87, respectively. Questions pertain to cognitive, behavioral and interpersonal aspects of depression that occurred during the past week. Items are rated on a 4-point Likert-type scale with responses ranging from 1 = Rarely or None of the Time (Less than one day) to 4 = Most or All of the Time (5-7 days). Sample items included "I felt depressed." Scores range from 0 – 60 with higher scores indicated more severe depressive symptoms. The developers of the scale set a cutoff score of 16 to distinguish between depressed and non-depressed individuals.

Anxiety. The State Trait Anxiety Inventory (STAI; Spielberger, 1968, 1977) is a widely used measure of anxiety symptoms and demonstrates strong validity and reliability. In the current study, baseline $\alpha = .95$ and time 2 $\alpha = .91$. The state version of the STAI measures anxiety symptoms at the present time and consists of 20 items that are rated on a four-point scale ranging from "not at all" to "very much so." Sample

items included “I am tense.” Scores range from 20-80 with proposed categories for mild (20-39), moderate (40-59) and severe (60-80) anxiety symptoms. Patients with scores $\geq$ 40 are classified as having clinically-significant anxiety.

Sleep quality. The Pittsburgh Sleep Quality Index (PSQI; Buysse et al.,1989) is a widely used 18-item measure of sleep quality and disturbance assessed for the past month. The scale has good internal consistency (α = .83). For the current study, baseline Cronbach’s alpha was .77 at baseline and .78 at time 2. The measure comprises 7 different domains of sleep including: sleep quality, latency, duration, efficiency, disturbances, use of medications, and daytime dysfunction. Participants were asked to rate responses on a 4-point scale ranging from 1 (not during the past month) to 4 (three or more times a week). Items included: “During the past 4 weeks, how often have you had trouble sleeping because you wake up in the middle of the night or early morning?” Total scores range from 0 to 21 with scores greater than or equal to 8 indicating poor sleepers among patients with chronic illness.

Mindfulness. Mindfulness was assessed using the Mindful Attention and Awareness Scale (MAAS; Brown & Ryan, 2003). This instrument consists of 15 items (e.g., “I find it difficult to stay focused on what’s happening in the present”- reverse scored). Participants rated their responses on a 6-point Likert-type scale ranging from “almost always” to “almost never” with higher scores indicating more mindfulness. The scale has demonstrated convergent and discriminant validity as well as good internal consistency with Cronbach’s alphas ranging from .80 to .87 (Brown & Ryan, 2003). In the current study, baseline Cronbach’s alpha was .90 and time 2 alpha was .91.

Self-Efficacy. The Self-Efficacy for Managing Chronic Illness (SE-CI) scale is a 10-item instrument that measures level of confidence in one's ability to manage disease and communicate with health professionals (Lorig et al., 1996) and has demonstrated good internal consistency with alphas ranging from .87 to .91. In the current study, baseline Cronbach's alpha was .89 and time 2 alpha was .90. The scale was modified for living with an organ transplant. Participants were asked to rate how confident they were at performing tasks at the present time including "Do all of the things necessary to manage your transplant on a regular basis?" The scale ranges from 1 (not at all confident) to 10 (totally confident).

Stress. The Transplant Related Stressors (TRS) Scale is a 10-item scale modified from a scale developed by Frazier et al. (1994). Participants noted how much stress each item caused them in the past 4 weeks. Sample items include: "uncertainty about your health" and "medication side effects." Items are scored on a 5-point Likert-type scale ranging from "not at all stressful" to "extremely stressful." The alpha coefficient reported by the developers of the measure was .89. For the baseline data of the current study $\alpha = .88$ and time 2 $\alpha = .86$.

Procedure

Patients were recruited primarily via direct mail and transplant clinics as well as through newspaper ads and brochures placed at pharmacies. Participants were stratified by transplant type (kidney or kidney-pancreas; liver; and heart or lung), type I diabetes, and use of depression, anxiety, or sleep medication within the past year. A two-stage randomized design was used in this study. Participants were randomized equally within strata to the MBSR group; an active control, referred to as Health Education (HE); or a

passive control delayed–intervention group (DI). The DI waitlist group was then re-randomized to either the MBSR or HE group after 26 weeks. Measurements were taken at baseline, post-intervention (8 weeks), and 26 weeks and 52 weeks post-baseline. Assessments consisted of self-report surveys that were mailed to participants at all time points.

Results

Descriptive Information

Table 1 provides demographic information about the sample as well as tests of differences between groups on baseline assessments. There were no significant differences between the MBSR and HE groups on any of these variables. Participants were primarily European American, in their early 50s, married, and fairly well educated.

Baseline (Time 1) means, standard deviations, t-tests, p-values and between-group effect sizes for the moderators are presented in Table 2. There were no significant differences between the MBSR and HE groups on any of these measures. Based on cutoffs for the outcome measures, 66% of the sample at baseline were considered “poor sleepers,” over 35% had clinically significant depressive symptoms, and 31% had clinically significant anxiety symptoms.

Post-intervention means, standard deviations, t-tests, and effect sizes for the two groups post-intervention are shown in Table 3. No significant differences were found between the groups post-intervention on any of the moderators or outcome variables. The lack of significant differences between the two groups provides the justification for performing moderation analyses to determine whether these nonsignificant differences

mask important information regarding for whom each intervention may be most effective.

Within group differences from Time 1 to Time 2 for the MBSR and HE groups are presented in Tables 4 and 5, respectively. Within the MBSR group, all measures significantly improved from pre- to post-intervention, whereas only depression and mindfulness significantly improved in the HE group. The largest effects in the MBSR group were improvements in sleep quality (Cohen's d = .50), decreases in anxiety (Cohen's d = .45), and decreases in stress (Cohen's d = .40) indicating medium effect sizes. According to Cohen (1992), an effect size of .20 is considered small, .50 is a medium effect, and .80 is a large effect size. The largest effect sizes within the HE group were decreases in depression (Cohen's d = .33) and improvements in mindfulness (Cohen's d = -.11), both indicating small effect sizes.

Reliable change calculations for the three main outcome variables are presented in Table 6. Reliable change is defined as change that is not attributable to measurement error. The criterion for reliable change is calculated using the following formula: 1.96*SD1*sqrt (2)*sqrt (1-rel) where SD1 is the sd of the variable at Time 1 and "rel" is the reliability of the measure of that variable (Evans et al, 1998). For the three outcome variables in both groups, the majority of participants reported no reliable change over time. Those who did report reliable change in symptoms were more likely to report decreases in symptoms than increases in both groups. Nearly a quarter of the MBSR group decreased in depressive symptoms and nearly a third in anxiety symptoms. In the HE group, a quarter reported reliable reductions in depression and anxiety.

Correlations between outcome variables and moderators for the MBSR and HE groups are shown in Tables 7 and 8, respectively. The MBSR group demonstrated significant positive correlations between changes in depression and changes in anxiety ($r = .54$; $p < .01$), changes in depression and changes in sleep quality ($r = .58$; $p < .01$), and changes in anxiety and changes in sleep quality ($r = .44$; $p < .01$). Within the HE group, the only significant correlation between outcome variables was changes in depression and changes in anxiety ($r = .67$; $p < .01$).

Means, standard deviations, t-scores, p values, and effect sizes for unstandardized residuals of each of the three primary outcome measures for the MBSR and HE groups are shown in Table 10. As per MacKinnon's (2008) recommendation, unstandardized residuals were used as a measure of change because they control for any differences between individuals in baseline values and minimize error associated with simple difference scores. They were calculated by regressing post-intervention outcome variables on baseline variables and selecting residuals to be displayed in the output. Greater improvement in these symptoms is indicated by negative residual score. Inspection of mean residual scores suggested that the MBSR group experienced significantly more change than the HE group on sleep quality ($t = -1.99$; $p < .05$; $d = -.37$). The MBSR group also improved more than the HE group on anxiety (Cohen's $d = -.28$*);* however, this between-group difference did not reach statistical significance. There were no significant differences between the groups on changes in depression.

Table 1. Demographics

	MBSR	HE	Chi-square*
Sex			
Men	34	31	p = .92
Women	33	29	
Ethnicity			
European American	63	56	p = .71
African American	1	0	
American Indian/ Alaskan Native	2	2	
Asian American	1	2	
Education			
Partial High School	0	1	p = .21
High School Graduate	3	9	
Some College	23	19	
College Graduate	26	22	
Post Graduate	15	9	
Marital Status			
Never	7	5	p = .48
Married	44	34	
Widowed	2	3	
Separated	0	2	
Divorced	11	10	
Others	3	6	
Type of Transplant			
Lung	3	4	p = .63
Liver	10	11	
Kidney	36	36	
Heart	7	3	
Double Lung	2	1	
Pancreas	1	2	
Kidney Pancreas	8	3	

	M (SD)	M (SD)	t	df	p
Age	54.39 (10.37)	51.32 (10.23)	1.67	125	.10

	Age by Decade	N	%
MBSR	20	1	1.5
	30	3	4.5
	40	17	25.5
	50	25	37.5
	60	16	24
	70	5	7.5
HE	20	1	1.7
	30	7	11.8
	40	17	28.4
	50	24	39.9
	60	8	13.4
	70	3	5.1

*Pearson’s chi-square significance level

Table 2. Baseline (Time 1) Measures

	MBSR M (SD)	HE M (SD)	t	df	p	Cohen's *d*
Depression	14.51 (10.08)	13.47 (11.32)	.55	125	.58	.10
Anxiety	37.30 (12.74)	35.19 (13.29)	.91	125	.36	.16
Sleep Quality	8.72 (4.83)	7.35 (3.89)	1.73	124	.09	.31
Mindfulness	4.21 (.75)	4.41 (.95)	-1.34	124	.18	-.23
Self-Efficacy	7.95 (1.58)	8.25 (1.19)	-1.18	125	.24	-.21
Stress	2.31 (.78)	2.26 (.83)	.34	125	.73	.06

Table 3. Post-Intervention (Time 2) Measures

	MBSR M (SD)	HE M (SD)	t	df	p	Cohen's *d*
Depression	10.44 (10.12)	10.19 (7.48)	.15	112	.22	.03
Anxiety	31.55 (9.34)	32.98 (9.53)	-.81	112	.42	-.15
Sleep Quality	6.17 (3.83)	6.72 (3.77)	-.77	112	.44	-.14
Mindfulness	4.46 (.67)	4.57 (.80)	-.81	109	.42	-.15
Self-Efficacy	8.59 (1.24)	8.50 (1.03)	.42	108	.67	.08
Stress	1.90 (.72)	2.08 (.67)	-1.31	107	.19	-.26
Classes attended	6.18 (2.05)	6.11 (2.16)	.17	125	.87	.03

Table 4. MBSR Within Groups Differences From Time 1 to Time 2

	Mean Difference (SD)	t	df	p	Cohen's *d*
Depression	-3.62 (8.33)	-3.39	60	.001	.36
Anxiety	-4.93 (10.12)	-3.81	60	.000	.45
Sleep Quality	-2.14 (3.42)	-4.89	60	.000	.50
Mindfulness	.26 (.65)	3.05	58	.003	-.36
Self Efficacy	.50 (1.12)	3.42	58	.001	-.36
Stress	-.29 (.51)	-4.34	57	.000	.40

Table 5. HE Within Groups Differences From Time 1 to Time 2

	Mean Differences (SD)	t	df	p	Cohen's *d*
Depression	-3.07 (10.48)	-2.14	52	.04	.33
Anxiety	-1.91 (10.51)	-1.32	52	.19	.17
Sleep Quality	-.74 (2.78)	-1.91	51	.06	.20
Mindfulness	.20 (.66)	2.16	50	.04	-.11
Self-Efficacy	.21 (1.06)	1.40	50	.17	-.19
Stress	-.09 (.70)	.95	50	.35	.12

Table 6. Percentage of Sample that Experienced Reliable Change from Time 1 to Time 2

MBSR	Total N	Reliable Change Criterion	Reliable Decrease N	Reliable Decrease %	Reliable Increase N	Reliable Increase %
Depression	61	8.31	14	23%	2	1.6%
Anxiety	61	7.77	19	31.1%	5	6.6%
Sleep	61	6.30	5	8.2%	0	0.0%

HE	Total N	Reliable Change Criterion	Reliable Decrease N	Reliable Decrease %	Reliable Increase N	Reliable Increase %
Depression	54	9.18	14	25.9%	4	5.6%
Anxiety	54	7.97	14	25.9%	7	11.1%
Sleep	53	5.01	3	5.7%	1	1.9%

Table 7. MBSR Correlations of Outcome Variables and Moderators (n = 67)

		1	2	3	4	5	6	7	8	9
1.	Δ Depression	--	.54**	.58**	.25*	.30*	.18	.06	-.15	.32*
2.	Δ Anxiety		--	.44**	.12	.02	.07	.04	-.17	.42**
3.	Δ Sleep Quality			--	.15	.07	-.05	-.03	-.10	.20
4.	Depression T1				--	.81**	.68**	-.62**	-.56**	.66**
5.	Anxiety T1					--	.70**	-.49**	-.54**	.62**
6.	Sleep Quality T1						--	-.48**	-.37**	.61**
7.	Mindfulness T1							--	.55**	-.49**
8.	Self Efficacy T1								--	-.67**
9.	Transplant Stress T1									--

*p < .05; **p < .01

Table 8. HE Correlations of Outcome Variables and Moderators (n = 60)

		1	2	3	4	5	6	7	8	9
1.	Δ Depression	--	.66**	.01	-.30*	-.22	-.03	-.04	.39**	-.05
2.	Δ Anxiety		--	.02	.08	.00	-.21	-.21	.10	.26
3.	Δ Sleep Quality			--	.03	-.16	.14	.13	.25	-.10
4.	Depression T1				--	.80**	.55**	-.62**	-.56**	.43**
5.	Anxiety T1					--	.48**	-.62**	-.62**	.55**
6.	Sleep Quality T1						--	-.24	-.26	.14
7.	Mindfulness T1							--	.36**	-.44**
8.	Self Efficacy T1								--	-.54**
9.	Transplant Stress T1									--

*p < .05; **p < .01

Table 9. Percentage of Patients Meeting Cutoffs for Clinically Significant Symptoms

	MBSR		HE	
	Time 1	Time 2	Time 1	Time 2
Depression	37.3%	27.9%	31.7%	20.8%
Anxiety	40.3%	18%	28.3%	22.6%
Sleep Quality	52.2%	32.8%	45.8%	39.6%

Table 10. Unstandardized Residuals

	MBSR	HE				
	M (SD)	M (SD)	t	df	p	Cohen's *d*
Depression	-.04 (7.90)	.08 (7.22)	-.08	112	.93	-.02
Anxiety	-1.03 (7.51)	1.11 (7.67)	-1.50	112	.14	-.28
Sleep Quality	-.44 (2.73)	.54 (2.53)	-1.99	111	.05	-.37

Moderator Analyses

Procedures for moderation analyses outlined by Baron and Kenny (1986) and Frazier et al. (2004) were followed, which included performing a series of linear regressions. The three outcome variables - changes in depression, anxiety, and sleep quality - were regressed on each of the potential moderators and group (MBSR vs. HE) in the first step (see Tables 11, 12, and 13). Supplemental moderation analyses on demographic and additional psychosocial variables are discussed in Appendix B. Effects coding was used for group such that codes of 1 were used for MBSR participants and codes of -1 were used for HE participants. Unstandardized residual scores were used for the outcome measures as these control for any differences between individuals in baseline depression, anxiety, and sleep disturbance. They are calculated using simple regression and represent the difference between posttest scores and predicted values using pretest scores as the predictor (Dimitrov & Rumrill, 2003). Moderators were standardized so they had a mean of 0 and a standard deviation of 1. An interaction term between each moderator and group was created and entered into the second step. One limitation of this analysis is that power to detect differences will be compromised because of the sample size. Nevertheless, these preliminary analyses can provide the first step toward determining for whom these treatments are most effective. Because of the difficulty of finding interactions in field studies, those interactions with $p < .10$ were plotted. Potential moderators that were examined included baseline values of depression, anxiety, sleep quality, mindfulness, self-efficacy, and stress.

Table 11. Moderator Analyses for Changes in Depression

Step and Variable	B	SE B	p value	95% CI	β	R^2 Δ
Depression and Changes in Depression						
Step 1						
Group	-.06	.72	.94	-1.48, 1.36	-.01	
Depression	-.001	.73	.99	-1.45, 1.44	.00	.00
Step 2						
Group x Depression	2.09	.71	.004	.69, 3.49	.27	.07
Anxiety and Changes in Depression						
Step 1						
Group	-.09	.72	.90	-1.51, 1.33	-.01	
Anxiety	.51	.72	.49	-.93, 1.94	.07	.004
Step 2						
Group x Anxiety	2.01	.70	.005	.62, 3.40	.26	.07
Sleep Quality and Changes in Depression						
Step 1						
Group	-.19	.72	.80	-1.62, 1.25	-.03	
Sleep Quality	.74	.72	.31	-.69, 2.17	.10	.01
Step 2						
Group x Sleep Quality	.77	.76	.31	-.72, 2.27	.10	.01
Mindfulness and Changes in Depression						
Step 1						
Group	-.06	.73	.94	-1.50, 1.38	-.01	
Mindfulness	-.05	.71	.94	-1.36, 1.46	.01	.00
Step 2						
Group x Mindfulness	.38	.73	.61	-1.07, 1.82	.05	.002
Self Efficacy and Changes in Depression						
Step 1						
Group	-.02	.72	.98	-1.44, 1.40	-.002	
Self Efficacy	.52	.73	.48	-.94, 1.92	.07	.004
Step 2						
Group x Self Efficacy	-2.13	.73	.004	-3.58, -.68	-.26	.07
Stress and Changes in Depression						
Step 1						
Group	-.13	.71	.86	-1.53, 1.28	-.02	
Stress	1.16	.72	.11	-.26, 2.58	.15	.02
Step 2						
Group x Stress	1.47	.71	.04	.07, 2.87	.19	.04

Table 12. Moderator Analyses for Changes in Anxiety

Step and Variable	B	SE B	p value	95% CI	β	R^2 Δ
Depression and Changes in Anxiety						
Step 1						
Group	-1.10	.71	.13	-2.51, .31	-.14	
Depression	.78	.73	.28	-.54, 2.22	.10	.01
Step 2						
Group x Depression	.16	.73	.83	-1.28, 1.60	.02	.00
Anxiety and Changes in Anxiety						
Step 1						
Group	-1.07	.72	.14	-2.49, .35	-.14	
Anxiety	.06	.72	.93	-1.37, 1.50	.01	.00
Step 2						
Group x Anxiety	.06	.73	.93	-1.38, 1.50	.01	.00
Sleep Quality and Changes in Anxiety						
Step 1						
Group	-1.00	.73	.17	-2.43, .44	-.13	
Sleep Quality	-.32	.72	.66	-1.76, 1.11	-.04	.002
Step 2						
Group x Sleep Quality	1.15	.75	.13	-.35, 2.64	.15	.02
Mindfulness and Changes in Anxiety						
Step 1						
Group	-1.13	.72	.12	-2.56, .30	-.15	
Mindfulness	-.70	.71	.33	-2.10, .70	-.09	.01
Step 2						
Group x Mindfulness	.86	.72	.24	-.57, 2.29	.11	.01
Self Efficacy and Changes in Anxiety						
Step 1						
Group	-1.10	.72	.13	-2.52, .32	-.15	
Self Efficacy	-.45	.73	.55	-1.90, 1.01	-.06	.003
Step 2						
Group x Self Efficacy	-1.04	.75	.17	-2.53, .45	-.13	.02
Stress and Changes in Anxiety						
Step 1						
Group	-1.22	.67	.07	-2.55, .11	-.16	
Stress	2.64	.68	.00	1.29, 3.98	.34	.12
Step 2						
Group x Stress	.63	.68	.35	-.71, 1.98	.08	.01

Table 13. Moderator Analyses for Changes in Sleep Quality

Step and Variable	B	SE B	p value	95% CI	β	R^2 Δ
Depression and Changes in Sleep Quality						
Step 1						
Group	-.51	.25	.05	-1.00, -.01	-.19	
Depression	.25	.25	.32	-.25, .76	.09	.01
Step 2						
Group x Depression	.17	.25	.50	-.33, .67	.06	.004
Anxiety and Changes in Sleep Quality						
Step 1						
Group	-.49	.25	.05	-.985, .01	-.18	
Anxiety	-.09	.25	.72	-.59, .41	-.03	.001
Step 2						
Group x Anxiety	.29	.25	.25	-.21, .79	.11	.01
Sleep Quality and Changes in Sleep Quality						
Step 1						
Group	-.50	.25	.05	-1.00, -.002	-.19	
Sleep Quality	.06	.25	.82	-.44, .56	.02	.00
Step 2						
Group x Sleep Quality	-.26	.26	.33	-.78, .26	-.10	.01
Mindfulness and Changes in Sleep Quality						
Step 1						
Group	-.47	.25	-.18	-.97, .03	-.18	
Mindfulness	.14	.25	.57	-.35, .64	.05	.003
Step 2						
Group x Mindfulness	-.19	.25	.45	-.69, .32	-.07	.01
Self Efficacy and Changes in Sleep Quality						
Step 1						
Group	-.49	.25	.06	-.98, .01	-.18	
Self Efficacy	.12	.26	.65	-.39, .62	.04	.002
Step 2						
Group x Self Efficacy	-.48	.26	.07	-.99, .04	-.17	.03
Stress and Changes in Sleep Quality						
Step 1						
Group	-.50	.25	.05	-.99, -.01	-.19	
Stress	.16	.25	.52	-.33, .66	.06	.004
Step 2						
Group x Stress	.41	.25	.11	-.09, .90	.15	.02

To further understand the form of the significant interactions, predicted values for the outcome variables were plotted for both the MBSR and HE groups (as per recommendations from Cohen et al., 2003, and Frazier et al., 2004). Scores at the mean and at low (-1 SD from the mean) and high (+1 SD from the mean) values of the standardized moderator variables were inputted. Predicted values for each group were obtained by multiplying the unstandardized regression coefficients by the appropriate value (e.g. -1 SD from the mean) and adding the constant. The significant interaction term indicates that the slopes of the lines differ from each other. To test whether the lines differ significantly from zero, simple slopes were tested using Interaction software (Soper, 2009). The group term was recoded using dummy coding twice to interpret the regression coefficient for each group. First, the group variable was dummy coded such that MBSR was coded 0 and HE was coded 1 and all significant interactions were entered into Interaction. The regression coefficients for the relationship between the moderators and outcome variables reflected the values for those in the MBSR group. This analysis was repeated with group dummy coded so that HE was coded 0 and MBSR was coded 1.

