PHASE I PILOT OF A MINDFULNESS-BASED STRESS REDUCTION INTERVENTION FOR HEAD AND NECK CANCER PATIENTS RECEIVING TREATMENT OF CURATIVE INTENT

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Mindfulness-Based Stress Reduction Pilot for Head and Neck Cancer Patients
KEY MESSAGES

- A novel one-on-one mindfulness intervention for Head and Neck Cancer patients undergoing potentially curative radiotherapy has been shown to be of interest to eligible patients.
- Feasibility has been demonstrated with excellent adherence of participants to the intervention, although patients with higher treatment side effects are less likely to complete the entire program.
- Compliance with the program requirements has been demonstrated, with participants meditating regularly outside of sessions. Moreover, patient adherence to meditation practice continues independent of their levels of radiotherapy side effects and pain.
- Clinicians were able to deliver the intervention with a high degree of fidelity, again independent of patient’s level of radiotherapy side effects and pain.
- This intervention was found to be generally attractive to eligible HNC patients, with the exception of patients with heavier current alcohol and tobacco use.
- Finally, the results of this study offer preliminary evidence that the intervention may improve patient’s levels of mindfulness and have positive effects on post-intervention psychological distress and quality-of-life. However, these results need to be confirmed using a further, Phase II study.
This study was motivated by previous work which found that Head and Neck Cancer (HNC) patients undergoing radiotherapy experience very high levels of distress; in particular, elevated depression and anxiety and poor quality-of-life. We have adapted a group Mindfulness-Based Stress Reduction (MBSR) program to fit in with the particular needs of this patient group. This program has a preventative focus, aiming to reduce post-treatment depression and anxiety and improve quality-of-life during this period.

MBSR is particularly well suited to the challenges faced by cancer patients. The cancer experience is often marked by a feeling of a loss of control, uncertainty, constant change and being “betrayed” by one’s body. Mindfulness gives patients the tools to deal with these feelings, allowing them to accept things the way they are, turn towards difficult emotional experiences, embrace change, and become gently reacquainted with their bodies. Our MBSR program made several adjustments to a traditional MBSR approach, including delivery in a one-to-one format, reducing the length and number of the sessions, removing the silent retreat and simplifying the yoga exercises. These changes made it possible for a group of patients suffering from severe treatment toxicities to participate in an MBSR program.

This study reports the results of a pilot intervention trial with HNC patients while they underwent radiotherapy or chemoradiotherapy. The primary aims of the study were to assess whether patients were interested in and able to participate in the MBSR intervention. This was assessed through their attendance of sessions (feasibility), their meditation practice outside of sessions (compliance), the clinicians’ adherence to the treatment manual (fidelity) and whether differences existed between those who participated in the intervention and those that did not (acceptability). The secondary aims of the study were to assess whether participation in the intervention was associated with less psychological distress and higher quality-of-life at the end of treatment.
Nineteen HNC patients undertook this intervention. The primary aims of this study were generally met, with eligible patients interested in the program and able to complete the program, and clinicians able to adhere to the treatment manual. Feasibility was satisfied, with 84% of patients completing 4 or more sessions of the 7-session intervention, and the majority of patients (58%) completing all sessions. However, it should be noted that participants with higher treatment toxicities were less likely to complete all 7 sessions of the intervention. Compliance was largely met, with 81% of patients meditating 3 times a week for every week they were on the study. Fidelity was also met, with the amount of session content delivered by the clinicians exceeding 80% for every patient. In addition, compliance and fidelity were unaffected by increasing treatment side effects and pain. Finally, patients who participated in the program differed from those who declined only in levels of substance use before beginning treatment. Those who participated in the program drank alcohol less frequently and were less likely to be currently smoking than those who declined the intervention or withdrew.

The secondary aims of the study were also met. An association between mindfulness and the amount of meditation practice a person completed was found, suggesting that greater participation in this program increases a person’s levels of mindfulness. In addition, post-intervention mindfulness was associated with lower psychological distress and better quality-of-life when controlling for baseline levels of mindfulness. Specifically, mindfulness was associated with significantly lower anger, confusion, depression, fatigue and anxiety. In addition, mindfulness was also associated with better physical, social, emotional and functional quality-of-life, although the relationships between mindfulness and social and emotional wellbeing were the strongest of these. This is an important result, given that previous studies have found that depression increases over the course of radiotherapy for HNC patients and that HNC treatment is associated with poorer quality-of-life.

The results of this study are unique. Few studies have attempted to administer a structured psychological intervention to HNC patients while they undergo radiotherapy, despite the fact that this is an especially vulnerable time for an already highly distressed population. In addition, this is the first study to use an MBSR intervention with HNC patients. MBSR has
been demonstrated to lower anxiety and depression for survivors of breast and prostate cancer in several studies to date, suggesting it is likely to be a highly efficacious intervention for cancer patients. We intend to validate the ability of this intervention to prevent post-radiotherapy anxiety and depression and improve quality-of-life using a randomised-controlled trial.
Part 1: Context

Psychological Distress in Cancer

Diagnosis and treatment of cancer can be a particularly stressful time for an individual, with psychological distress being reported in approximately 25-30% of patients. Psychological distress can be described as a combination of symptoms of anxious mood, depression, and cognitive and behavioural impairments (1). The intensity of psychological distress is related to many factors; however it is often associated with medical considerations such as the site, stage and aggressiveness of the cancer, treatments offered and the presence of pain. In addition, psychological factors also impact on patients’ coping abilities such as resilience, communication and support from family and friends (2). Many people diagnosed with cancer experience transient periods of distress; however, a significant group develop clinical levels of anxiety and depression (3). For example, research suggests between 20-30% cancer patients will develop major depression at some stage during their illness (e.g., 4, 5). Although the data regarding anxiety amongst cancer patients is less clear, observational studies suggest about 50% of patients will experience clinically significant anxiety symptoms (e.g., 6).

Head and Neck Cancer

Head and neck cancer (HNC) is a term used to collectively describe cancers arising in the nasal cavity, sinuses, lips, mouth, salivary glands, throat or larynx (7). HNCs are the 6th most common type of cancer in the world, with approximately 650,000 new cases diagnosed each year (8). Although survival from these cancers is high, with a 5-year survival rate of approximately 60% (8), HNC patients suffer some of the highest rates of psychological distress among all cancer patients (9). HNC patients face a uniquely distressing set of challenges during treatment and recovery, including difficulties eating, breathing, swallowing and speaking, facial disfigurement, and changes in sexuality (7, 10). The high
survival rates mean that many survivors of HNC live with chronic functional impairment for many years (11). Due to this combination of factors, HNC has been described as the most emotionally traumatic of all cancers (8, 12).

**Psychosocial Research in Head and Neck Cancer**

The experience of psychological distress in HNC patients has largely focused on depression (8). HNC patients experience some of the highest rates of major depressive disorder of all cancer patients, with incidence rates ranging between 15-50% (9). Less attention has focused on anxiety, although one of the few studies examining this aspect of psychological distress found that 15% of HNC patients showed clinical caseness for anxiety (13). In addition, given that treatment for HNC is often associated