Moderator Findings

Of the 18 moderator analyses conducted (6 moderators X 3 outcome variables), five significant interactions were found, including four for changes in depression, one marginally significant finding for changes in sleep quality, and none for changes in anxiety. These findings will be organized by outcome variables, beginning with the four significant moderators of the effect of group on changes in depression followed by the one moderator of the effect of group on changes in sleep quality.

Changes in Depression

Baseline depression. Baseline depression was a significant moderator of the effect of group on changes in depression ($\beta = .27$; $p < .005$; r^2 change = .07). Tests of slopes showed that the relation between baseline depression and changes in depression was significant for both the MBSR group (slope = .25; $t = 2.11$; $p < .05$) and the HE group (slope = -.29; $t = -2.09$; $p < .05$). A pattern emerged suggesting that the two interventions yielded opposite results depending on level of baseline depression. Higher levels of baseline depression were related to greater improvements in depression for individuals in the HE group than for those in the MBSR group (see Table 14 and Figure 1).

Specifically, in the HE group, those with high baseline levels of depression experienced a decrease in depression with an effect size of $d = .27$. Participants in the HE group with low baseline levels of depression increased in depression with an effect size of $d = .27$. Effect sizes were calculated by taking the difference of the group means divided by the standard deviation of the two conditions. When comparing those in the HE group with initially high versus low depression on the outcome variable, there was more than half of a standard deviation difference between the two on changes in depression, indicating a medium effect.

The opposite was the case in the MBSR group. Participants in MBSR with lower levels of baseline depression experienced a greater decrease in depression type symptoms in the MBSR group with an effect size of $d = .27$ whereas those in the MBSR group with higher levels of depression increased in depressive symptoms with an effect size of $d = .26$. Further examination of the relationship between those with initially high

and low levels of depression indicates that there was more than a half of a standard deviation difference between these groups for changes in depression indicating a medium effect. Clinically, half of a standard deviation translates into a difference of more than five points on the CES-D. Given that the baseline mean for depression in the MBSR group was 14.51 (SD = 10.08) and the cutoff for significant symptoms is 16, a difference of five points on this measure has important clinical implications.

Thus, those who benefited most were patients with low baseline depression scores in the MBSR group and those with high baseline depression scores in the HE group. Those who benefited the least were patients with high levels of depression in the MBSR group and low levels of depression in the HE group. For these individuals, the respective interventions appeared to be associated with increases in depression. Baseline depression did not moderate the effect of intervention type on changes in anxiety or sleep quality.

Baseline anxiety. Baseline anxiety also was a significant moderator of the effect of group on changes in depression ($\beta = .26$; $p < .005$; r^2 change = .07). Tests of slopes showed that the relation between anxiety and changes in depression was significant for the MBSR group (slope = .30; $t = 2.53$; $p < .05$) but not for the HE group (slope = -.22; $t = -1.58$; $p > .05$; see Table 15 and Figure 2). In other words, higher levels of baseline anxiety were related to fewer improvements in depression for individuals in the MBSR group (effect size $d = .30$), whereas those with low levels of baseline anxiety experienced greater decreases in depressive symptoms (effect size $d = .31$). There was more than a half of a standard deviation between those with low and high baseline anxiety on changes in depression indicating a medium effect. Initial levels of anxiety

did not predict subsequent changes in depression for the HE group. However, the overall pattern was the same as the previous interaction such that those who benefited most were patients with low baseline anxiety scores in the MBSR group and those with high baseline anxiety scores in the HE group. Those who benefited the least were patients with high levels of baseline anxiety in the MBSR group and low levels of baseline anxiety in the HE group

Baseline Self-efficacy. Self efficacy was a significant moderator of the effect of group on changes in depression ($\beta = -.26$; $p < .005$; r^2 change = .07). Tests of slopes showed that the relation between self efficacy and changes in depression was significant for the HE group (slope = .38; $t = 2.71$; $p < .01$) but not for the MBSR group (slope = -.15; $t = -1.23$; $p > .05$; see Table 16 and Figure 3). For those in the HE group, lower levels of baseline self-efficacy were related to greater improvements in depressive symptoms whereas those with high baseline self-efficacy experienced fewer improvements in depressive symptoms. A comparison between those with initially high and low levels of self efficacy in the HE group indicate more than 4/5 of a standard deviation difference in changes in depression, indicating a large effect. Levels of baseline self efficacy did not predict changes in depression for the MBSR group.

Transplant related stress. Transplant related stress was a significant moderator of the effect of group on changes in depression ($\beta = .19$; $p < .05$; r^2 change = .04). Tests of slopes showed that the relation between transplant related stress and changes in depression was significant for the MBSR group (slope = .32; $t = 2.57$; $p < .05$) but not for the HE group (slope = -.05; $t = -.38$; $p > .05$; see Table 17 and Figure 4). Lower levels of baseline stress were related to greater improvements in depression for

individuals in the MBSR group. Participants in the MBSR group with high levels of baseline stress experienced fewer improvements in depressive symptoms compared to those with less stress. There was nearly three-quarters of standard deviation difference between those with high and low stress on changes in depression indicating a medium effect. Initial levels of stress did not predict subsequent changes in depression for the HE group.

Changes in Sleep Quality

Self Efficacy. Self efficacy was a significant moderator of the effect of group on and changes in sleep quality ($\beta = -.17$; $p < .09$; r^2 change = .03). Tests of slopes indicated that the relation between self efficacy and changes in sleep quality was significant at the $p = .09$ level for the HE group (slope = .24; $t = 1.64$; $p = .08$) but not for the MBSR group (slope = -.10; $t = -.77$; $p > .10$; see Table 18 and Figure 5). Lower levels of baseline self efficacy were related to greater improvements in sleep quality for individuals in the HE group, whereas those in the HE group with higher levels of self efficacy did not experience as much improvement in sleep quality. Comparison between those initially low and high on self efficacy indicated half a standard deviation difference on changes in sleep quality suggesting a medium effect. Self efficacy did not predict changes in sleep quality for the MBSR group.

Table 14. Simple Slopes

Outcome: Changes in Depression
Moderator: Depression Time 1

	Simple Slope	t	df	p	95% CI
MBSR	.25	2.11	111	.04	.12, 4.08
HE	-.29	-2.09	111	.04	-4.03, -.11

Table 15. Simple Slopes

Outcome: Changes in Depression
Moderator: Anxiety Time 1

	Simple Slope	t	df	p	95% CI
MBSR	.30	2.53	111	.01	.53, 4.37
HE	-.22	-1.58	111	.12	-3.57, .40

Table 16. Simple Slopes

Outcome: Changes in Depression
Moderator: Self Efficacy Time 1

	Simple Slope	t	df	p	95% CI
MBSR	-.15	-1.23	111	.22	-2.90, .68
HE	.38	2.71	111	.01	.83, 5.35

Table 17. Simple Slopes

Outcome: Changes in Depression
Moderator: Transplant Related Stress Time 1

	Simple Slope	t	df	p	95% CI
MBSR	.32	2.64	111	.01	.64, 4.51
HE	-.05	-.37	111	.71	-2.38, 1.63

Table 18. Simple Slopes

Outcome: Changes in Sleep Quality
Moderator: Self Efficacy Time 1

	Simple Slope	t	df	p	95% CI
MBSR	-.10	-.77	110	.44	-.89, .39
HE	.24	1.64	110	.09	-.14, 1.46

Figure 1. Moderating Effects of Depression on Changes in Depression

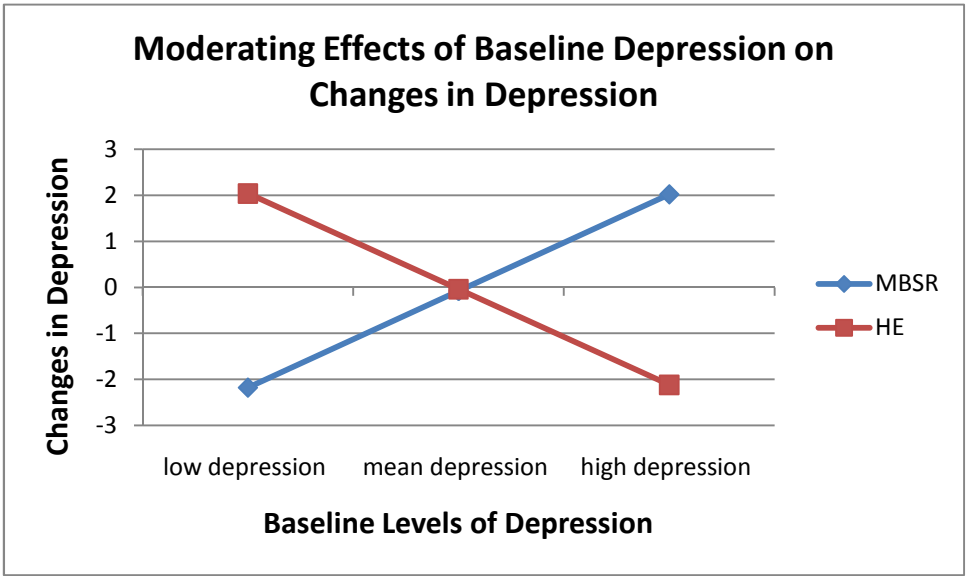


Figure 2. Moderating Effects of Anxiety on Changes in Depression

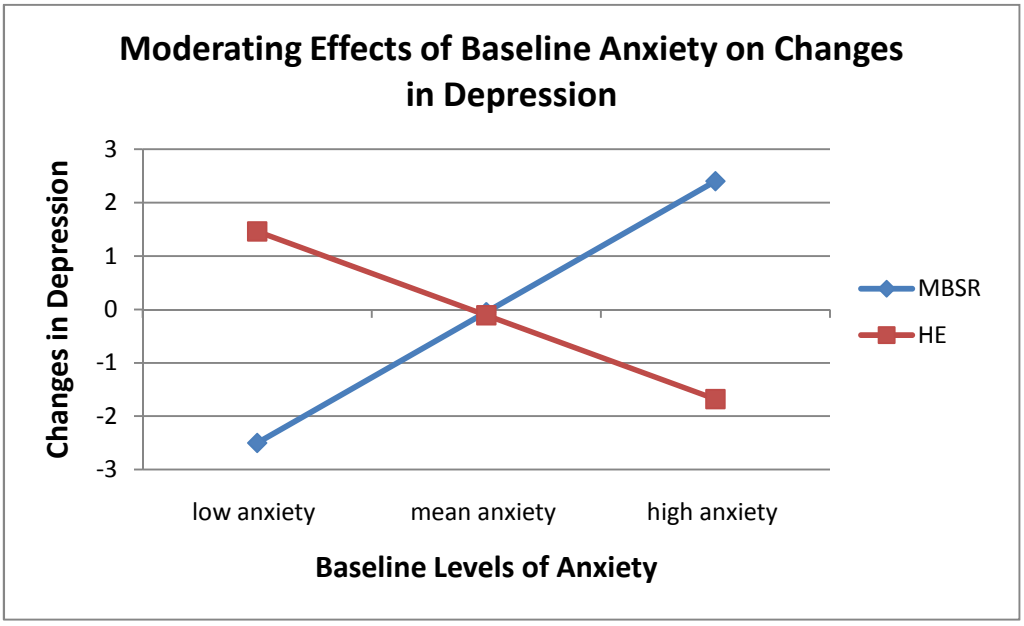


Figure 3. Moderating Effects of Self Efficacy on Changes in Depression

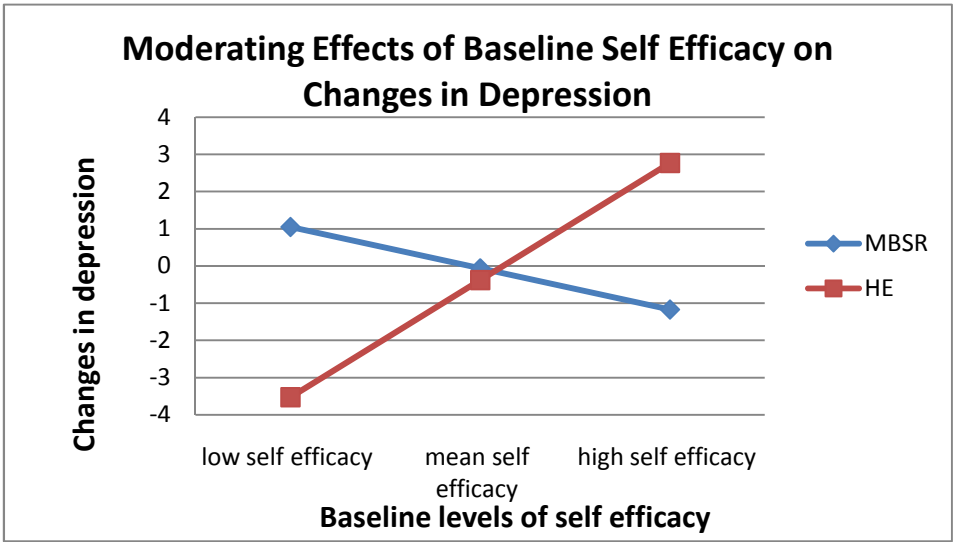


Figure 4. Moderating Effects of Transplant Related Stress on Changes in Depression

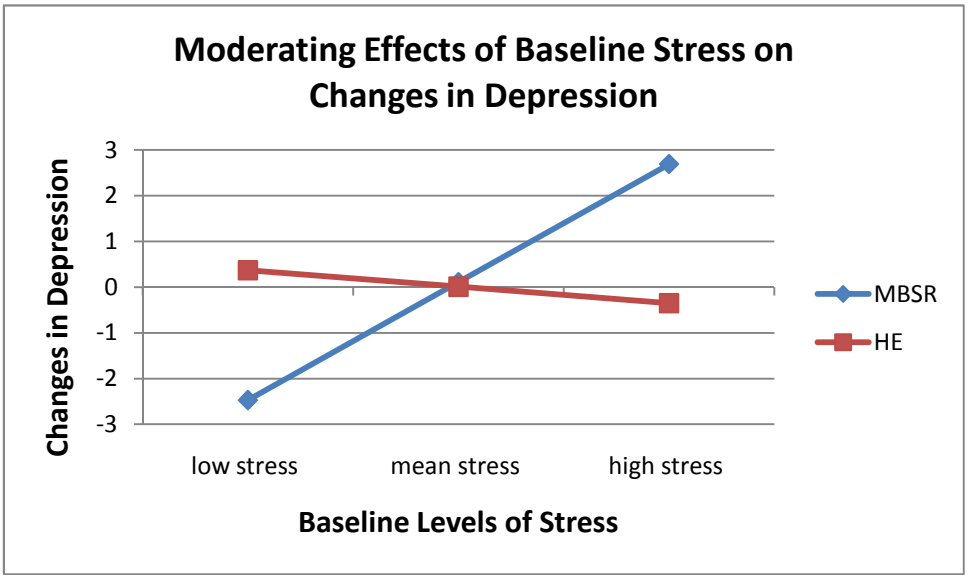
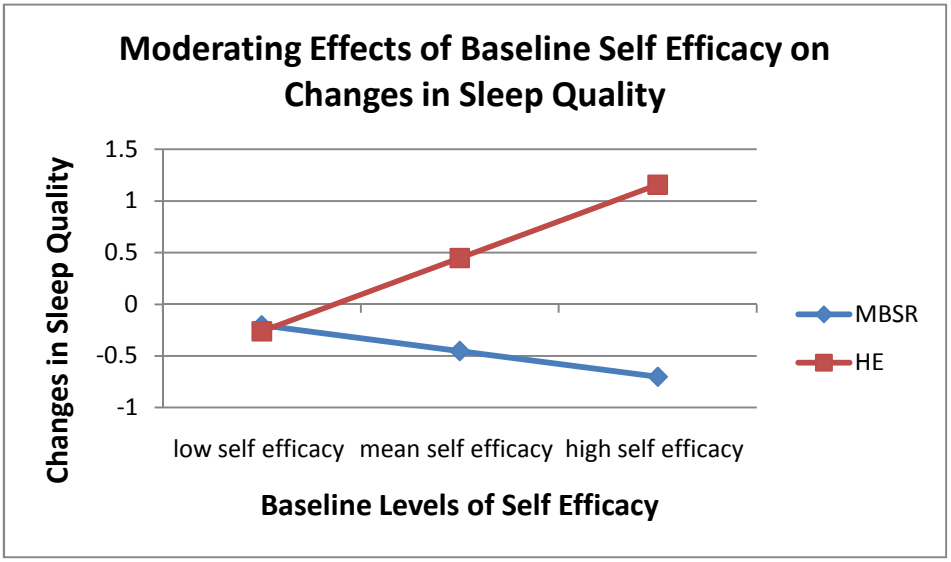


Figure 5. Moderating Effects of Self Efficacy on Changes in Sleep Quality



Discussion

The goal of the present study was to determine whether baseline depression, anxiety, sleep quality, mindfulness, self-efficacy, and stress moderated the effects of an MBSR program compared to an active control for decreasing psychological distress and sleep dysfunction in a sample of solid organ transplant patients. In other words, this was a treatment matching study that investigated for whom which intervention would be most effective in decreasing depression, anxiety, and sleep disturbance. This is the first study to investigate moderators of the effectiveness of MBSR for patients with chronic illness.

Findings suggest that there are differential effects of MBSR and HE on symptom reduction for solid organ transplant patients depending on patient characteristics. Specifically, patients with less psychological distress had greater symptom reduction in the MBSR group whereas patients with higher baseline levels of depression and lower levels of self-efficacy appeared to have greater symptom relief in the HE group. These findings partially confirmed the hypotheses in that those individuals with greater distress in the HE group, not the MBSR group, benefited more from the intervention than individuals with less distress.

More specifically, within the MBSR group, those with lower levels of baseline depression and anxiety experienced a greater decrease in depressive symptoms after the intervention, whereas those with initially higher levels of baseline depression and anxiety appeared to experience an increase in these respective symptoms at the conclusion of the intervention. Interestingly, participants with higher levels of baseline

stress experienced fewer improvements in depression, whereas those with lower levels of stress experienced a greater reduction in depression post-intervention.

Individuals in the HE group with higher baseline levels of depression experienced greater improvements in depressive symptoms after the intervention. Those with lower levels of baseline depression in the HE group experienced an increase in their depressive symptoms at the end of the intervention. Additionally, those in the HE group with initially lower levels of self-efficacy experienced greater improvements in sleep quality and depression at the post-intervention assessment than did those with higher levels of self-efficacy.

There were no significant moderators of the relationship between group and changes in anxiety. One possibility for this may be that the MBSR group was more effective than the HE group in reducing anxiety. Within group effect sizes for the difference between time 1 and time 2 scores indicated that MBSR significantly reduced anxiety with an effect size of .45 which is a medium effect whereas there was no significant within group difference for the HE group on anxiety time 1 to time 2.

These findings partially mirror the research on moderators of psychosocial interventions for adults with chronic illness which suggests that individuals with high levels of distress and fewer psychosocial resources benefit more from an intervention than those with lower distress and more psychosocial resources. This pattern was evident for the HE group whereas the opposite was true for the MBSR group. One possible explanation for the differential effects may be related to the stated goals of each intervention. The aim of MBSR is to increase moment-to-moment, non-judgmental acceptance (Kabat-Zinn, 1990) whereas HE focuses on changing health-related

cognitions behaviors through action planning (Lorig et al., 2000). These differing philosophies of acceptance-based vs. change-based treatments may impact patients differently depending on the level of psychosocial resources available to them, although this remains an empirical question. Changing ineffective behaviors and learning to make healthier choices in an intentional way may be more beneficial than practicing acceptance for those patients who are more distressed and lack resources. Actively changing to mitigate the distress one feels, rather than accepting it, may be more appealing and more helpful for patients who are struggling with significant psychological distress. Once patients have attenuated high levels of mood disturbance and developed a stronger foundation of confidence in their ability to follow through on specific goals, an acceptance-based intervention, such as MBSR, may be beneficial.

Although baseline mindfulness was not found to moderate the treatment effectiveness of MBSR or HE, correlational analyses indicated that baseline mindfulness was negatively correlated with baseline levels of depression, anxiety, and stress, and positively correlated with self-efficacy. These results are similar to other studies suggesting that there is an inverse relationship between mindfulness and psychological distress (Coffey & Hartman, 2008; Brown & Ryan, 2003).

Results suggest that the HE intervention may have a unique effect for those with lower levels of self-efficacy. As predicted, participants with lower baseline levels of self-efficacy derived greater benefits with regard to improvements in depression and sleep quality if they were in the HE group rather than the MBSR group. This finding is consistent with the research on the HE intervention, which was designed specifically to target and increase participants' levels of self-efficacy (Lorig et al., 1999, 2000, 2001).

It remains an empirical question whether MBSR is contraindicated for individuals with clinically severe levels of depression and anxiety, although the findings in the present study suggest that this question is worthy of consideration as scores of one standard deviation above the mean in the present sample are clinically significant. One line of research has suggested that mindfulness training may be unhelpful for certain individuals. Teasdale et al. (2000) developed Mindfulness-Based Cognitive Therapy (MBCT), which is a combination of MBSR and Cognitive-Behavioral Therapy (CBT), to prevent relapse of major depressive disorder (MDD). Findings indicated that MBCT plus treatment as usual (TAU) significantly reduced relapse of MDD in patients with three or more previous episodes of MDD, whereas those with two previous episodes did not experience a significantly reduced risk of relapse/reoccurrence but showed a nonsignificantly greater risk of relapsing after MBCT (Teasdale et al., 2003). Although this study provides important information about potential benefits and contraindications of MBCT, the question of whether MBSR is contraindicated for some participants depending on degree of psychological distress remains open. These findings suggest that until further research clarifies this issue, the application of mindfulness training be thoughtfully and intentionally applied with awareness that the practice of mindfulness may be contraindicated in some instances.

This study adds to previous studies on the benefits of MBSR and HE by addressing the question of who benefits from these interventions. Preliminary evidence suggests that transplant patients presenting with higher levels of depression and less self efficacy may be better served by enrolling in the HE program, whereas patients with

lower levels of stress and depression, and higher levels of self-efficacy may benefit from enrolling in an MBSR course.

Limitations and Future Directions

A limitation of the current study includes a relatively small sample size that was underpowered to detect moderation. A power analysis was done prior to data collection for the larger randomized WIAT trial (Gross et al., in press) on which this study was based. Moderation analyses in this study were intended as exploratory and hypothesis-generating, not hypothesis-testing (Kraemer, Frank & Kupfer, 2010); thus, no a priori power analysis was conducted to determine the appropriate sample size needed for testing of moderation. Because of the significant moderators detected in this study, future researchers are encouraged to adhere to Kraemer et al's (2010) recommendation to stratify by these variables, develop hypothesis-testing designs, and conduct a priori power analyses to detect moderation.

Other limitations noted in the WIAT study (Gross et al., in press) include unblinded delivery of the interventions and self-report assessments on all measures. Attrition and missing evaluations were additional limitations, although these problems were split evenly across interventions.

The field of MBSR research would be well served by the inclusion of more rigorous randomized controlled studies with a sufficient number of subjects, active control groups (with both acceptance and change based goals), in addition to wait-list controls to address instructor attention and social support, heterogeneous samples in terms of demographic variables, and more a priori attention paid to moderator effects. Additionally, because of the diverse components in an MBSR program (e.g. formal and

informal meditation practice, hatha yoga, body scans, and home practice), a component analysis is recommended to determine which elements, or combination of elements, of this intervention are most effective. These types of considerations will serve to deepen our knowledge about how MBSR works and who may be best served by this promising intervention.

REFERENCES

Antoni, M., Lehman, J., Kilbourn, K., Boyers, A., Culver, J., Alferi, S., Yount, S., McGregor, B., Arena, P., Harris, S., Price, A., & Carver, C. (2001). Cognitive-behavioral stress management intervention decreases the prevalence of depression and enhances benefit finding among women under treatment for early-stage breast cancer. *Health Psychology*, 20, 20-32.

Arch, J., & Craske, M. (2006). Mechanisms of mindfulness: Emotion regulation following a focused breathing induction. *Behaviour Research and Therapy*, 44, 1849-1858.

Argus, G., & Thompson, M. (2007). Perceived social problem solving solving, perfectionism, and mindful awareness in clinical depression: an exploratory study. *Cognitive Therapy and Research*, 32, 745-757.

Astin, J. (1997). Stress reduction through mindfulness meditation: effects of psychological symptomatology, sense of control, and spiritual experiences. *Psychotherapy and Psychosomatics*, 66, 97-106.

Astin, J., Berman, B., Bausell, B., Lee, W., Hochberg, M., & Forys, K. (2003). The efficacy of mindfulness meditation plus qigong movement therapy in the treatment of fibromyalgia: a randomized controlled trial. *The Journal of Rhumatology*, 30, 2257-2262.

Baer, R. (2003). Mindfulness training as a clinical intervention: a conceptual and empirical review. *Clinical Psychology Science and Practice*, 10, 126-143.

Baer, R., Smith, G., & Allen, K. (2004). Assessment of mindfulness by self-report: the Kentucky Inventory of mindfulness skills. *Assessment*, 11, 191-206.

Bandura, A. (1997) *Self-efficacy: The exercise of control*. New York: W.H. Freeman and Company.

Barnes, P. & Bloom, B. (2008). Complementary and alternative medicine use among adults and children: United States, 2007. *National Health Statistics Reports,* 12, 1-24.

Baron, R. & Kenny, D. (1986). The moderator-mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*, 51, 1173-1182.

Bedard, M., Felteau, M, Mazmanian, D., Fedyk, K., Klein, R., Richarson, J., Parkinson, W., & Minthorn-Biggs, M. (2003). Pilot evaluation of a mindfulness-based intervention to improve quality of life among individuals who sustained traumatic brain injuries. *Disability and Rehabilitation*, 25, 722-731.

Beddoe, A., & Murphy, S. (2004). Does mindfulness decrease stress and foster empathy among nursing students? *Journal of Nursing Education*, 43, 305-312.

Berscheid, E., & Reagan, P, (2005). *The Psychology of Interpersonal Relationships.* New Jersey: Pearson, Prentice Hall.

Bishop, S. (2004). What do we really know about mindfulness-based stress reduction? *Psychosomatic Medicine,* 64, 71-84.

Bohlmeijer, E., Prenger, R., Taal, E., & Cuijpers, P. (in press). *Journal of Psychosomatic Research.*

Broderick, P. (2005). Mindfulness and coping with dysphoric mood: contrasts with rumination and distraction. *Cognitive Therapy and Research*, 29, 501-510.

Brown, K. Ryan, R. (2003) The benefits of being present: mindfulness and its role in psychological well-being. (2003) *Journal of Personality and Social Psychology*, 84, 822-48.

Buysse, D., Reynolds, C., Monk, T., Berman, S., & Kupfer, D. (1989). The Pittsburgh Sleep Quality Index: a new instrument of psychiatric practice and research. *Psychiatry Research*, 28, 193-213.

Cardaciotto, L., Herbert, J., Forman, E., Moitra, E., & Farrow, V. (2008). The assessment of present-moment awareness and acceptance: the Philadelphia mindfulness scale. *Assessment,* 15, 204-223.

Carlson, L, & Brown, K.W. (2005). Validation of the Mindful Attention Awareness Scale in a cancer population. *Journal of Psychosomatic Research,* 58, 29-33.

Carlson, L., & Garland, S. (2005). Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *International Journal of Behavioral Medicine,* 12, 278-285.

Carlson, L, Speca, M., Patel, K., & Goodey, E. (2004). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress and levels of cortisol, dehydroepiandrosterone sulfate (DHEAS) and melatonin in breast and prostate cancer outpatients. *Psychoneuroendocrinology,* 29, 448-474.

Carlson, L., Ursuliak, Z., Goodey E., Angen, M., & Speca, M., (2001). The effects of mindfulness-based stress reduction program on mood and symptoms of stress in cancer outpatients: 6 month follow-up. *Support Care Cancer,* 9, 112-123.

Carmody, J., & Baer, R. (2008). Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of Behavioral Medicine*, 31, 23-33.

Carson, J., Carson, K., Gil, K., & Baucom, D. (2004). Mindfulness-based relationship enhancement. *Behavior Therapy*, 35, 471-494.

Chambers, R., Lo, B., & Allen, N. (2008). The impact of intensive mindfulness training on attentional control, cognitive style, and affect. *Cognitive Therapy and Research*, 32, 303-322.

Chang, V., Palesh, O., Caldwell, R., Glasgow, N., Abramson, M, Luskin, F., et al. (2004). The effects of mindfulness-based stress reduction program on stress, mindfulness self-efficacy, and positive states of mind. *Stress and Health*, 20, 141-147.

Coffey, K., & Hartman, M. (2008). Mechanisms of action in the inverse relationship between mindfulness and psychological distress. *Complementary Health Practice Review*, 13, 79-91.

Cohen, L., Littlefield, C., Kelly, P., Maurer, J., & Abbey, S. (1998). Predictors of quality of life and adjustment after lung transplantation. *Chest*, 113, 633-644.

Cohen, J. (1992). A power primer. *Psychological Bulletin*, 112, 155–159.

Cohen-Katz, J., Wiley, S., Capuana, T., Baker, D., & Shapiro, S. (2004). The effects of mindfulness-based stress reduction on nurse stress and burnout: a quantitative and qualitative review. *Holistic Nursing Practice*, 18, 302-308.

Cordon, S., Brown, K., & Gibson, P. (2009). The role of mindfulness-based stress reduction on perceived stress: preliminary evidence for the moderating role of attachment style. *Journal of Cognitive Psychotherapy: An International Quarterly*, 23, 258-269.

Cukor, D., Newville, H., & Jindal, R. (2008). Depression and immunosuppressive medication adherence in kidney transplant patients. *General Hospital Psychiatry*, 30, 386-387.

Davidson, R., Kabat-Zinn, J., Schumacher, J., Rosenkranz, M., Muller, D., Santorelli, S., et al. (2003). Alterations in brain and immune function produced by mindfulness meditation. *Psychosomatic Medicine*, 65, 564-570.

Dekeyser, M., Raes, F., Leijssen, M., Leysen, S., & Dewulf, D., (2008). Mindfulness skills and interpersonal behavior.*Personality and Individual Differences*, 44, 1235-1245.

Dew, M., Kormos, R., DiMartini, A., Switzer, G., Schulberg, H., Roth, L., & Griffith, B. (2001). Prevalence and risk of depression and anxiety-related disorders during the first three years after heart transplantation. *Psychosomatics*, 42, 300-313.

Dimitrov, D. & Rumrill, P. (2003). Pretest-posttest designs and measurement of change. *Work*, 20, 159–165.

Dobbels, F., Skeans, M., Snyder, J., Tuomari, A, Maclean, J., & Kasiske, B. (2008). Depressive disorder in renal transplantation: an analysis of Medicare claims. *American Journal of Kidney Diseases*, 51, 819-828.

Eisenberg, D., Davis, R., Ettner, S., Appel, S., Wilkey, S., Van Rompay, M., & Kessler, R. (1998). Trends in alternative medicine use in the United States, 1990-1997:

results of a follow-up national survey. *Journal of the American Medical Association*, 280, 1569-1575.

El-Agroudy, A., Wafa, E., Gheith, O., Shehab El-Dein, A., & Ghoneim, M. (2004). Weight gain after renal transplantation is a risk factor for patient and graft outcome. *Transplantation*, 77, 1381-1385.

Erylimaz, M., Ozdemir, C., Yurtman, F., Cilli, A., & Karaman, T. (2005). Quality of sleep and quality of life in renal transplantation patients. *Transplantation Proceedings*, 37, 2072-2076.

Evans, C., Margison, F., & Barkham, M. (1998). The contribution of reliable and clinically significant change methods to evidence-based mental health. *Evidence Based Mental Health*, 1, 70-72.

Frazier, P., Davis-Ali, S., & Dahl, K. (1994). Correlates of non-compliance among renal transplant recipients. *Clinical Transplantation*, 1994, 550-557.

Frazier, P., Tix, A., & Barron, K. (2004). Testing mediator and moderator effects in Counseling Psychology research. *Journal of Counseling Psychology*, 51, 115-134.

Fusar Poli, P., Lazzaretti, M., Ceruti, M., Hobson, R., Petrouska, K., Cortesi, M., et al. (2007). Depression after lung transplantation: causes and treatment. *Lung*, 185, 55-65.

Galantino, M., Baime, M., Maguire, M., Szapary, P., & Farrar, J. (2005). Short communication: association of psychological measures of stress in health-care professionals during an 8-week mindfulness meditation program: mindfulness in practice. *Stress and Health*, 21, 255-261.

Gallant, M, (2003). The influence of social support on chronic illness self-management: A review and directions for research. *Health Education & Behavior*, 30, 170-195.

Garland, S., Carlson, L, Cook, S., Lansdell, L., & Speca, M. (2007). A non-randomized comparison of mindfulness-based stress reduction and healing arts programs for facilitating post-traumatic growth and spirituality in cancer outpatients. *Supportive Care in Cancer*, 15, 949-961.

Goetzmann, L., Klaghofer, R., Wagner-Huber, R., Halter, J., Boehler, Muellhaupt, B., Schanz, U., & Buddeberg, C. (2006). Quality of life and psychosocial situation before and after a lung, liver, or an allogenic bone marrow transplant. *Swiss Medical Weekly*, 136, 281-290.

Goetzmann, L., Ruegg, L., Stamm, M., Ambuhl, P., Boehler, A., Halter, J., et al. (2008). Psychosocial profiles after transplantation: a 24-month follow-up of heart, lung, liver, kidney, and allogeneic bone-marrow patients. *Transplantation*, 86, 662-668.

Goldenberg, D., Kaplan, K., Nadeau, M., Brodeur, C., Smith, S., & Schmid, C. (1994). A controlled study of a stress-reduction, cognitive-behavioral treatment program in fibromyalgia. *Journal of Musculoskeletal Pain*, 2, 53-66.

Goodwin, P., Leszcz, M., Ennis, M., Koopmans, J., Vincent, L., Guther, H., Drysdale, E., Hundleby, M., Chochinov, H., Navarro, M., Speca, M., & Hunter, J. (2001). The effect of group psychosocial support on survival in metastatic breast cancer. *The New England Journal of Medicine*, 345, 1719-1726.

Grady, K., Naftel, D., Pamboukian, S., Frazier, O., Hauptman, P., Jerre, J., Eisen, H., Smart, F., & Bourge, R. (2005). Post-operative obesity and cachexia are risk factors for morbidity and mortality after heart transplant: multi-institutional study of post-

operative weight change. *The Journal of Heart and Lung Transplantation*, 24, 1424-1430.

Gross, C., Kreitzer, M.J., Thomas, W., Reilly-Spong, M., Cramer-Bornemann, M., Nyman, J., Frazier, P., & Ibrahim, H. (in press). Mindfulness-Based Stress Reduction for Solid Organ Transplant Recipients: A Randomized Controlled Trial. *Alternative Therapies in Health and Medicine.*

Gross, C., Kreitzer, M.J., Russas, V., Treesak, C, & Frazier, P. (2004). Mindfulness meditation to reduce symptoms after organ transplant: a pilot study. *Alternative Therapies in Health and Medicine*,10, 58-66.

Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits: a meta-analysis. *Journal of Psychosomatic Research*, 57, 35-43.

Grossman, P., Tiefenthaler-Gilmer, U., Raysz, A., & Kesper, U. (2007). Mindfulness training as an intervention for fibromyalgia: evidence of postintervention and 3-year follow-up benefits in well-being. *Psychotherapy & Psychosomatics*, 76, 226-233.

Helgeson, V., Lepore, S., & Eton, D. (2006). Moderators of the benefits of psychoeducational interventions for men with prostate cancer. *Health Psychology*, 25, 348-354.

Helgeson, V., Cohen, S., Schulz, R., & Yasko, J. (2000). Group support interventions for women with breast cancer: who benefits from what? *Health Psychology*, 19, 107-114.

Heo, M., Pietrobelli, A., Fontaine, K., Sirey, J., & Faity, M. (2006). Depressive mood and obesity in US adults: comparison and moderation by sex, age, and race. *International Journal of Obesity*, 30, 513-519.

Heppner, P, Cook, S., Wright, D., & Johnson, C. (1995). Progress in resolving problems: a problem-focused style of coping. *Journal of Counseling Psychology*, 3, 279-293.

Hoffman, S., Sawyer, A., Witt, A., & Oh, D. (2010). The effect of mindfulness-based therapy on anxiety and depression: a meta-analytic review. *Journal of Consulting and Clinical Psychology*, 78, 169-183.

Holroyd, K., Labus, J., & Carlson, B. (2009). Moderation and mediation in the psychological and drug treatment of chronic tension-type headache: the role of disorder severity and psychiatric comorbidity. *Pain*, 143, 213-222.

Jain, S., Shapiro, S., Swanick, S., Roesch, S., Mills, P., Bell, I., & Schwartz, G. (2007). A randomized controlled trial of mindfulness meditation versus relaxation training: effects on distress, positive states of mind, rumination, and distraction. *Annals of Behavioral Medicine*, 33, 11-21.

Jalowiec A, Grady K., White-Williams, C., Frzekas, S., Laff, M., Davidson-Bell, V., et al. (1997). Symptom distress three months after heart transplantation. *Journal of Heart and Lung Transplantation*, 16, 604-614.

Jerant, A., Moore, M., Lorig, K., & Franks, P. (2008). Perceived control moderated the self-efficacy-enhancing effects of a chronic illness self-management intervention. *Chronic Illness*, 4. 173-182.

Jerant, A., Kravitz, R., Moore-Hill, M., & Franks, P. (2008). Depressive symptoms moderated the efficacy of chronic illness self-management training on self-efficacy. *Medical Care*, 46, 523-531.

Jofre, R., Lopez-Gomez, J., Moreno, F., Sanz-Guajardo, D., Valderrabano, F. Changes in quality of life after renal transplantation. *American Journal of Kidney Disease*, 32**,** 93–100.

Johnston, E., Johnston, S., McLeod, P., & Johnston, M. (2004). The relation of body mass index to depressive symptoms. *Canadian Journal of Public Health*, 95, 179-183.

Kabat-Zinn, J. (1990). *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain and Illness.* New York: Delta.

Kabat-Zinn J. (1982). An out-patient program in behavioral medicine for chronic pain patients based on the practice of mindfulness-meditation: theoretical considerations and preliminary results. *General Hospital Psychiatry*, 4, 33-47.

Kabat-Zinn, J, Massion, A., Kristeller, J., Peterson, L., Fletcher, K., Pbert, L., Lenderking, W., & Santorelli, S. (1992). Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. *American Journal of Psychitatry*, 149, 936-43.

Kabat-Zinn, J., Wheeler, E., Light, T., Skillings, A., Scharf, M., Cropley, T., Hosmer, D., & Bernhard, J. (1998). Influence of a mindfulness meditation-based stress reduction intervention on rates of skin clearing in patients with moderate to severe psoriasis undergoing phototherapy (UVB) and photochemotherapy (PUVA). *Psychosomatic Medicine*, 60, 625-632.

Kaplan, K., Goldenberg, D., & Galvin-Nadeau, M. (1993). The impact of a meditation-based stress reduction program on fibromyalgia. *General Hospital Psychiatry*, 15, 284-289.

Karam, V., Castaing, D., Danet, C., Delvart, V., Gasquet, I., Adam, R., Azoulay, D., Samuel, D., & Bismuth, H. (2003). Longitudinal prospective evaluation of quality of life in adult patients before and one year after liver transplantation. *Liver Transplantation*, 9, 703-711.

Kieviet-Stijnen, A., Visser, A., Garssen, B., & Hudig, W. (2008). Mindfulness-based stress reduction training for oncology patients: patients' appraisal and changes in well-being. *Patient Education and Counseling*, 72, 436-442.

Kraemer, H., Frank, E., & Kupfer, D. (2006). Moderators of treatment outcomes: clinical, research, and policy importance. *The Journal of the American Medical Association*, 296, 1286-1289.

Kreitzer, M., Gross, C., Ye, X., Russas, V., & Treesak, C. (2005). Longitudinal impact of mindfulness meditation on illness burden in solid-organ transplant recipients. Progress in Transplantation, 15, 166-72.

Kristeller, J., & Hallett, B. (1999). An exploratory study of a meditation based intervention for binge eating disorder. *Journal of Health Psychology,* 4, 357-363.

Kruse, B., Heinemann, D., Moody, L., Beckstead, J., & Conley, C. (2005). Psychometric properties of the serenity scale. *Journal of Hospice and Palliative Nursing*, 7, 337-344.

Kugler, K., Strueber, M., Tegtbur, U., Jiedermeyer, J., & Axel, H. (2004). Quality of life 1 year after lung transplantation. *Progress in Transplantation,* 14, 331-336.

Lau, M., Bishop, S., Segal, Z., Buis, T., Anderson, N., Carlson, L., Shapio, S., & Carmody, J. (2006). The Toronto mindfulness scale: development and validation. *Journal of Clinical Psychology*, 62, 1445-1467.

Ledesma, D., & Kumano, K. (2009). Mindfulness-based stress reduction and cancer: a meta-analysis. *Psycho-Oncology*, 18, 571-579.

Lepore, S., Helgeson, V., Eton, D., & Schulz, R. (2003). Improving quality of life in men with prostate cancer: A randomized controlled trial of group education interventions. *Health Psychology*, 22, 443-452.

Limbos, M., Joyces, D., Chan, K., & Kesten, S. (2000). Psychological functioning and quality of life in lung transplant candidates and recipients. *Chest*, 118, 408-416.

Lorig, K., Holman, H., Sobel, D., Laurent, D., Gonzalez, V., & Minor, M. (2000). *Living a Healthy Life with Chronic Conditions.* Boulder: James Bull.

Lorig, K., Ritter, P., Stewart, A., Sobel, D., Brown, B., Bandura, A. et al. (2001). Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Medical Care*, 39, 1217-1223.

Lorig, K., Sobel, D., Stewart, A., Brown B., Bandura, A., Philip, R., et al. (1999). Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. *Medical Care*, 37, 5-14.

Lorig, K., Stewart, A., Ritter, P., Gonzalez, V., Laurent, D., & Lynch, J.(1996). *Outcome Measurse for Health Education and Other Health Care Intervnetions*. Thousand Oaks, CA: Sage Publications.

MacKinnon, D. (2008). *Introduction to Statistical Mediation Analysis.* New York: Lawrence Erlbaum Associates.

Majumdar, M., Grossman, P., Dietz-Waschkowski, B., Kersig, S., & Walach, H. (2002). Does mindfulness meditation contribute to health? Outcome evaluation of a German sample. *The Journal of Alternative and Complementary Medicine*, 8, 719-730.

Marcus, M., Fine, M, Moeller, G., Khan, M., Pitts, K., Swank, P., & Liehr, P. (2003). Change in stress levels following mindfulness-based stress reduction in a therapeutic community. *Addictive Disorders and Their Treatment,* 2, 63-68.

Mazuelos, F., Abril, J., Zaragoza, C., Rubio, E., Moreno, J., Turrión, V., & Cuervas-Mons, V. (2003). Cardiovascular morbidity and obesity in adult liver transplant recipients. *Transplantation proceedings*, 35, 1909-10.

Matthees, B., Anantachoti, P, Kreitzer, M.J., Savik, K., Hertz, M., & Gross, C. (2001). Use of complementary therapies, adherence, and quality of life in lung transplant recipients. *Heart & Lung,* 30, 258-268.

Miller, J., Fletcher K., Kabat-Zinn, J. (1995). Three-year follow-up and clinical implications of a mindfulness meditation-based stress reduction intervention in the treatment of anxiety disorders. *General Hospital Psychiatry*, 17, 192-200

Minor, H., Carlson, L., Mackenzie, M., & Zernicke, K. (2005). Evaluation of a mindfulness-based stress reduction (MBSR) program for caregivers of children with chronic conditions. *The Journal of Health Care Social Work*, 43, 91-109.

Monti, D., Peterson, C., Shakin Kunkel, E., Hauck, W., Pequignot, E., Rhodes, L., & Brainard, G. (2006). A randomized, controlled trial of mindfulness-based art therapy (MBAT) for women with cancer. *Psycho-Oncology*, 15, 363-373.

Morone, N., Greco, C., & Weiner, D. (2008). Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study. *Pain*, 134, 310-319.

National Center for Complementary and Alternative Medicine (NCCAM) definitions retrieved April 27, 2010 from http://nccam.nih.gov/health/whatiscam/overview.htm.

Nguyen, H., & Carrieri-Kohlman, V. (2005). Dyspnea self-management in patients with chronic obstructive pulmonary disease: moderating effects of depressed mood. *Psychosomatics*, 46, 402-410.

Nickel, R., Wunsch, A., Egle, U., Lohse, A., & Otto, G. (2002). The relevance of anxiety, depression, and coping in patients after liver transplantation. *Liver Transplantation,* 8, 63-71.

Noohi, S., Khaghani-Zadeh, M., Javadipour, M., Najafi, M., Ebrahiminia, M., & Pourfarziani, V. (2007). Anxiety and depression are correlated with higher morbidity after kidney transplantation. *Transplantation Proceedings*, 39, 1074-1078.

Novak, M., Zs, M., Molnar, M., Ambrus, C., Zs, A., Kovacs, A., Remport, A., Szeifert, L., Szentkiralyi, A., Shapiro, C., Kopp, M., & Mucsi, I. (2006). Chronic insomnia in kidney transplant recipients. *American Journal of Kidney Diseases,* 47, 655-665.

Nyklicek, I., & Kuijpers, K. (2008). Effects of mindfulness-based stress reduction intervention on psychological well-being and quality of life: is increased mindfulness indeed the mechanism? *Annals of Behavioral Medicine,* 35, 331-340.

Oman, D., Shapiro, S., Thoresen, C., Plante, T., & Flinders, T. (2008). Meditation lowers stress and supports forgiveness among college students: a randomized controlled trial. *Journal of American College Health,* 56, 569-578.

Onyike, C., Crum, R., Lee, H., Lyketsos, C., & Eaton, W. (2003). Is obesity associated with major depression? Results from the third National Health and Nutrition Examination Survey. *American Journal of Epidemiology*, 158, 1139-1147.

Ospina, M., Bond, T., Karkhaneh, M., Tjosvold, L., Vandermeer, B., Liang, Y., Bialy, L., Hooton, N., Buscemi, N., Dryden, D., & Klassen, T. Meditation Practices for Health: State of the Research. Evidence Report/Technology Assessment No. 155. (Prepared by the University of Alberta Evidence-based Practice Center under Contract No. 290-02-0023.) AHRQ Publication No. 07-E010. Rockville, MD: Agency for Healthcare Research and Quality. June 2007.

Ott, M., Norris, R., & Bauer-Wu, S. (2006). Mindfulness meditation for oncology patients: a discussion and critical review. *Integrative Cancer Therapies,* 5, 98-108.

Palinkas, L., Wingard, D., & Barrett-Connor, E. Depressive symptoms in overweight and obsess older adults: a test of the “jolly fat” hypothesis. *Journal of Psychosomatic Research,* 40, 59-66.

Park, C, & Gaffey, A. (2007). Relationships between psychosocial factors and health behavior change in cancer survivors: an integrative review. *Annals of Behavioral Medicine,* 34, 115-134.

Pérez-San Gregorio, M., Martin-Rodriguez, A., Diaz-Dominguez, R., & Pérez-Bernal, J. (2006). The influence of posttransplant anxiety on the long-term health of patients. *Transplantation Proceedings,* 38, 2406-2408.

Pischon, T., Sharma A. (2001). Obesity as a risk factor in renal transplant patients. *Nephrology, Dialysis, Transplantation*, 16, 14-17.

Pradhan, E., Baumgarten, M., Langenberg, P., Handwerger, B., Kaplan Gilpin, A., Magyari, T., et al. (2007). Effect of mindfulness-based stress reduction in rheumatoid arthritis patients. *Arthritis & Rheumatism*, 57, 1134-1142.

Praissman, S. (2008). Mindfulness-based stress reduction: a literature review and clinician's guide. *Journal of the American Academy of Nurse Practitioners*, 20, 212-216.

Reibel, D., Greeson, J., Brainard, G., & Rosenzweig, S. (2001). Mindfulness-based stress reduction and health-related quality of life in a heterogeneous patient population. *General Hospital Psychiatry*, 23, 183-192.

Roberts, K., & Aspy, C. (1993). Development of the serenity scale. *Journal of Nursing Measurement*, 1, 145-164.

Rosenzweig, S., Greeson, J., Reibel, D., Green, J., Jasser, S., & Beasley, D. (2010) Mindfulness-based stress reduction for chronic pain condition: variation in treatment outcomes and role of home meditation practice. *Journal of Psychosomatic Research*, 68, 29-36

Russell, R., Feurer, I., Wisawatapnimit, P., Salomon, R., & Pinson, C. (2008). The effects of physical quality of life, time, and gender on change in symptoms of anxiety and depression after liver transplantation. *Journal of Gastrointestinal Surgery*, 12, 138-144.

Sagula, D., & Rice, K. (2004). The effectiveness of mindfulness training on the grieving process and emotional well-being of chronic pain patients. *Journal of Clinical Psychology in Medical Settings*, 11, 333-342.

Sabbatini, M., Pisani, A., Crispo, A., Nappi, R., Gallo, R., Cianciaruso, B., & Federico, S. (2008). Renal transplantation and sleep: a new life is not enough. *Journal of Nephrology*, 21, S97-101.

Scheier, M., Helgeson, V., Schulz, R., Colvin, S., Berga, S., Knapp, J, & Gerszten, K. (2007). Moderators of interventions designed to enhance physical and psychological functioning among younger women with early-stage breast cancer. *Journal of Clinical Oncology*, 25, 5710-5714.

Scheier, M., Helgeson, V., Schulz, R., et al. (2005). Interventions to enhance physical and psychological functioning among younger women who are ending nonhormonal adjuvant treatment for early stage breast cancer. *Journal of Clinical* Oncology, 23, 4298-4311.

Sephton, S., Salmon, P., Weissbecker, I., Ulmer, C., Floyd, A., Hoover, K., & Studts, J. (2007). Mindfulness meditation alleviates depressive symptoms in women with fibromyalgia: results of a randomized clinical trial. *Arthritis & Rheumatism (Arthritis Care & Research)*, 57, 77-85.

Shapiro, S., Astin, J., Bishop, S., & Cordova, M. (2005). Mindfulness-based stress reduction for health care professionals: results from a randomized trial. *International Journal of Stress Management*, 12, 164-176.

Shapiro, S., Oman, D., Thoresen, C., Plante, T., & Flinders, T. (2008). Cultivating mindfulness: effects on well-being. *Journal of Clinical Psychology*, 64, 840-862.

Simon, G., Von Korff, M., Saunders, K., Miglioretti, D., Crane, P., van Belle, G., & Kessler, R. Association between obesity and psychiatric disorders in the US adult population. *Archives of General Psychiatry*, 63, 824-830.

Smith, B., Shelley, B., Dalen, J., Wiggins, K., Tooley, E., & Bernard, J. (2008). A pilot study comparing the effects of mindfulness-based and cognitive-behavioral stress reduction. *The Journal of Alternative and Complementary Medicine,* 14, 251-258.

Smith, J., Richardson, J., Hoffman, C., & Pilkington, K. (2005). Mindfulness-based stress reduction as supportive therapy in cancer care: systematic review. *Journal of Advanced Nursing*, 52, 315-327.

Soper, D. (2009). *Interaction*. Retrieved from http://www.danielsoper.com/Interaction/default.aspx.

Speca, M, Carlson, L, Goodey, E., & Angen, M. (2000). A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosomatic Medicine*, 62, 613-622.

Stewart, A., Hays, R., & Ware, J. (1992). Health perceptions, energy/fatigue and health distress measures. In Stewart & Ware (ed). *Measuring Functioning and Well-being.* Durham: Duke University Press.

Stunkard, A., Faith, M., & Allison, K. (2003). Depression and obesity. *Biological Psychiatry*, 54, 330-337.

Surawy, C., Roberts, J., & Silver, A. (2005). The effect of mindfulness training on mood and measures of fatigue, activity, and quality of life in patients with chronic

fatigue syndrome on a hospital waiting list: a series of exploratory studies. *Behavioural and Cognitive Psychotherapy*, 33, 103-109.

Tacon, A., Caldera, Y., Ronaghan, C. (2004). Mindfulness-based stress reduction in women with breast cancer. *Families, Systems, & Health*, 22, 193-203.

Tacon, A., McComb, J., Caldera, Y., & Randolph, P. (2003). Mindfulness meditation, anxiety reduction, and heart disease. *Family and Community Health*, 26, 25-33.

Teasdale J, Segal Z, Williams J, Ridgeway V, Soulsby J. Lau M. (2000). Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *Journal of Consulting and Clinical Psychology*, 68:615-623.

Teixeira, M., (2008). Meditation as an intervention for chronic pain. *Holistic Nursing Practice*, 22, 225-234.

Tobin, D., Holroyd, K., Reynolds, R., & Wigal, J. (1989). The hierarchical factor structure of the Coping Strategies Inventory. *Cognitive Therapy &* Resaerch, 13, 343-361.

Toneatto, T., & Nguyen, L. (2007). Does mindfulness meditation improve anxiety and mood symptoms? A review of the controlled research. *Canadian Journal of Psychiatry*, 52, 260-266.

Turner, J., Holtzman, S., & Mancl, L. (2007). Mediators, moderators, and predictors of therapeutic change in cognitive-behavioral therapy for chronic pain. *Pain*, 127, 276-286.

Transplant statistics. Retrieved September 15, 2008 from http://www.ustransplant.org/national_stats.aspx

Waelde, L, Thompson, L., & Gallagher-Thompson, D. (2004). A pilot study of a yoga and meditation intervention for dementia caregiver stress. *Journal of Clinical Psychology*, 60, 677-687.

Ware, J., & Sherbourne, C., 1992. The MOS 36-item short-form health survey (SF-36). *Medical Care,* 30, 473-483

Witek-Janusek, L., Alburquerque, K., Rambo Chroniak, K., Chroniak, C., Durzao-Arvizu, R., & Mathews, H. (2008) Effect of mindfulness based stress reduction on immune function, quality of life and coping in women newly diagnosed with early stage breast cancer. *Brain, Behavior, and Immunity*, 22, 969-981.

Wolsko, P., Eisenberg, D., Davis, R., & Phillips, R. (2004). Use of mind-body therapies: results of a national survey. *Journal of General Internal Medicine,* 19, 43-50.

World Health Organization (1997). Preventing and managing the global epidemic of obesity. Report of the World Health Organization Consultation of Obesity.

Appendix A

Effects of MSBR on Main Outcome Variables

Method

The search strategy for this review involved using PsychInfo, Medline, and Pubmed databases. The terms used for the searches included depression, anxiety, sleep, sleep quality, and sleep dysfunction combined with mindfulness, meditation, mindfulness-based stress reduction, or MBSR. Limitations imposed included articles written in English, and published in peer-reviewed journals between 1990 and 2010. In addition to the primary resources listed for each search, citations from each article were checked for relevant articles.

Inclusion criteria for relevant articles included both randomized controlled and uncontrolled studies; participants with chronic medical illnesses or pain; studies that included measures of at least one of the three outcome variables investigated in this paper (i.e., depression, anxiety, or sleep quality); and an intervention that was based on the standardized MBSR program.

The organization of the literature review is as follows: first, each outcome variable will be briefly introduced and defined. The outcome of the literature search will be noted. Measures used for each of the variables will be described. Next, relevant articles will be discussed and attention will be paid to the strengths and limitations of each study. Finally, the review will conclude with a brief summary of the findings along with limitations of this review and suggestions about future directions for research.

Depression and Anxiety

Because the majority of studies located examined depression and anxiety simultaneously, results pertaining to both will be reported together in this literature review in the interest of increasing efficiency and minimizing redundancy. Criteria for depression include a depressed mood, lack of interest or pleasure in activities, as well as cognitive, physical, and emotional impairment. Criteria for anxiety are quite broad and cover nearly a dozen codable diagnoses in the DSM-IV-TR; thus definitions of anxiety depend on the measure used for assessment. Twenty-three potentially relevant articles were identified, retrieved, and considered for inclusion. Seven studies used interventions other than the standardized MBSR program and were excluded (Astin, Berman, Bausell, Lee, Hochberg, & Forys, 2003; Garland, Carlson, Cook, Lansdell, & Speca, 2007; Goldenberg, Kaplan, Nadeau, Brodeur, Smith, & Schmid, 1994; Kabat-Zinn 1998; Kabat-Zinn, Massion, Kristeller, Peterson, Fletcher, Pbert, Lenderking, & Santorelli,1992; Monti, Peterson, Shakin Kunkel, Hauck, Pequignot, Rhodes, & Brainard, G., 2006; Surawy, Roberts & Silver, 2005). One study consisted of a heterogeneous patient population that included those with chronic psychological illnesses and was excluded (Majumdar, Grossman, Dietz-Waschkowski, Kersig, & Walach, 2002). The remaining studies consist of four randomized controlled trials (Pradhan, Baumgarten, Langenberg, Handwerger, Gilpin, Magyari, Hochberg & Berman, 2008; Sephton, Salmon, Weissbecker, Ulmer, Floyd, Hoover, & Studts, 2007; Tacon, McComb, Caldera & Randolph, 2003; Speca, Carlson, Goodey, & Angen, 2000), one controlled trial (Sagula & Rice, 2004), and eight uncontrolled studies (Rosenzweig, Greeson, Reibel, Green, Jasser, & Beasley, 2010; Kieviet-Stijnen, Visser, Garssen, & Hudig, 2008; Carlson & Garland, 2005; Carlson, Speca, Patel, & Goodey,

2004; Tacon, Caldera & Ronaghan, 2004; Carlson, Speca, Patel & Goodey, 2003; Brown & Ryan, 2003; & Carlson, Ursuliak, Goodey, Angen & Speca, 2001).

Measures of Depression and Anxiety. Measures used to assess depression and anxiety include the Medical Outcomes Study Short Form 36 Health Survey (SF-36), Medical Outcomes Study Short Form-36-Mental Health Component (SF-36-MHC), Symptom Checklist-90-Revised (SCL-90-R), Profile of Mood States (POMS), Beck Depression Inventory (BDI), and the State Trait Anxiety Inventory (STAI).

The SF-36 Health Status Inventory contains 36 questions that are aggregated by eight scales consisting of physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role–emotional, mental health. These eight scales are then aggregated into two summary scores (physical and mental health) and a global score with higher scores indicating improvement.

The SCL-90-R contains 90 questions that cover 9 subscales, including depression and overall psychological distress. Scale scores range from 0 – 4 with higher values indicating a higher degree of symptom severity. The instrument has demonstrated validity and reliability and has been used in several studies assessing the effects of MBSR on psychological distress.

The POMS is a widely used inventory that consists of 65 mood states that respondents rate on a 5-point Likert-type scale based on how well each item describes their mood. Factor analysis was used to derive six transient and fluctuating mood states including tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia, vigor-activity, and confusion-bewilderment.

The BDI is widely used 21-item self report measure that assesses cognitive, emotional, physical, and behavioral symptoms of depression. Respondents are asked to choose which of four statements best describes the way they have been feeling in the past week. Scores range from 0 – 39 with higher scores indicating more depression. Cutoffs used indicate that scores of 0-13 indicate minimal depression, 14-19 mild depression, 20-28 moderate depression, and 29-63 as severe depression.

The STAI measures both state and trait anxiety with higher scores indicating greater levels of anxiety. The state anxiety version contains 20 items that assess current situational feelings of anxiety, whereas the trait version consists of 20 items that pertain to how the respondent "generally" feels.

Randomized Controlled Trials. Pradhan et al. (2007) conducted a randomized controlled trial of MBSR for rheumatoid arthritis patients. Sixty-three participants were randomized to the MBSR intervention or a waitlist control group. Patients were predominantly European-American females, married, and possessed a college degree or higher. Assessments were taken at baseline, 8-weeks (post intervention) and 6-month follow-up. Instruments included the Symptom Checklist-90-Revised, Disease Activity Score, Psychological Well-Being, and the Mindfulness Attention Awareness Scale (MAAS). Although the treatment group improved in the expected direction on all measures, the control group participants improved as well; thus, no significant differences were found between groups post intervention. The authors provided possible explanations for this lack of difference. One suggestion was that a floor effect may have occurred in that the RA patients in this study had initially low rates of psychological distress compared to other RA populations studied. Improvements in the control group

were hypothesized to be due to placebo or Hawthorne effects. At the 6-month follow-up, participants who completed the MBSR group reported significantly less psychological distress and more well-being than those in the control group, whereas controls had returned to near baseline levels. The authors indicated that the differing trajectories of the two groups, along with continued practice among nearly 90% of participants in the MBSR group, suggest unique mechanisms of change underlying the MBSR intervention and increased sustainability of effects. Strengths of the study include using a randomized controlled design in a population of patients for whom the MBSR intervention had not yet been studied. Additionally, the inclusion of 6-month follow-up data strengthens the rigor of the design and provided evidence of the long-term effects of MBSR. Limitations of the study include a relatively small sample size, lack of an attention control, and the inclusion of participants with low baseline levels of psychological distress.

A randomized controlled trial of MBSR was conducted in a sample of women with fibromyalgia with the goal of reducing symptoms of depression (Sephton et al., 2007). Participants were predominantly European American (96%), married (54%), employed (53%), and mean age was 48 years (SD = 10.6). A total of 91 women were randomized into the MBSR intervention or a waitlist control group. Assessments were collected at baseline prior to randomization, at the end of the 8-week intervention, and 2 months after the intervention concluded. Depression symptoms were measured by the BDI. Baseline BDI scores were 15.6 (7.0) for the MBSR group and 14.7 (6.9) indicating mild depressive symptoms. Results indicated that those in the MBSR group experienced a significant reduction in depression symptoms compared to controls at post

intervention and this effect persisted at the 2-month follow-up. Those in the MBSR group reduced their BDI scores from mild to minimal depression, whereas those in the control group remained at the mild level throughout follow-up. Although this study supports the use of MBSR for the treatment of depression in women with fibromyalgia, a floor effect was likely occurring in that baseline levels of depression were initially low prior to randomization.

A pilot study was conducted to determine the effects of an MBSR program for treating anxiety symptoms in a sample of 20 women with heart disease (Tacon et al., 2003). Participants were primarily European American, well-educated, upper-middle-class, Protestant, employed, and married. The mean age was 60.5 with a range of 48-74. Participants were randomized into the MBSR intervention or a wait list control group. Anxiety was assessed using the STAI and measures were taken pre and post intervention. Results indicated that within-groups, only the MBSR participants experienced a significant reduction in state anxiety after the intervention, whereas little change occurred in the control group. No between groups differences for anxiety were reported. Limitations of this study are related to the pilot design and include a very small sample size and low power to detect differences. Additionally, the sample was homogenous in terms of demographic variables which limit generalizability. Strengths include focusing on a sample of women with heart disease, which is the number one cause of death among American women.

One of the earliest randomized controlled trials of MBSR for chronically ill patients examined the effects of the intervention on mood and stress in a sample of outpatients with cancer (Speca et al., 2000). Participants included a convenience sample

of 86 women and 23 men who were heterogeneous in terms of type and stage of cancer. Breast cancer was the largest category of cancer (n = 38) and stage II cancer was the modal stage. Mean age was 51 years with a range from 27 – 75. Mood was assessed with the POMS and measurements were taken pre and post intervention. After baseline measures were taken, participants were randomized into the MBSR treatment or a wait-list control group. Nineteen patients dropped out of the study. Analyses determined that there were no differences in rate of dropout between the intervention and control groups, nor were there differences in stage of cancer, sex, or age of participants. There was a significant difference in baseline mood disturbance such that dropouts had higher rates of anxiety, depression, fatigue, and total mood disturbance compared to those who completed the study. After the intervention, the MBSR group demonstrated significantly more improvement than controls on measures of anxiety, depression, anger, vigor, confusion, and total mood disturbance. Frequency of meditation time, not duration, was a predictor of improvements in POMS change scores and accounted for more than 15% of variance in mood improvement. Higher initial POMS scores predicted improvements on the POMS between pre- and post intervention. Strengths of this study include the use of a heterogeneous sample of cancer patients which increases external validity and reflects real-world practices. Another important finding is that practicing meditation matters and can be predictive of improvement in mood. Limitations include self selection of participants who were motivated to seek alternative treatment which may limit generalizability of results.

Controlled Trial. A controlled trial explored the effectiveness of an MBSR intervention on depression, anxiety, and grief in a sample of chronic pain patients

(Sagula & Rice, 2004). Participants in the treatment group consisted of 29 women and 10 men who were recruited from psychologists at a clinic informing their clients about the study. Additional recruitment efforts consisted of brief psychoeducational and psychotherapy presentations at a pain clinic. These individuals were enrolled in the MBSR intervention. An additional 22 chronic pain patients seeking or receiving medical care or on a wait-list for psychological treatment agreed to serve as wait-list controls. Study participants were European American (76%), African American (2%), Hispanic (2%) and Native American (2%) with the remainder not providing their racial/ethnic background. There were no differences in gender between the two groups. Measures included the BDI and STAI and were taken pre- and post- intervention. Participants in the MBSR group experienced a significant reduction in depressive symptoms compared to controls; however, both groups were at minimal levels of depression at baseline. Those in the MBSR group had significant decreases in state anxiety compared to controls. The authors conclude that MBSR may be effective in reducing depression for people with chronic pain, yet this may be a premature declaration given the low initial levels of depression among participants. Limitations of the study include the use of a comparison rather than control group, the lack of an ethnically diverse sample, and small sample size.

Uncontrolled Trials. A study of chronic pain patients was conducted to determine whether the effects of MBSR on psychological distress differed across medical diagnoses (Rosenzweig et al., 2010). This study was nested within a larger, prospective cohort study of heterogeneous patients participating in MBSR from 1997 to 2003. The final sample of the nested study consisted of 99 patients including 35 with

back/neck pain, 24 with arthritis, 15 with headache/migraine, 11 with fibromyalgia, and 30 with comorbid pains. Participants were primarily female (84%), European American (93%), fairly well educated (67% graduated college), and actively employed (54%). Standard MBSR courses were offered six times per year and data collection occurred over the course of the seven years of the larger study. Measures of psychological distress included the Medical Outcomes Study Short-Form 36 Health Survey (SF-36) and the Symptom Checklist-90-Revised (SCL-90-R). Assessments were collected pre- and post-intervention. Results indicated that participants differed on outcomes based on type of chronic pain condition. Patients with back/neck pain and those with comorbid pain conditions experienced the greatest improvements on average whereas those with fibromyalgia and headache/migraine experienced the fewest improvements. Regarding psychological distress as measured by the SCL-90-R, those with back/neck pain, arthritis, comorbid pain, and the combined sample experienced a significant decrease in depression symptoms from pre- to post-intervention measures. Effect sizes ranged from $d = .66$ for the combined sample to $d = .88$ for individuals with arthritis indicating medium to large effects. Patients with back/neck pain, arthritis, headache/migraine and comorbid pain, and the combined sample experienced significant decreases in anxiety symptoms with medium to large effect sizes ranging from $d = .60$ for headache/migraine to $d = .87$ for arthritis. The one exception to these results was the group with fibromyalgia in that they did not experience any significant pre to post changes and effect sizes were small. Results from the SF-36 Health Survey indicated that participants in all categories of chronic pain condition significantly increased mental health from pre to post intervention. The mental summary subscale was

significant for all conditions except fibromyalgia. The study also found that better adherence to formal home meditation practice was associated with greater improvements in overall psychological distress, somatic symptoms, and self-rated health.

An uncontrolled study was conducted to examine the impact of MBSR on improving well being and decreasing psychological distress in a heterogeneous sample of cancer patients (Kieviet-Stijnen et al., 2008). Participants were recruited from ongoing MBSR classes at an oncology clinic. Data were collected from 47 subjects at pre- and post-intervention, and one year follow-up. The group consisted of 34 women and 13 men; mean age was 48.4 (SD = 7.6) with a range of 31-65. Types of cancer included breast (40%), hematological (13%), gynecological (13%) gastrointestinal (9%), skin (6%), other types (13%), and missing (6%). Measures included the POMS, a Visual Analogue Scale for overall quality of life, a subscale of the Health and Disease Inventory to measure joy in life, and four questions to measure experienced meaning in life. Quality of life and joy in life significantly increased from pre- to post-assessment, and these improvements were maintained at one year follow up. None of the mood variables significantly improved from baseline to post-intervention; however, one year follow-up found significant improvements on depression, anger, vigor, tension, and total mood disturbance as compared to baseline levels. Two unique aspects of this study are the inclusion of measures of well-being in addition to measures of psychological distress and having a one-year follow-up assessment. Because of the lack of a control group and small sample size, these results are to be interpreted with caution.

The primary question of Carlson & Garland's (2005) study was whether MBSR can improve sleep quality in a heterogeneous sample of cancer patients (for a further discuss of their findings regarding sleep, please refer to the heading entitled sleep quality). Secondary analyses were conducted on mood and stress variables. Sixty-three patients were recruited from a waiting list for an MBSR program at a cancer center and consisted of 49 women and 14 men. No restrictions were placed on type or stage of cancer. The most common type of cancer diagnosis was breast (59%), followed by prostate, ovarian, and Non-Hodgkin's lymphoma (all 6%). Mean age was 54 years; most (71%) were married, and had a mean of 16 years of formal education. All POMS scores significantly improved from pre- to post-intervention assessment time points. Preliminary results suggest that this intervention may be helpful in improving mood in a heterogeneous sample of cancer patients, although – like several of the other uncontrolled studies in this review – the small sample size and lack of a control group are significant methodological limitations.

Carlson et al. (2004, 2003) reported on the effects of MBSR on stress, mood, and immune function in a sample of breast and prostate cancer outpatients. Fifty-nine patients were enrolled in the study (49 with breast cancer and 10 with prostate cancer) and 42 completed both pre- and post-intervention assessments. The mean age was 50 years (SD = 10.9); most (N = 42) were married and well educated with a mean of 14.7 years of formal education. The median time from diagnosis was 1.1 years. Nearly two-thirds had stage II cancer and the remainder had stage I cancer. Mood disturbance was measured with the POMS; however, there were no significant changes in mood from baseline to post-assessment. The authors point out that the sample had relatively low

levels of mood disturbance at baseline and suggest that this may have been due, in part, to the inclusion criteria for patients to be in the early stage of the disease and at least three months post-treatment; whereas greater levels of distress have been noted during the period of diagnosis and active treatment.

Tacon et al.'s (2004) pilot study investigated the effects of MBSR on anxiety, stress, mental adjustment to cancer, and health locus of control in women with breast cancer. Twenty-seven women participated in the intervention and completed pre-and post-intervention assessments. The sample was predominantly European American (92%), Protestant (92%), married (76%), employed full-time (64%), and had obtained education beyond high school (68%). The group was heterogeneous in terms of stage of cancer and time since diagnosis. State anxiety was measured using the STAI. There was a significant reduction in state anxiety from baseline to post-intervention. Scores on two scales of the Mental Adjustment to Cancer Scale – helplessness-hopelessness and anxious preoccupation – significantly decreased from baseline to post-intervention. A follow-up investigation at the end of the intervention asked participants which of the components of the MBSR program they preferred the most. Participants said they liked yoga (50.6%) and the body scan (42%) the most. Only two participants preferred sitting meditation. Women who preferred yoga noted that it improved upper body/arm flexibility and increased their comfort, especially on the side in which their cancer was located. Although the authors discussed the distressing nature of receiving a cancer diagnosis and included a measure of helplessness-hopelessness, it is unclear why they did not include a measure of depression in the study.

Brown and Ryan (2003) studied the effects of MBSR on mood, quality of life, stress, and mindfulness in a sample of 41 breast and prostate cancer patients. Seventy-eight percent were female; mean age was 55.3 (SD = 10.02) with a range from 36-75. Most were married (85.4%) and had a mean of 14.6 years of formal education. Patients were heterogeneous in terms of stage of cancer and time since diagnosis. Mood was assessed using the POMS. Paired *t* tests found no significant difference in POMS scores from pre- to post-intervention. The authors noted a high standard deviation and range of the scores at both assessment periods.

Carlson et al. (2001) reported six month follow-up data on former MBSR participants with cancer who took part in Speca et al.'s (2000) randomized controlled trial. Fifty-four participants returned the 6-month assessment forms, 44 were women, mean age was 50.6 (SD = 9.3), duration of illness was 3.7 years (SD = 5.7), and all four stages of cancer were represented. Mood was assessed using the POMS. Paired-samples *t* tests were used to compare post-intervention and 6-month follow-up scores. Although depression and anxiety score decreased over the follow-up period, these reductions were not significantly different from post-intervention scores. This suggests that the significant improvements in mood from baseline to post-intervention (as reported in Speca et al., 2000) were maintained over time. *Sleep Quality*

Sleep quality is an important construct in clinical domains because complaints about sleep disturbance, such as difficulty falling asleep or staying asleep, are common and reported in 15-35% of the adult population (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Additionally, poor sleep quality is a criterion for many psychological, medical, and sleep disorders. A total of three studies were located that studied changes

in sleep quality after an MBSR intervention in chronically ill patients (Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003; Carlson & Garland, 2005; Carlson et al., 2004).

Measures of sleep quality. Three measures were used to assess sleep quality in these studies: the Pittsburgh Sleep Quality Index (PSQI), a sleep diary, and a brief self-report measure. The PSQI is one of the most widely used instruments to assess sleep quality in clinical populations. It consists of 19 self-reported questions that cover sleep quality, sleep latency, sleep duration, sleep disturbance, habitual sleep efficiency, use of sleep medication, and daytime dysfunction over a period of one month. The sleep diary included entries for naps, sleep latency, number and duration of awakenings, total sleep, quality of sleep, feelings upon awakening, and whether the night described was typical. Weekly averages of sleep efficiency and quality were computed. Sleep efficiency was defined as a ratio of the time asleep divided by the total time in bed from the time the individual intended to sleep until the final awakening. The self report measure was part of a larger health behaviors form and asked participants to note hours per night slept and quality of sleep (poor, adequate, good).

Randomized controlled trial. Shapiro et al. (2003) reported data on sleep quality from a larger research study (National Cancer Institute, 1997) examining psychological, immunological, and sleep effects of an MBSR program for women with Stage II breast cancer. Sixty-three subjects were randomized into a 6 week MBSR program or FC (free choice) control which encouraged participants to choose their own preferred method of stress reduction. The authors hypothesized that sleep disturbance would be associated with psychological distress, MBSR would be more effective in improving sleep quality than the control group, and within the MBSR group, this improvement would be

associated with time spent practicing mindfulness. The authors found significant baseline differences between groups on measures of depression, trait anxiety, worry, sense of control, quality of life, and sense of coherence and hypothesized that this was due to what they called the premature disclosure effect (PDE) of informing participants of their randomization assignment prior to collecting baseline data. Because of this effect, the remainder of the analyses was treated as a corrective quasi-experimental nonequivalent groups design. Additionally, the six affected variables were combined to create a single unit-weighted scale for psychological distress which had a Cronbach's α of .91, indicating excellent internal validity. Neither experimental group reported significant improvement in sleep efficiency or sleep quality over time. Participants who practiced informal mindfulness (bringing mindful awareness to daily activities) experienced a significant increase in feeling rested over time. Neither sleep efficiency nor sleep quality was associated with amount of mindfulness practice. The authors noted that both conditions focused on stress reduction rather than targeting sleep directly, which may partially explain the limited number of significant findings. This study supports the notion that practicing mindfulness is beneficial; however, the authors note that mean practice times were generally low, with an average of 5 minutes/day, far below the standard recommendation of 45 minutes of daily practice.

Uncontrolled trials. A study conducted to determine if an MBSR program could decrease stress and improve sleep function in a heterogeneous sample of cancer patients also sought to determine the relationship between levels of stress and sleep quality (Carlson & Garland, 2005). Sixty-three patients with a range of cancer diagnoses, including breast, prostate, ovarian, and Non-Hodgkins lymphoma, participated in an

MBSR program. Measures included the Pittsburgh Sleep Quality Index (PSQI), Symptoms of Stress Inventory (SOSI), and the Profile of Mood States (POMS). Results indicated that all subscales of the PSQI significantly improved from pre- to post-intervention. At baseline, 91% of the sample met the cutoff of 5 or higher on the PSQI indicating sleep disturbance. More than half of the sample (51%) reported sleep disturbance scores of 10 or above. After the intervention, less than a third of the sample (27%) had scores of 10 or above. A more conservative cutoff of 8 on the PSQI was analyzed. Using this cutoff score, 70% of participants reported disturbed sleep pre intervention; after the intervention, less than half of the sample (49%) obtained a score of 8 and above. The largest improvements occurred in sleep quality, sleep efficiency, and duration. Findings also suggest that sleep quality was significantly correlated with symptoms of stress and levels of mood disturbance pre and post intervention. Levels of stress decreased significantly from pre- to post-intervention on the total SOSI stress score and all subscales except for cardiopulmonary symptoms. A significant moderate negative correlation was found between sleep quality and stress such that reductions in stress were associated with improved sleep quality. Reductions in mood disturbance were not significantly associated with improvements in sleep quality. Strengths of this study include investigating the extent of sleep disturbance in a population of cancer patients using a valid and reliable measure, as well as examining the relationship between sleep quality, stress, and mood disturbance. Additionally, the heterogeneous sample mirrors those found in community settings and thus increases the external validity of the results. Limitations include a quasi-experimental design and small sample size.

Carlson et al. (2004) investigated the effects of an MBSR program for improving quality of life, sleep quality, stress, and physiological measures in a sample of prostate and breast cancer outpatients. Pre- and post-intervention measures were taken from 58 and 42 patients, respectively. Paired samples t-tests were conducted to measure mean differences on outcomes. At baseline, participants were sleeping an average of 7.1 hours per night, although nearly half of the sample (40.7%) reported having poor sleep quality. One third reported having adequate quality sleep, while the remainder reported having good sleep quality. At post-intervention, sleep quality significantly improved, with 80% of participants reporting good or adequate sleep quality. One limitation of this study was the small sample size, particularly at the post intervention collection point. Additionally, the measure of sleep quality was overly simplistic and was not supported by validity or reliability data. In defense of the authors, the main focus of the study was measuring changes in stress using both self report and physiological measurements; thus, sleep quality was not one of the primary research questions in this paper.

Summary

Depression and anxiety. A dozen articles investigated the effects of MBSR on decreasing depression, anxiety, and psychological distress in patients with a range of chronic illnesses; however, the results are mixed. Three of the five randomized controlled trials reported non-significant between groups differences in change from from pre- to post-intervention. One of these studies found significant differences in psychological distress at the 6-month follow-up assessment such that those in the MBSR group were significantly less distressed than controls. Two studies found that

MBSR significantly decreased psychological distress. All of these studies utilized a wait-list control group. Among uncontrolled trials, three of the seven studies demonstrated significant reductions in distress, whereas four studies found no significant difference in scores from pre- to post-intervention. Limitations of the uncontrolled trials include small sample sizes and participants with minimal amounts of psychological distress at baseline. These findings suggest that there is preliminary evidence for a small to medium effect of MBSR in reducing psychological distress although additional research is needed to address methodological problems such as inclusion of larger samples, active control groups in addition to wait-list controls, and demographically heterogeneous samples.

Sleep quality. Research on the effects of MBSR on sleep quality is very limited. The three studies located were either quasi-experimental or uncontrolled trials and limited to patients with cancer. Two studies found significant improvement in sleep quality whereas the third study found no significant improvements over time. Three different measures of sleep were used, only one of which (the PSQI) has demonstrated validity and reliability.

Limitations of this Review

This review of the literature is limited in a number of ways. First, the inclusion criteria were kept fairly narrow and limited to studies investigating MBSR in those with chronic illness. As a result, several studies investigating these variables in other populations were excluded. Additionally, this review focused on only three psychosocial variables: depression, anxiety, and sleep quality. It is likely that there are other potential outcome variables to investigate; however, these variables were chosen

based on significant findings in the literature suggesting that they are associated with an efficacious MBSR intervention and are significant concerns for post-operative transplant patients.

Appendix B

Supplemental Moderator Analyses

In addition to the moderator analyses already discussed, a number of baseline variables were tested as potential moderators in an effort to generate hypotheses about treatment effectiveness for the MBSR and HE groups in reducing depression, anxiety, sleep dysfunction. Two sets of moderators were tested including demographic and psychosocial variables. Demographic variables included: sex, age, marital status, education level, transplant type, and body mass index. As over 90% of the sample identified as European American, race/ethnicity was not included as a moderating variable. Psychosocial variables tested included coping styles (including cognitive restructuring and problem avoidance), social support, and serenity (please refer to Appendix C for more detail on these measures). In keeping with the treatment outcome research on moderators of psychosocial interventions, it was hypothesized that participants with more distress and fewer psychosocial resources would benefit more from the interventions than participants with less distress and greater resources. As no research was located on demographic variables as moderators of the effectiveness of MBSR or HE interventions, moderator analyses on those variables were exploratory in nature. Of the supplemental moderators tested, only BMI was significant.

BMI was a significant moderator of the effect of group on changes in depression ($\beta = .17$; $p = .07$; r^2 change = .03). Tests of slopes showed that the relation between BMI and changes in depression was significant for the MBSR group (slope = .27; $t = 2.21$; $p < .05$) but not for the HE group (slope = -.05; $t = -.36$; $p > .05$). A lower BMI was related to greater improvements in depression for individuals in the MBSR group

whereas participants in the MBSR group with a higher BMI experienced fewer improvements in depressive symptoms. A comparison between patients with initially high versus low BMI indicated more than half a standard deviation difference on changes in depression which constitutes a medium effect. Baseline BMI did not predict subsequent changes in depression for the HE group. Please refer to figure 6 and tables 19 and 20.

The mean BMI of the sample at baseline was 27.27 (SD = 5.89) with a range of 17 – 46. According to the World Health Organization (1997), a BMI of $\leq$ 18.5 is underweight; 18.5 – 24.9 is normal, $\geq$ 25 – 29.9 is overweight, $\geq$ 30 – 34.9 is obese and $\geq$ 35 is classified as severe obesity. Based on these guidelines, the sample mean BMI at baseline can be classified as overweight. One standard deviation above the mean can be classified as obese whereas one standard deviation below the mean can be classified as within the normal range. Therefore, moderator findings in the current study suggest that obese participants in the MBSR group experienced fewer decreases in depressive symptoms than those participants who were of normal weight. As this finding was marginally significant, any conclusions drawn from these results must be tentative and intended to generate, rather than confirm, hypotheses.

Research suggests that there is an association between obesity and depression in the general population (Johnston et al., 2004; Simon et al., 2006; Stunkard, Faith, & Allison, 2003), although findings vary by severity of obesity (Onyike et al., 2003), gender (Palinkas, et al, 1996) and age (Heo et al., 2006). No studies were located that investigated the relationship between obesity and mood symptoms in transplant patients. Transplant patients are at increased risk for weight gain after transplantation

due to a number of factors including the use of steroid medication (El-Agroudy et al., 2004; Grady et al., 2005; Mazuelos et al., 2003). Studies of renal and heart patients suggests that post-operative obesity puts patients at greater risk of developing hypertension, diabetes, heart disease, graft failure, and mortality (El-Agroudy et al., 2004; Grady et al, 2005; Pischon & Sharma, 2001). Given the findings that many transplant patients continue to experience significant psychological distress after surgery (Dew et al., 2001; Goetzmann et al., 2008; Jalowiez et al., 1997), coupled with their increase risk of gaining weight, it is likely that the relationship between obesity and depression for transplant patients post-operatively is complicated and future research is needed to better understand this issue.

The preliminary finding of this study suggests that MBSR may be contraindicated for obese transplant patients. One explanation for this finding is that a primary focus of MBSR is to increase awareness of one's body through hatha yoga, body scans, and sitting meditation, all of which may be more challenging for a participant carrying a significant amount of extra body weight. An individual of normal body weight may more easily engage in the MBSR practices and therefore benefit from them in terms of experiencing a reduction in depression. As with the other moderator analyses, this finding is meant to be hypothesis generating, rather than hypothesis confirming, and additional research is needed to further understand this relationship.

Figure 6. Moderating Effects of Body Mass Index (BMI) on Changes in Depression

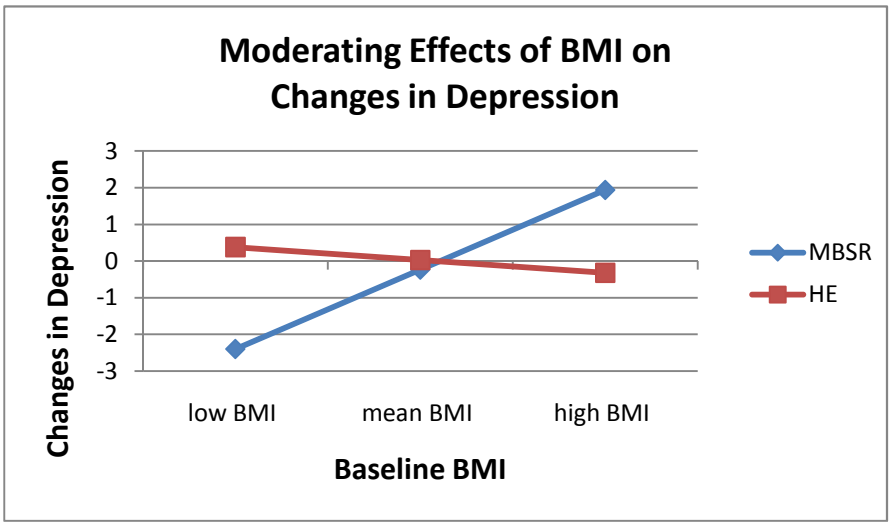


Table 19. Moderator Analysis for Changes in Depression

Step and Variable	B	SE B	p value	95% CI	β	R^2 Δ
Body Mass Index (BMI) and Changes in Depression						
Step 1						
Group	-.16	.72	.82	-1.58, 1.26	-.02	
BMI	.91	.71	.20	-.49, 2.31	.12	.20
Step 2						
Group x BMI	1.26	.70	.07	-.12, 2.65	.17	.07

Table 20. Simple Slopes

Outcome: Changes in Depression
Moderator: Body Mass Index Time 1

	Simple Slope	t	df	p	95% CI
MBSR	.27	2.21	111	.03	.23, 4.12
HE	-.05	-.36	111	.72	-2.31, 1.59

Appendix C

Mediators of the Effectiveness of MBSR Compared to Wait-List Controls

Results of the Wellness Intervention After Transplant (WIAT) study (Gross et al, in press) found that MBSR significantly improved depression and sleep disturbance compared to waitlist controls (DI) at the post-intervention assessment with effect sizes ranging from Cohen's d = 0.49 to 0.65 respectively. The effect of MBSR on anxiety approached significance (Cohen's d = .44; p = .06). There were no significant differences between the HE group and wait-list controls on depression, anxiety, or sleep quality at 8 weeks.

To understand what factors contributed to the effectiveness of MBSR over the wait-list in reducing distress and sleep disturbance, mediation analyses were conducted. According to MacKinnon (2008), a mediator is described as being "intermediate in the causal sequence relating an independent variable to a dependent variable. That is, the independent variable causes the mediating variable which then causes the dependent variable (p. 8)." In this current study, the independent variable tested was the experimental condition of MBSR compared to the wait-list control group, and the dependent variables were changes in depression, anxiety, and sleep quality. Potential mediators of the effectiveness of MBSR on outcomes in this study included changes in mindfulness, self-efficacy, stress, coping strategies (i.e., cognitive restructuring and problem avoidance), serenity, and social support.

Literature Review

Potential Mediators

The following section reviews literature regarding MBSR and the seven mediators tested. First, each potential mediator variable will be briefly introduced and defined. Measures used for each of the variables will be described. Next, relevant articles will be discussed and attention will be paid to the strengths and limitations of each study. In some instances, articles were included that did not contain a sample of individuals with chronic medical illness or pain or did not contain an MBSR program if there was an extremely limited body of literature available on the potential mediator. Finally, the review will conclude with a brief summary of the findings.

Mindfulness

Mindfulness is defined as moment-to-moment, non-judgmental awareness (Kabat-Zinn, 1990). Four studies were located that investigated changes in mindfulness after an MBSR intervention in a sample of individuals with chronic illness (Brown & Ryan, 2003; Lau et al., 2006; Pradhan, et al., 2007; Witek-Janusek et al., 2008). Five additional studies were located that investigated mediators related to the effectiveness of MBSR or mindfulness. One study measured mindfulness after a short breathing induction (Arch & Craske, 2006); however, this study was excluded because the intervention was a significant departure from the standardized program. Two of the mediator studies used the standardized MBSR program (Carmody & Baer, 2008; Nyklicek & Kuijpers, 2008), whereas one study randomized participants into one of two meditation conditions or a wait-list control group (Shapiro, Oman, Thoresen, Plante, & Flinders, 2008). The fifth study examined mindfulness as an individual difference variable using structural equation modeling in a cross-sectional design (Coffey & Hartman (2008).

Measures of mindfulness. Despite the abundance of outcome studies of MBSR in a wide range of populations, few have included a measure of mindfulness in their investigation. This may be because valid and reliable measures of mindfulness were only recently developed (Baer, Smith & Allen, 2004; Brown & Ryan, 2003; Cardaciotto et al., 2008; Lau et al., 2006). Two scales were used in the studies described below: the Mindful Attention and Awareness Scale (MAAS; Brown & Ryan, 2003) and the Toronto Mindfulness Scale (TMS; Lau et al., 2006). The MAAS is a one-factor instrument that assesses individual differences in the presence or absence of attention and awareness of what is occurring in the present moment. In contrast, the TMS consists of two factors – Curiosity and Decentering – and was designed to measure state, rather than trait, mindfulness.

Randomized controlled trials. A pilot study investigating an MBSR intervention in patients with rheumatoid arthritis (RA) randomized participants to either MBSR or a wait-list control group (Pradhan et al., 2007). The final sample included 63 adult patients with RA recruited through newspaper ads, health fairs, and informational flyers. In addition to the standardized 8-week protocol, the MBSR group participated in a 2-month follow-up session and three refresher courses over the next 4 months with the final outcome measures taken at 6 months post-baseline. Outcome measures included the Symptom Checklist-90-Revised (SCL-90-R), Disease Activity Score in 28 joints (DAS28), Psychological Well Being Scales, and the MAAS. Contrary to other findings in the literature, there were no significant differences between the groups on measures of psychological distress, depression, or well-being immediately after the intervention. The authors noted that there was likely a floor effect in their study as participants had

less psychological distress at baseline than is typically reported in this population. One puzzling outcome was that the control group demonstrated significantly higher levels of mindfulness than the MBSR group immediately postintervention. The authors speculated that those in the MBSR group might have become more attuned to the multitude of ways in which they were not mindful in their day-to-day lives. There was a significant group x time interaction at six months post-baseline such that the MBSR group reported less psychological distress and more well-being than the control group. Limitations of this study include a small sample size, lack of an active control group, and a floor effect for baseline psychological distress and RA disease functioning. Strengths of this study include a randomized controlled design, utilizing a sample of chronic disease patients, and including refresher classes and a six-month follow-up assessment. Findings suggest that an MBSR program along with a maintenance program may be helpful for decreasing psychological distress and improving well being for those with RA.

The first of only two randomized controlled trials investigating mediators of MBSR sought to determine if increased mindfulness in distressed individuals after participation in a MBSR program actually leads to improved psychological functioning compared to a wait-list control group (Nyklicek and Kuijpers, 2008). Additionally, they tested whether home practice time was associated with outcome. Finally, they wanted to determine whether changes in mindfulness mediated the effects of group membership (MBSR vs. control) on perceived stress and quality of life outcomes. Participants included 57 distressed individuals (38 females) who were randomized to either the MBSR intervention or a wait-list control. Results indicated that psychological distress

decreased from baseline to post-intervention in both groups and that the MBSR group had a significantly larger reduction than the control group. Quality of life scores increased significantly in both groups from pre- to post-intervention with the MBSR group having a significantly larger increase. Mindfulness scores increased significantly pre to post intervention in the MBSR group compared to controls. Results of the mediation analysis suggested that changes in mindfulness (as measured by the MAAS) partially mediated the relationship between group membership and quality of life and perceived stress. In contrast to Carmody and Baer's (2008) results, they found no association between amount of practice time and any outcome. One limitation of this study was the small sample size. An additional shortcoming was the definition and assessment of "distressed individuals." Participants were recruited via advertisements in local papers and asked over the phone how often they feel distressed. Eligible participants stated that they were distressed "regularly" or "often." Although it is the only known study to investigate mediators of the effectiveness of MBSR in a distressed population, use of a valid and reliable assessment tool to determine more accurately the level and type of distress and related psychopathology would have significantly increased the rigor of this study's design. Nevertheless, this study provides support for the hypothesis that increased mindfulness is a partial mediator of the effects of an MBSR program aiming to reduce psychological distress.

In their study comparing two different types of meditation practice, Shapiro et al. (2008) provided additional support for the hypothesis that a structured meditation program leads to increases in mindfulness in a sample of college undergraduates. Participants were randomized into one of three groups: an MBSR program, Easwaran's

Eight Point Program (EPP), or a wait-list control group. At the end of the interventions, both meditation groups experienced a significant increase in mindfulness compared to controls. Furthermore, a mediation analysis revealed that mindfulness, as measured by the MAAS, mediated the relationship between treatment and reduced stress in the pooled treatment groups. These findings suggest that there are different pathways to increased mindfulness and that these increases can lead to positive outcomes. One strength of this study is the inclusion of both active and wait-list control groups. This is an important methodological advance in the field as there are few studies in the MBSR literature that control for instructor attention and group support.

Controlled trial. An investigation of women newly diagnosed with breast cancer sought to determine the effects of an MBSR intervention on mindfulness, immune function, coping, and quality of life compared to a control group (Witek-Janusek et al., 2008). Subjects included 75 women (35-75 years of age) who were self-selected into an MBSR intervention (n = 44) or assessment only control group (n = 31). No significant baseline differences in demographics or cancer related variables were observed in the two groups. Additionally, an age-matched group of healthy women with no cancer or history of cancer was included to provide normative data for immune variables. Outcome measures included the MAAS, Quality of Life Index Cancer Version III, Jalowiec Coping Scale (JCS), and immune functioning and cortisol measures. Repeated measures ANOVAs were conducted to analyze within-group differences over time, between group differences (MBSR vs. no treatment), as well as interactions of treatment group with time. Assessments occurred at baseline, one month, two months (at the completion of the MBSR program) and three months postbaseline.

There were no significant changes in mindfulness within groups and no significant differences between groups at all time periods measured. The authors hypothesized that this non-significant finding may have been due to their inclusion of the MAAS rather than a measure that captures more than one facet of mindfulness. Other explanations include a small sample size and self-selection rather than randomization into conditions. Other outcomes, such as immune function, quality of life and coping (see below for a discussion of this finding), significantly improved post-intervention in the MBSR group compared to the control group.

Uncontrolled trials. A quasi-experimental study investigated the effects of an MBSR program to enhance well-being in a clinical sample (Brown & Ryan, 2003). Participants included 41 early-stage breast and prostate cancer patients (78% female, age range 37 – 76). Outcome measures included the MAAS, Profile of Mood States (POMS), Symptoms of Stress Inventory (SOSI), and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ). Pre and post intervention assessments were made. Greater mindfulness predicted lower stress and mood disturbance both before and after the intervention. Neither MAAS nor POMS scores demonstrated a significant change from pre to post intervention. The authors noted that the mean baseline MAAS score was higher than in other non-clinical samples they tested and hypothesized that the experience of cancer may serve to heighten present-moment awareness. They also suggested that longer time spans for follow-up measures may be necessary to detect increases in mindfulness. Limitations of this study included a quasi-experimental design, lack of control group, and small sample size.

A validation study of the Toronto Mindfulness Scale (TMS) was conducted on a heterogeneous patient population including those with general stress, anxiety, chronic pain disorder, diabetes, cancer at all stages, and multiple sclerosis (Lau et al., 2006). Participants included 99 individuals recruited from two separate MBSR programs (68% female, mean age 47, range 19-79). Participants were assessed pre-and post-intervention. Outcome measures included the TMS, the Perceived Stress Scale (PSS), and the Brief Symptom Inventory (BSI). Paired t-tests were conducted on pre- to post-MBSR measures. Results indicated that the two subscales of the TMS, Curiosity and Decentering, increased significantly after the intervention. Additionally, decentering was a predictor of less reported stress at post-treatment. Limitations of the study include lack of a randomized controlled design and small sample size.

Carmody and Baer's (2008) study sought to determine whether participation in an MBSR program and amount of time spent practicing meditation leads to increases in mindfulness. Additionally, a mediation analysis was conducted to determine whether an increase in mindfulness mediates the relationship between practice time and psychological outcomes. The sample consisted of 174 participants (63% female) with a variety of medical, psychological, and stress related issues drawn from the University of Massachusetts Medical School's MBSR program. The design was quasi-experimental and analysis consisted of paired sample t-tests on pre- and post-intervention data. Results indicated that mindfulness increased significantly from pre- to post-MBSR intervention, with effect sizes in the moderate to large range. The extent of home practice of formal meditation practices (e.g., sitting, hatha yoga, body scan) significantly correlated with the degree of change in most facets of mindfulness (as

measured by the Five Facets of Mindfulness Questionnaire). Mediation analyses indicated that the relationship between total practice time and decreases in psychological symptoms was completely mediated by increases in mindfulness. The relationship between practice time and decreased stress was also entirely mediated by increases in mindfulness. Finally, the association between practice time and improvements in psychological well-being was partially mediated by increases in mindfulness. These findings provide support for one of the basic tenets of MBSR - that regular practice of mindfulness actually increases mindfulness and improves psychological functioning. Although findings on the relationship between home practice and outcome are generally mixed, these findings provide justification for the rigorous requirement of daily home practice in an MBSR program. Limitations of this study included a quasi-experimental design and the fact that the sample was drawn from those already enrolled in an MBSR program at the University of Massachusetts Medical School. These subjects were well educated, with the financial resources to pay for the intervention, thus limiting generalizability.

Using as their springboard the growing body of evidence suggesting that mindfulness is negatively associated with psychological distress, Coffey and Hartman (2008) proposed and tested a theoretical model using correlational data and Structural Equation Modeling (SEM). The sample included 197 (65% female) university students who filled out paper and pencil questionnaires in groups ranging from 20-50 participants. They posited that mindfulness is inversely related to psychological distress and examined three potential mediators of this relationship: emotion regulation or the ability to regulate negative affect; ruminative thinking defined as the tendency to

engage in negative, repetitive, frequently self-focused thought about the past or future; and nonattachment, or the extent to which individuals view their happiness as independent from specific external circumstances. The original model included paths from mindfulness (as measured by the MAAS) to emotion regulation, non-attachment, and psychological distress. From non-attachment, another path was drawn to rumination and then psychological distress. Results indicated that the original specified model was a poor fit for the data. Interestingly, there was no significant direct effect of mindfulness on psychological distress. The model was respecified to include direct effects between mindfulness and rumination and between emotion regulation and rumination. The second model proved to be a good fit for the data with the first sample and was tested on a second independent sample. Results supported the respecified model, with rumination accounting for the largest amount of indirect effects, followed by emotion regulation, and nonattachment. Unlike Sample 1, mindfulness exerted a direct effect on psychological distress in Sample 2 and accounted for nearly 40% of the variance. Indirect effects through the mediators accounted for over 50% of the variance of psychological distress in the model. The authors argued that rumination might be the strongest mediator because it is nearly impossible to be mindful and ruminate simultaneously. The findings from the second sample suggest that mindfulness itself, as an individual difference variable, is inversely related to psychological distress, although it also appears as if mindfulness exerts its effect on psychological functioning via other important cognitive processes. One major critique of this study is that, because of the cross-sectional design, causal relationships between variables cannot be determined.

Self-efficacy

Self-efficacy is a major principle in social cognitive theory (Bandura, 1997) and is defined as an individual's confidence in his or her ability to perform a task or achieve a specific goal. Research has found a strong association between individuals' health promotion behaviors and their self-efficacy regarding the performance of such behaviors (Park & Gaffey, 2007). Thus, self-efficacy may play a critical role in self-management for those with chronic illnesses. Furthermore, the development of self-efficacy regarding mindfulness practice (e.g., the ability to maintain non-judgmental awareness during different situations) may have important psychological benefits for those managing chronic pain and illness and provide them with tools during a long course of treatment and disease self-management.

Only one relevant article on MBSR or mindfulness and self-efficacy was retrieved (Chang et al., 2004). Although this study used a community rather than clinical population, this article was included in this review for two reasons. First, this is the only article that addresses mindfulness self-efficacy and may serve as a basis for further investigation of self-efficacy among those with chronic illness. Second, the authors included a pain rating scale among their outcome variables, which allows for consideration of the effects of mindfulness self-efficacy among those with pain.

Uncontrolled study. The study conducted by Chang et al. (2004) examined the effects of MBSR on stress, mindfulness self-efficacy (MSE), positive states of mind, and pain in a general population sample. Mindfulness self-efficacy was defined as confidence in one's ability to maintain non-judgmental awareness during different situations (e.g., being hungry and reaching for junk food, when experiencing pain). The

authors hypothesized that the MBSR program would increase participants' MSE. Participants included 43 adults (28 completed follow up measures) who were enrolled in a standardized MBSR program including a full-day retreat. Measures included a pain rating scale, Positive States of Mind (PSOM), Perceived Stress Scale (PSS), and the MSE measure. After the MBSR program, there was a significant reduction in perceived stress and significant improvements in self-efficacy and positive states of mind scores.

Disadvantages of this study included a quasi-experimental design, lack of validity and reliability data regarding the mindfulness self-efficacy measure, a small sample, and a significant dropout rate. Strengths included the development of a self-efficacy scale, which may be helpful in determining whether participant commitment to an MBSR program is associated with mindfulness self-efficacy.

Stress

Stress refers to the process by which people perceive and respond to events that threaten their welfare (Berscheid, & Reagan, 2005) and consists of physiological and psychological responses. The General Adaptation Syndrome (GAS), first identified by Hans Selye, and also referred to as the "fight or flight" response, is when the body physiologically prepares to face or flee a threat or stressor. This response is adaptive when there is an immediate and discrete threat in the environment; however, long-term activation of this system via chronic and repeated stress, including contending with chronic illness, can result in impairments in cognitive functioning, reduced immunocompetence, and mood disturbances (Berscheid & Reagan, 2005). Twenty potentially relevant articles were identified, retrieved, and considered for inclusion. Eight studies that used non-clinical samples were excluded (Beddoe & Murphy, 2004;

Cohen-Katz, Wiley, Capuano, Baker, & Shapiro, 2004; Galantino, Baime, Maguire, Szapary, & Farrar, 2005; Minor, Carlson, Mackenzie, Zernicke, & Jones, 2005; Oman et al., 2008; Shapiro, Astin, Bishop, & Cordova, 2005; Shelley, Dalen, Waelde, Thompson, & Gallagher-Thompson, 2004; Wiggins, Tooley, & Bernard, 2008). An additional study examined psychological and physiological stress in individuals with substance abuse in a therapeutic community (Marcus et al., 2003). Although chemical dependence may be chronic in many individuals, this article was excluded, as it did not address chronic medical concerns. One study examined changes in perceived stress in women with fibromyalgia after an MBSR intervention; however, only the abstract was located (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007). Contact with the author was made to locate the entire article; however, as it is not forthcoming, this study was excluded. One article examining mindfulness in patients with traumatic brain injuries was excluded because it combined MBSR with an additional experiential learning cycle thus compromising the standardization of the MBSR program (Bedard et al., 2003). Finally, one article that assessed mindfulness and stress symptoms in a cancer population was excluded because it consisted of pre-intervention data only (Carlson & Brown, 2005). Eight articles met inclusion criteria including one randomized controlled trial and seven uncontrolled studies (Brown & Ryan, 2003; Carlson, et al., 2001; Carlson & Garland, 2005; Carlson, Speca, Patel, & Goodey, 2003; Carlson, Speca, Patel, & Goodey, 2004; Kreitzer, Gross, Ye, Russas, & Treesak, 2005; Speca, Carlson, Goodey, & Angen, 2000; Tacon, Caldera, & Ronaghan, 2004).

Measures of stress. Four outcome measures were used to assess stress in these eight studies: the Symptoms of Stress Inventory (SOSI), daily cortisol measurements, a

single item asking about stress levels, and the Transplant Related Stressors (TRS) scale. Five of the following studies, including the one randomized controlled trial, used the SOSI. The SOSI measures physical, psychological, and behavioral responses to stressful situations in the past week and consists of 10 subscales (e.g., central neurological, gastrointestinal, muscle tension, depression) and a total stress score. The remaining three outcome measures were each used in one study. Daily cortisol measurements are a biological marker of stress and were collected via saliva swabs at three time periods daily. The single item measure was created for the study and asked participants to rate their current stress level on a 10-point scale. Finally, the TRS scale is self-report measure that assesses concerns that may be salient for transplant patients, such as fear of organ rejection and concerns about subsequent infections.

Randomized controlled trial. Only one randomized controlled was retrieved that investigated the effects of an MBSR intervention on stress in patients with chronic illness. A convenience sample of 90 cancer patients with a variety of cancer diagnoses was randomized into an MBSR or control group with assessments made pre and post intervention (Speca et al., 2000). Stress was measured by the Symptoms of Stress Inventory (SOSI). Post-intervention, the MBSR group had significantly lower levels of stress than the control group on the SOSI Total Stress Scale and several subscales including fewer cardiopulmonary and gastrointestinal symptoms, less emotional irritability, depression, cognitive disorganization, and fewer habitual patterns of stress. One limitation of the study was that this sample had higher premorbid levels of mood disturbance than other large outpatient samples of cancer patients.

Uncontrolled studies. Six of the seven uncontrolled studies included in this review investigated MBSR for stress reduction in cancer patients whereas the seventh studied transplant patients. In all but one study, stress was found to significantly decrease following an MBSR intervention.

The first study was a follow up of Speca et al's (2000) randomized trial of cancer patients (Carlson et al., 2001). A convenience sample of cancer patients with a variety of cancer diagnoses was measured pre, post and 6 months after a 7-week MBSR intervention group (n = 89, 80, 54 for time 1, 2, 3 respectively). Five treatment cohorts were combined to make up the final sample. Analyses in this study did not include a comparison control group. Main outcome measures included the POMS and SOSI. Paired-samples t-tests comparing post-intervention to six-month follow-up were calculated. Patients' scores decreased significantly after the MBSR intervention on the SOSI total scores, and on most subscales and these improvements were maintained at six month follow up. Female gender and more education were associated with higher initial SOSI scores. Greater decreases in stress were predicted by more education and higher initial mood disturbance.

In their paper describing the development and validation of their Mindful Attention Awareness Scale (MAAS), Brown and Ryan (2003) noted that cancer patients were chosen for this study as research has demonstrated that this population commonly experiences moderate to high levels of stress due to coping with their illness. Participants in their study included 41 early-stage breast and prostate cancer patients recruited from advertisements and referrals at a major cancer center. Measures included the SOSI, the MAAS, the Cancer Quality of Life Questionnaire (EORTC QLQ), and the

POMS. The intervention consisted of a standardized MBSR program adapted for cancer patients. Paired t-tests comparing Time 1 and Time 2 SOSI data showed a significant reduction from baseline to post-intervention. This study demonstrated that stress in cancer patients decreased significantly after an MBSR program; however, as this was a quasi-experimental study, caution must be made in interpreting results and attributing causation to the intervention. Without a control group and randomization, these results must be considered as preliminary findings. Other limitations include a small, heterogeneous sample. Although all participants were in early stages of cancer, they consisted of both men and women with prostate and breast cancer, respectively. It is not yet known if there are differential effects of an MBSR program on men versus women particularly with regard to cancerous organs closely aligned symbolically with Western conceptions of gender.

An additional study investigating breast and prostate cancer patients tested whether an MBSR program would affect quality of life, mood, symptoms of stress, and immune function (Carlson et al., 2003). A sample of 49 breast and 10 prostate cancer outpatients (final n = 42) recruited from a cancer center participated in an 8-week MBSR program. Measures included a Health Behaviors Form, a weekly meditation form, the EORTC QLQ-C30, POMS and the SOSI. The mean SOSI total score and eight of the ten SOSI subscales decreased significantly from pre- to post-intervention. Interestingly, there was no correlation between residual stress change scores and amount of weekly home practice. This is surprising given that an important component of the MBSR program is a dedicated daily home practice.

These researchers published an additional paper addressing levels of cortisol and other hormones in the same sample of breast and prostate cancer patients (Carlson et al., 2004). They theorized that the MBSR program would reduce levels of cortisol, a stress hormone that has been reported to demonstrate abnormal levels in breast cancer patients. For the cortisol measure, participants were asked to collect salivary swabs three times daily. The daily mean of the three cortisol values did not significantly change; however, after splitting the sample at the median, those with initially high cortisol values decreased significantly from pre- to post-intervention at all three time periods, whereas those with initially low cortisol values increased over time. The authors argued that this change represented a normalization of mean cortisol levels for participants as well as a regression to the mean and explains why there was not a significant mean change for the total group.

A study conducted to determine if an MBSR program could decrease stress and improve sleep function in a heterogeneous sample of cancer patients also sought to determine the relationship between levels of stress and sleep quality (Carlson & Garland, 2005). Sixty-three patients with a range of cancer diagnoses, including breast, prostate, ovarian, and Non-Hodgkins lymphoma, participated in an MBSR program. Measures included the Pittsburgh Sleep Quality Index (PSQI), SOSI, and the POMS. Levels of stress decreased significantly from pre- to post-intervention on the total SOSI stress score and all subscales except for cardiopulmonary symptoms. A significant moderate negative correlation was found between sleep quality and stress such that reductions in stress were associated with improved sleep quality.

The only paper that focused solely on women with breast cancer also found significant reductions in stress after an MBSR intervention (Tacon et al., 2004). Twenty-seven women with breast cancer recruited within medical settings and support groups participated in an MBSR program modified for cancer patients (e.g., applying mindfulness skills during treatments). Measures included the State-Trait Anxiety Inventory (STAI), the Mental Adjustment to Cancer Scale (MAC), and the Multidimensional Health Locus of Control Scale (MHLC). Stress was measured by a single item asking participants to rate their current level of stress on a 10-point scale ranging from *low stress* (1) to *high stress* (10). There was a significant decrease in stress from pre- to post-intervention. Limitations of this study included a small sample size and the lack of a valid and reliable measure of stress. One strength of the study was the use of a homogenous sample of women with breast cancer.

Only one paper included in this review of stress used a sample other than cancer patients. This pilot study (conducted by the same team that collected the data used in the present study) investigated whether an MBSR intervention would affect anxiety, depression, sleep quality, illness intrusiveness, and transplant-related stress in solid-organ transplant recipients at three and six months after completion of the program (Kreitzer et al., 2005). Participants included 20 solid-organ transplant patients (60% had received kidney transplants) at least six months after transplantation. Measures included the Center for Epidemiologic Studies – Depression scale (CES-D), the STAI, the PSQI, the Illness Intrusiveness Rating Scale (IIRS), and the TRS Scale. Scores on the transplant-specific stress measure declined but the change did not reach statistical significance. Upon further analysis of the individual stress items, there were significant

reductions at the 6-month follow up such that patients reported less uncertainty about health. The authors noted that caution should be taken in the interpretation of these findings as the sample was small and no adjustments were made for multiple hypothesis testing.

Coping

Coping is defined as any specific cognitive, affective or behavioral strategy employed in an attempt to adapt to internal and external demands or challenges (Heppner & Krauskopf, 1987). Research has found that approach-focused coping (e.g., problem solving) generally is associated with more positive health outcomes whereas avoidance coping (e.g., ignoring problems) generally is associated with poorer health outcomes (Park & Gaffey, 2007).

Eight potentially relevant articles on MBSR and coping were identified, retrieved, and considered for inclusion. Two studies that used non-clinical samples were excluded (Broderick, 2005; Jain et al., 2007). The intervention in one study consisted of MBSR in conjunction with Qigong in a sample of university students (Astin et al., 2003). In another article, a non-clinical group of novice meditators engaged in an intensive 10-day mindfulness retreat (Chambers, Lo, & Allen, 2008). Because these modifications significantly changed the standardized MBSR program and neither study contained a sample of chronic disease patients, these articles were excluded. Finally, one abstract was located that assessed coping in fibromyalgia patients following an MBSR intervention; however, the article could not be located despite a request made to the author (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007). Therefore, three studies met inclusion criteria (Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Tacon,

McComb, Caldera, & Randolph, 2003; Witek-Janusek et al., 2008). All of these studies used an MBSR intervention in a sample of individuals with chronic illness and contained outcome measures of coping styles.

Measures of coping skills. The Problem-Focused Styles of Coping (PF-SOC) instrument was designed to assess an individual's typical manner of coping with stressful events and includes a variety of cognitive, affective, and behavioral items (Heppner, Cook, Wright, & Johnson, 1995). It consists of 18 items that load onto three factors: a reflective style that demonstrates cognitive problem solving, a suppressive style that includes avoidance and denial of problems, and a reactive style that indicates an emotional response to problems.

The Coping Strategies Questionnaire (CSQ) measures a chronic pain patient's ability to control and decrease pain. It contains 50 items and eight subscales and assesses the frequency with which respondents engage in five cognitive and three behavioral coping strategies when experiencing pain. Cognitive strategies include: Coping Self-Statement, Catastrophizing, Diverting Attention, Reinterpreting Pain Sensation, and Ignoring Pain Sensation. The behavior strategies include: Praying, Hoping, and Increasing Behavioral Activities. Two additional questions assess the individual's perceived ability to control or decrease pain by using the strategies endorsed.

The Jalowiec Coping Scale (JCS; Jalowiec, 1993) is a 60-item instrument that assesses eight dispositional coping styles including: evasive, confrontive, fatalistic, palliative, supportant, self-reliant, emotive, and optimistic.

Randomized controlled trial. The first study was a randomized controlled pilot trial to assess the effectiveness of MBSR in reducing anxiety in women with heart disease (Tacon et al., 2003). Participants were 20 women (mean age 61, range 48-74) randomized into either an MBSR group or waitlist control group. Measures were obtained at baseline and post-intervention and included the STAI, Courtauld Control Scale, PF-SOC, and a Multidimensional Health Locus of Control measure. Repeated measures ANOVAs were conducted with group as the independent variable and each of the dependent variables before and after the intervention as the repeated measure. The MBSR group had significant decreases from pre to post intervention for reactive coping, emotional suppression, and anxiety. In comparison, the control group demonstrated no changes over time on any of the measures. These findings, although limited, suggest that the MBSR intervention was able to help modify one ineffective form of coping, specifically reactive coping. Limitations of this study include the very small sample size, lack of power to detect differences, and no between groups analysis.

Controlled trial. The second study was a non-randomized, controlled trial of women newly diagnosed with early stage breast cancer (Witek-Janusek et al., 2008). Participants self-selected into either an MBSR group or an assessment only control group. Coping styles were measured using the JCS. At the end of the intervention, the MBSR group had significantly higher scores on two of the eight coping styles compared to the control group: supportant coping and optimistic coping. Supportant coping includes the use of personal, professional, and spiritual support systems. Optimistic coping includes the use of positive thinking and maintaining a positive outlook. The

authors hypothesized that the increase of support and positive thinking would yield long-term quality of life benefits for those newly diagnosed with cancer.

Uncontrolled study. The final study evaluated an MBSR program for patients with fibromyalgia (Kaplan et al., 1993). Seventy-seven patients (59 completers) who met the 1990 criteria of the American College of Rheumatology for fibromyalgia participated in a 10-week MBSR program. Pre- and post-intervention measures included 100-mm visual analog scales (VAS) for each of the following variables: global well-being, pain, sleep, fatigue, and feeling refreshed in the morning; a Medical Symptom Checklist (MSCL); the General Severity Index (GSI) of the SCL-90 as a global measure of psychological distress; the Coping Strategies Questionnaire (CSQ); the Fibromyalgia Impact Questionnaire (FIQ); Fibromyalgia Attitude Index (FAI); and an Overall Assessment (OA) of Outcome Questionnaire.

Improvements on all scales were measured as mean percent change. Patients who completed the program were divided into "responders" (n = 30) and "non-responders" (n = 29). Responders were defined as showing 25% improvement on at least 50% of the 10 instruments used to measure change. This group included "marked responders" who were defined as showing at least a 50% improvement in 50% of the instruments. Results indicated that the mean scores on all measures in all 59 completers showed a positive change. Mean percentage change on the CSQ was 20%, with 65% of patients demonstrating improvement. The authors did not provide means, standard deviations, p values, confidence intervals or effect sizes for any of the data; thus, it is not clear whether these changes were statistically significant. Additionally, dividing completers into two groups with arbitrary cut-offs risks the loss of information and

unnecessarily complicates interpretation of results. Despite these significant methodological limitations, these findings suggest that an MBSR program may be effective in improving coping skills in patients with fibromyalgia.

Serenity

Serenity is defined as a sustained inner peace (Kruse, Heinemann, Moody, Beckstead, & Conley, 2005) and is thought to be a helpful quality for those struggling with chronic and terminal illness (Roberts & Aspy, 1993). No studies were located that investigated MBSR or mindfulness and serenity although it can be argued that the two variables are closely connected. Individuals with higher levels of moment-to-moment non-judgmental awareness are more likely to experience a greater degree of serenity. These may be particularly salient variables for those struggling with the difficulties of chronic illness. The developers of the Serenity Scale pointed out that the concept of serenity includes an acceptance of situations that cannot be changed, as well as an active pursuit of reasonable solutions to problems. This two-pronged conception of action and acceptance may appear, at first glance, to be contradictory. However, having serenity allows an individual to "detach or separate oneself from that part of the self that is suffering and find an inward sanctuary or fortress in the midst of turmoil" (Kruse et al., 2005, p. 339). Furthermore, for those with chronic illness, the ability to recognize when to fight and when to accept a situation with equanimity is likely to aid in their coping with and adjustment to disability.

Two potentially relevant studies were located that addressed serenity. One study described the development of the Serenity Scale and was excluded (Roberts & Aspy, 1993). The other study investigated psychometric properties of the instrument in a

sample of hospital workers (Kruse et al., 2005). Although this study did not specifically address MBSR or mindfulness, nor contain a sample of individuals with chronic illness, it is included in this analysis because it includes measures of coping, which is an important factor in the present study.

Measuring serenity. In its original form, the Serenity Scale (Roberts & Aspy, 1993) is a 40-item self-report instrument that consists of nine separate factors: (1) an inner haven of peace, (2) acceptance of situations that cannot be changed, (3) a sense of connectedness and belonging, (4) trust in a power greater than oneself, (5) a sense of perspective of the importance of one's self and life events, (6) contentment with situations that cannot be changed, (7) a present-centered orientation, (8) beneficence, or a giving of oneself unconditionally, and (9) cognitive restructuring. Although the developers of the Serenity Scale noted that the concept of serenity addresses an aspect of spirituality, they also noted that their conceptual definition of serenity was broad enough to encompass diverse religious and philosophical viewpoints.

Uncontrolled study. Kruse et al. (2005) designed a pilot study to investigate the reliability and validity of the Serenity Scale. Surveys were sent to a sample of older hospital volunteers (Sample 1: n = 130, mean age 63, range 50-80; 76% female; 52% Protestant, 24% Catholic; Sample 2: n = 140, mean age 70, range 52-90; 82% female; 49% Protestant, 34% Catholic). Results indicated a strong, positive relationship between cognitive and behavioral coping and serenity (.46 and .38, respectively). Additionally, there was a significant negative correlation between serenity and avoidance coping (-.29). These findings support the construct of serenity and indicate that those individuals with more serenity are able to more effectively cope with stressful

situations. One major shortcoming of this article is that the authors discussed serenity as being important for those facing chronic and terminal illnesses and included a measure of coping with illness (the Dealing With Illness – Coping Scale); however, they did not sample from this population nor did they ask participants about their health status.

Social Support

Social support is defined as the degree to which an individual feels integrated in and supported by one's environment (Park & Gafey, 2007). Social support is strongly associated with more positive health behaviors in those with chronic illness (Park & Gafey, 2007). Furthermore, large-scale epidemiological studies have found that mortality rates were significantly lower among those with greater levels of social integration (Berscheid & Regan, 2005) and a solid body of research over the past few decades has established the importance of social support for morbidity, mortality, and other chronic disease outcomes (Gallant, 2003). As both the standardized MBSR program and the active control condition were conducted in groups, social support provided by the group may be an important variable to help explain how these interventions may lead to more positive health outcomes.

Four potentially relevant studies were located that addressed factors related to mindfulness and social interactions; however, no studies were located that investigated MBSR or mindfulness and social support directly. One study examined mindful awareness and social problem solving in individuals with clinical depression (Argus & Thompson, 2007). Another study investigated the effects of mindfulness-based relationship enhancement in a community sample of heterosexual couples (Carson, Carson, Gil, & Baucom, 2004). An additional study analyzed correlations between a

multifaceted measure of mindfulness (Kentucky Inventory of Mindfulness Skills; Baer, Smith, & Allen, 2004) and interpersonal feelings and performance in a sample of Dutch psychology students (Dekeyser, Raes, Leijssen, Leysen, & Dewulf, 2008). These three studies were excluded because they did not contain an MBSR intervention nor did they include a sample of chronically ill patients.

The fourth study examined MBSR and social functioning in a heterogeneous patient population (Reibel, Greeson, Brainard, & Rosenzweig, 2001). Social functioning in this case was defined as the impact of physical health or emotional problems on social activities (Ware & Sherbourne, 1992). Although this study did not measure social support, it was included for two reasons. As with the self-efficacy variable, this was the only article located that addressed a social variable in a population of chronically ill patients undergoing an MBSR program and thus provides preliminary evidence for how social factors may be impacted by such a program. Second, it stands to reason that improved social functioning may be related to an individual's level of social support. If individuals are able to engage more fully in social activities despite the burden of managing a chronic illness, they may elicit more social support than those who are impaired in their ability to function socially.

Measure of social functioning. The Medical Outcomes Study Short-Form Health Survey (SF-36; Ware, & Sherbourne, 1992) was used to assess social functioning in the one study reviewed. This self-report questionnaire assesses health-related quality of life, including physical and mental functioning and well-being. As noted above, the social functioning subscale in this measure assesses the impact of physical health and emotional problems on social activities. This measure contains a total of 11 items, two

of which address social functioning in the past four weeks. Low scores indicate extreme and frequent interference with normal social activities due to physical and emotional problems and high scores indicate the performance of normal social activities without interference due to physical or emotional problems.

Uncontrolled study. Reibel, Greeson, Brainard, and Rosenzweig (2001) conducted 12 separate MBSR courses over two years to evaluate quality of life, and physical and psychological symptoms in a heterogeneous patient population. Participants consisted of a total of 136 patients (104 completers with pre- and post-intervention data) with the most prevalent diagnoses being chronic pain, hypertension, and anxiety/panic. The authors noted that this sample had a significant level of comorbidity as 27% of patients had two conditions, 19% had three conditions, 13% had four conditions, and 8% had more than four conditions. Participants were given pre- and post- intervention measures that included the Medical Outcomes Study Short-Form Health Survey (SF-36), Symptom Checklist-90 Revised (SCL-90-R), the Medical Symptom Checklist (MSCL), and a 10-point measure assessing body tension, mental clarity, and well-being given before and after each weekly MBSR session. Pre-intervention social functioning scores were below the 25^{th} percentile of U.S. population norms. T-tests performed comparing pre-and post-intervention data found significant improvement on all indices of the SF-36 including the social functioning measure (effect size d = .45). This change in score brought the study group above the 25^{th} percentile score for U.S. norms.

One strength of this study is the sample that was used. A heterogeneous patient population with significant comorbidity complicates research in that the population is

not clearly defined; however, it is reflective of the naturalistic setting in which clinicians and MBSR instructors are likely to practice. Furthermore, to have significant findings and improvement in functioning and well-being despite the heterogeneity of the sample speaks to the effectiveness of MBSR for a wide variety of patients. Limitations of this study include the lack of a control group and randomization.

Summary

Mindfulness. Research investigating mindfulness in those with chronic illness is limited. Two studies found no significant increases in mindfulness after an MBSR intervention in samples of those with rheumatoid arthritis and new breast cancer diagnoses. Studies investigating mindfulness as a mediator are more promising; however, these were performed on community, not medical, samples. In these studies, changes in mindfulness mediated the relationship between MBSR and quality of life and perceived stress. In addition, changes in mindfulness mediated the relationships among practice time and psychological distress, stress, and well-being. In all of these studies, mindfulness was found to have increased after an MBSR intervention. Finally, a cross-sectional SEM analysis found an inverse relationship between mindfulness and psychological distress in a university student sample. Rumination was the most significant mediator of this relationship.

Self-Efficacy. Examinations of the relationship between mindfulness and self-efficacy are very limited. The one relevant article reviewed focused on self-efficacy for mindfulness and its practice during different situations, including dealing with pain, and was conducted with a community rather than clinical sample. Results indicated that participants had significant improvements in self-efficacy after an MBSR intervention.

Stress. Several studies have explored the relationship between MBSR and stress in those with chronic illness. These studies are of varying quality and include a number of quasi-experimental studies, only one randomized controlled trial, small sample sizes, and a variety of stress measures. Additionally, all but one of the studies investigated stress in cancer patients, which limits the generalizability of the results. Despite these limitations, there is preliminary support for the effectiveness of MBSR in decreasing stress in chronically ill cancer and transplant patients.

Coping. Analyses of the effects of MBSR on coping strategies in chronically ill patients are limited. There is preliminary evidence to suggest that an MBSR intervention may be effective in reducing reactive coping in women with heart disease and improving coping skills in patients with fibromyalgia. Caution must be made in interpreting these results, as there are significant methodological flaws in both studies reviewed.

Serenity. No studies have addressed the relationship between serenity and mindfulness. There is some evidence that serenity is positively associated with cognitive and behavioral coping styles and negatively associated with avoidance coping in a population of older hospital volunteers. Nevertheless, the construct of serenity may be closely tied to mindfulness practice and a positive correlation between these two variables is likely. It remains to be seen if mindfulness practice via an MBSR program leads to increases in serenity.

Social support. No studies have addressed the direct relationship between MBSR and social support in patients with chronic illness, although one uncontrolled study found that an MBSR intervention significantly improved social functioning in a

heterogeneous patient population. Further research on this topic is important as the social support provided by the MBSR program may have significant effects on outcomes. Additionally, it will be important for research to explore the degree to which social support leads to beneficial outcomes in MBSR by including control groups that supply social support to participants.

Hypotheses

Based on the literature for the potential mediator variables, it is hypothesized that increases in mindfulness, self-efficacy, serenity, social support, and cognitive restructuring, and decreases in problem avoidance and stress will mediate the relationship between MBSR (vs. delayed intervention) and the improvements in depression, anxiety, and sleep dysfunction.

The Present Study

Participants

The sample consisted of 94 solid organ transplant recipients living in the community who were at least six months post-surgery. Fifty-one percent were male; 92% identified as European-American, 4% as Asian American, 2% as American Indian/Alaskan Native, and 2% as African American. The mean age was 55 (SD = 10.70) with the range between 21-75 years old. Transplanted organs included kidney (54%), liver (17%), heart (12%), kidney/pancreas (8.5%), lung (6%), double lung (2%), and pancreas (2%). Thirty-seven percent graduated from college, 35% completed some college, 23% had post-college study, and 3 % obtained a high school diploma. The majority of the sample (66%) was married, 15% were divorced, 11% never married 6.6% were widowed, and 1% separated.

Outcome Measures

The outcome measures used in the mediation analyses consisted of the Center for Epidemiological Studies – Depression Scale *(*CES-D; Radloff, 1977), The State Trait Anxiety Inventory (STAI; Spielberger, 1968, 1977), and The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989). For a discussion of these measures, please refer to the primary moderator study.

Mediators

Mindfulness. Mindfulness was assessed using the Mindful Attention and Awareness Scale (MAAS; Brown & Ryan, 2003). This instrument consists of 15 items (e.g., "I find it difficult to stay focused on what's happening in the present"- reverse scored). Participants rated their responses on a 6-point Likert-type scale ranging from "almost always" to "almost never" with higher scores indicating more mindfulness. The scale has demonstrated convergent and discriminant validity as well as good internal consistency with Cronbach's alphas ranging from .80 to .87 (Brown & Ryan, 2003). In the current study, baseline Cronbach's alpha was .90 and time 2 alpha was .91.

Self-Efficacy. The Self-Efficacy for Managing Chronic Illness (SE-CI) scale is a 10-item instrument that measures level of confidence in one's ability to manage disease and communicate with health professionals (Lorig et al., 1996) and has demonstrated good internal consistency with alphas ranging from .87to .91. In the current study, baseline Cronbach's alpha was .89 and time 2 alpha was .90. The scale was modified for living with an organ transplant. Participants were asked to rate how confident they were at performing tasks at the present time including "Do all of the things necessary to

manage your transplant on a regular basis?" The scale ranges from 1 (not at all confident) to 10 (totally confident).

Stress. The Transplant Related Stressors (TRS) Scale is a 10-item scale modified from a scale developed by Frazier et al. (1994). Participants noted how much stress each item caused them in the past 4 weeks. Sample items include: "uncertainty about your health" and "medication side effects." Items are scored on a 5-point Likert-type scale ranging from "not at all stressful" to "extremely stressful." The alpha coefficient reported by the developers of the measure was .89. In the current study, baseline and time 2 alphas were .88 and .86 respectively.

Coping. The Coping Strategies Inventory (CSI) measures eight primary coping strategies identified by factor analysis (Tobin et al., 1989). The subscales assessing cognitive restructuring and problem avoidance were used in the current study. Items for cognitive restructuring included: "I tried to get a new angle on the situation" and for avoidance included: "I tried to forget the whole thing." Items are rated on a 5-point scale ranging from 1 (not at all) to 5 (very much). The developers reported alpha coefficients for the two scales ranging from .72 for problem avoidance to .83 for cognitive restructuring. In the present study, baseline alpha's were .69 for Problem Avoidance and .86 for Cognitive Restructuring; time 2 alpha's were .69 for Problem avoidance and .86 for Cognitive Restructuring.

Serenity. The Serenity Scale is a 22-item shortened version of the original 40-item measure (Roberts & Aspy, 1993). Items include "I am aware of an inner source of comfort, strength, and security." Cronbach's alpha reported by the developer was .92. In the baseline data of the present study, $\alpha = .95$ and time 2 $\alpha = .95$. Participants rated

responses on a five-point scale ranging from 1 (never) to 5 (always) with higher scores indicating higher levels of serenity.

Social support. The Medical Outcome Study Social Support Survey (Stewart et al., 1992) is a 7-item measure that asks participants how often various kinds of support is available to them when needed (e.g., "Someone to confide in or talk to about yourself or your problems"). Cronbach's alpha reported by the developers was .87. For the baseline data in this study $\alpha = .94$; for time 2 $\alpha = .95$. Participants rated answers on a five-point scale ranging from 1 (none of the time) to 5 (all of the time).

Mediation Analyses

The purpose of these analyses was to assess what variables might mediate, or explain, the differences between the MBSR and DI groups in terms of improvements in depression, anxiety, and sleep quality. The steps for testing mediation as described by MacKinnon (2008) and Baron and Kenny (1986) were followed. First, a significant relationship must be established between the predictor and the outcome variable. Second, the predictor must be related to the mediator. Third, the mediator must be related to the outcome variable. Finally, the relationship between the predictor and outcome variable must be significantly reduced when the mediator is included in the model. Unstandardized residual scores for baseline to 8-week measures of depression, anxiety, sleep quality, and the mediators were used. As per MacKinnon (2008, p. 199), residualized change scores were used because this method adjusts for baseline differences and avoids some of the problems with reliability of difference scores. This two-wave model (baseline and 8 week data) was used because the main research question investigates potential mediators of MBSR to explain why this intervention was

effective. Extending the analysis to include 26-week or 52-week follow-up data is introducing a significant amount of error, as participants were no longer engaged in the standardized intervention after the 8-week assessment.

The mediation effect for each of the seven individual potential mediators was tested separately for each individual dependent variable (i.e., changes in depression, anxiety, and sleep quality). In other words, these analyses were testing whether improvement in depression, anxiety, and sleep quality in the MBSR group versus the control group could be partially explained by improvements in the proposed mediators seen in the MBSR group.

Results

Of the 21 mediation analyses conducted (7 mediators X 3 outcomes), only one significant mediator was found. Change in transplant related stress was a partial mediator of the relationship between group (MBSR vs. DI) and change in sleep quality (See Figures 7 and 8 and Table 21). In other words, participants in the MBSR group experienced a significant decrease in stress, which in turn was associated with improvements in sleep quality. Testing of the mediation model followed MacKinnon's (2008) recommendations. First, the direct effect was tested by establishing a significant relationship between the predictor (MBSR vs. DI) and outcome variable (changes in sleep quality ($\beta = -.25$, $p < .05$) with the MBSR group showing greater improvements in sleep quality than the DI group. Next, the mediator was regressed on the predictor. Change in transplant related stress was found to be significantly associated with Group ($\beta = -.31$, $p < .01$) such that the MBSR group had greater improvement in transplant related stress than the DI group. The third step involved regressing change in sleep

quality on both Group and change in transplant related stress. The relationship between changes in stress and changes in sleep quality was significant ($\beta = .36$, $p < .01$). After entering the mediator into the model, the relationship between group and changes in sleep quality was no longer significant ($\beta = -.17$, $p = .15$). A Sobel test determined that the drop in predictor-outcome relationship from the direct to the mediated model was significant (Sobel = -2.04, $p < .05$). In other words, compared to the DI group, the MBSR showed greater improvements in transplant related stress, which were associated with significant improvements in sleep quality. Thus, part of the reason why MSBR was more effective than DI in improving sleep was because MSBR was more effective than DI in decreasing stress.

Discussion

The goal of this study was to test several mediators that, based on past research, may have the potential to explain why the MBSR intervention was more effective than a wait-list in reducing depression and anxiety and improving sleep quality in a sample of solid organ transplant patients. The findings suggest that transplant related stress partially mediates the relationship between MBSR and improvements in sleep quality. In other words, MBSR led to decreased stress, which was associated with improvements in sleep quality. Because change variables were used for both the mediator and outcome variable, causation cannot be definitively stated.

This finding is consistent with other studies that have demonstrated that an MBSR intervention decreases stress and improves sleep quality in chronically ill patients (Carlson & Garland, 2005, Carlson et al., 2004). This is the first study located

to investigate transplant related stress as a mediator to partially explain how MBSR effects improvements in sleep quality.

Figure 7. Direct effect of Group on Changes in Sleep Quality

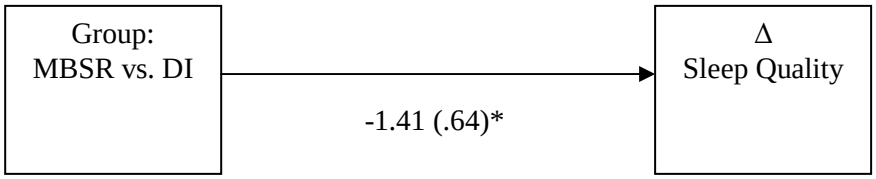
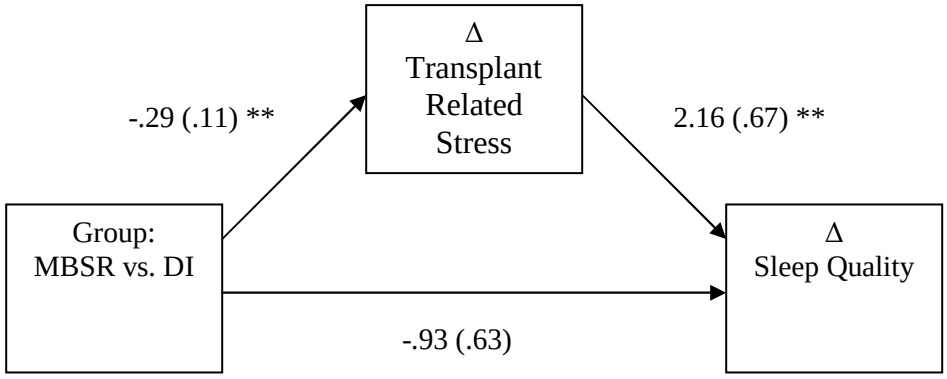


Figure 8. Mediated Effect of Group on Changes in Sleep Quality



* p < .05
** p < .01

Table 21
Testing Changes in Stress Mediating the Relationship Between Group and Changes in Sleep Quality

Steps in Mediation Model	B	SE B	95% CI	β
Step 1				
Outcome: Δ Sleep Quality				
Predictor: Group	-1.41	.64	-2.69, -.13	-.25*
Step 2				
Outcome: Δ Stress				
Predictor: Group	-.29	.11	-.50, -.08	-.31**
Step 3				
Outcome: Δ Sleep Quality				
Mediator: Δ Stress	2.16	.67	.82, 3.49	.36**
Predictor: Group	-.93	.63	-2.20, .33	-.17

* p < .05
** p < .01

Note. CI = Confidence interval

Appendix D

Alphabetically Ordered Measures

CENTER FOR EPIDEMIOLOGIC STUDIES DEPRESSION SCALE

Instructions: Below is a list of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week.

1	**2**	**3**	**4**
Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)

a. I was bothered by things that usually don't bother me.
b. I did not feel like eating; my appetite was poor.
c. I felt that I could not shake off the blues even with help from my family or friends.
d. I felt that I was just as good as other people.
e. I had trouble keeping my mind on what I was doing.
f. I felt depressed.
g. I felt that everything I did was an effort.
h. I felt hopeful about the future.
i. I thought my life had been a failure.
j. I felt fearful.
k. My sleep was restless.
l. I was happy.
m. I talked less than usual.
n. I felt lonely.
o. People were unfriendly.
p. I enjoyed life.
q. I had crying spells.
r. I felt sad.
s. I felt that people dislike me.
t. I could not get "going."

COPING STRATEGIES INVENTORY

Instructions: Take a few minutes to think about your transplant experience over the past 4 weeks. In particular, consider an event or situation that has been stressful or troubling to you. Please read each item below and determine the extent to which you used it in handling the stress of your organ transplant and caring for your health.

In the past 4 weeks…

1	2	3	4	5
Not at all	**A little**	**Somewhat**	**Much**	**Very Much**

a. I tried to get a new angle on the situation.
b. I looked for the silver lining, so to speak; tried to look on the bring side of things.
c. I went along as if nothing were happening.
d. I told myself things that helped me feel better.
e. I looked at things in a different light and tried to make the best of what was available.
f. I tried to forget the whole thing.
g. I asked myself what was really important, and discovered that things were not so bad after all.
h. I did not let it get to me; I refused to think about it too much.
i. I convinced myself that things aren't quite as bad as they seem.
j. I avoided thinking or doing anything about the situation.
k. I stepped back from the situation and put things into perspective.

MEDICAL OUTCOMES STUDY SOCIAL SUPPORT SURVEY

Instructions: People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it?

None of the the time	A little of the time	Some of the time	Most of the time	All of the time
1	2	3	4	5

a. Someone to have a good time with.
b. Someone to confide in or talk to about yourself or your problems.
c. Someone to get together with for relaxation.
d. Someone to share your most private worries and fears with.
e. Someone to turn to for suggestions about how to deal with a personal problem.
f. Someone to do something enjoyable with.
g. Someone who understands your problems.

MINDFUL ATTENTION AWARENESS SCALE

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what <u>really reflects</u> your experience rather than what you think your experience should be. Please treat each item separately from every other item. In the past 4 weeks…

Almost Always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never
1	2	3	4	5	6

a. I could be experiencing some emotion and not be conscious of it until some time later.
b. I break or spill things because of carelessness, not paying attention, or thinking of something else.
c. I find it difficult to stay focused on what's happening in the present.
d. I tend to walk quickly to get where I'm going without paying attention t what I experience along the way.
e. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.
f. I forget a person's name almost as soon as I've been told it for first time.
g. It seems I am "running on automatic," without much awareness of what I'm doing.
h. I rush through activities without being really attentive to them.
i. I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS: The following questions related to your usual sleep habits during the past 4 weeks only. Your answers should indicate the most accurate reply for the majority of days and nights in the past 4 weeks. Please answer all questions.

During the past 4 weeks, when have you usually gone to bed at night?

BED TIME: _____

During the past 4 weeks, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES: _____

During the past 4 weeks, what time have you usually gotten up in the morning?

GETTING UP TIME: _____

During the past 4 weeks, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

HOURS OF SLEEP PER NIGHT: _____

During the past 4 weeks, how often have you had <u>trouble sleeping</u> because you…

Not during The past month	Less than once a week	Once or twice a week	Three or more times a week
1	2	3	4

a. Cannot get to sleep within 30 minutes
b. Wake up in the middle of the night or early morning
c. Have to get up to use the bathroom
d. Cannot breathe comfortably
e. Cough or snore loudly
f. Feel too cold
g. Feel too hot
h. Have bad dreams
i. Have pain
j. Other reason(s), please describe & rate how often you had trouble sleeping because of this:_____
_____

During the past 4 weeks, how would you rate your sleep quality overall?

Very Good	Fairly Good	Fairly Bad	Very Bad
1	2	3	4

During the past 4 weeks, how often have you taken medicine (prescribed or "over the counter") to help you with:

Not during The past month	Less than once a week	Once or twice a week	Three or more times a week
1	2	3	4

Sleep
Anxiety
Depression

During the past 4 weeks, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during The past month	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
1	**2**	**3**	**4**

During the past 4 weeks, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem At all	**Only a very slight problem**	**Somewhat of problem**	**A very big problem**
1	**2**	**3**	**4**

SELF-EFFICACY FOR CHRONIC DISEASE

Instructions: Living with an organ transplant often means doing different tasks and activities to manage your condition. How confident are you that you can do these tasks regularly <u>at the present time</u>?

Not at all Confident									**Totally confident**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

a. Do all of the things necessary to manage your transplant on a regular basis?
b. Judge when the changes in your health mean you should visit a doctor?
c. Do the different tasks and activities needed to manage living with an organ transplant so as to reduce your need to see a doctor?
d. Reduce the emotional distress caused by living with an organ transplant so that it does not affect your everyday life?
e. Do things other than just taking medications to reduce how much living with an organ transplant affects your everyday life?
f. Ask your doctor things about living with an organ transplant that concern you?
g. Discuss openly with your doctor any personal problems that may be related to living with an organ transplant?
h. Keep the fatigue caused by living with an organ transplant from interfering with the things you want to do?
i. Keep the physical discomfort or pain of living with an organ transplant from interfering with the things you want to do?
j. Keep any other symptoms or health problems you have from interfering with the things you want to do?

SERENITY SCALE

Instructions: The following items describe experiences (thoughts and feelings, or actions). To the right of each statement are numbers that describe how often you have the experience. "1" means *never*, "5" means *always,* or you may select 2,3, or 4. The lower the number, the less often you have the experience. There are no "right" answers, only answers that best describe you. Do not think about the statement too long. Give the answer you think of first, based on how things have been with you in the last 4 weeks.

Never				**Always**
1	**2**	**3**	**4**	**5**

a. I am aware of an inner source of comfort, strength and security
b. During troubled times, I experience an inner source of strength
c. I trust that life events happen to fit a plan which is larger and more gentle than I can know.
d. I see the good in painful events that have happened to me.
e. I experience peace of mind
f. I am forgiving of myself for past mistakes.
g. I take care of today and let yesterday and tomorrow take care of themselves.
h. In problem situations, I do what I am able to do and then accept whatever happens even if I dislike it.
i. I accept situations I cannot change.
j. I try to place my problems in the proper perspective in any given situation.
k. I am aware of an inner peace.
l. I experience an inner quiet that does not depend on events.
m. I find ways to share my talents with others.
n. When I get upset, I become peaceful by getting in touch with my inner self.
o. I attempt to deal with what is, rather than what was, or what will be.
p. Even though I do not understand, I trust in the ultimate goodness of the plan of things.
q. I experience an inner calm even when I am under pressure.
r. I feel that I have done the best I could in life.
s. I can feel angry and observe my feeling of anger and separate myself from it and still feel an inner peace.
t. I trust that everything happens as it should.
u. I feel forgiving of those who have harmed me.
v. I feel serene.

STATE TRAIT ANXIETY INVENTORY

Instructions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Not at all	Somewhat	Moderately so	Very much so
1	2	3	4

a. I feel calm
b. I feel secure.
c. I am tense.
d. I feel strained.
e. I feel at ease.
f. I feel upset.
g. I am presently worrying over possible misfortunes.
h. I feel satisfied.
i. I feel frightened.
j. I feel comfortable.
k. I feel self-confident.
l. I feel nervous.
m. I am jittery.
n. I feel indecisive.
o. I am relaxed.
p. I feel content.
q. I am worried.
r. I feel confused.
s. I feel steady.
t. I feel pleasant.

TRANSPLANT RELATED STRESSORS SCALE

INSTRUCTIONS: People who have had a transplant sometimes have difficulty with the following aspects of their health. How much stress has each of these aspects caused you in the <u>past 4 weeks</u>?

Not at all Stressful	A little stressful	Somewhat stressful	Very stressful	Extremely stressful
1	2	3	4	5

a. Loss of income
b. Medical costs
c. Handling insurance matters (e.g. forms, claims, people, etc.)
   Medication side-effects (e.g. weight gain, hunger, change in appearance, etc.)
d. Fear of organ rejection
e. Susceptibility to infection
f. Susceptibility to other illnesses (besides infection)
g. Physical limitations (e.g. change in activity level, lack of energy)
h. Uncertainty about your health
i. Frequent clinic and follow-up visits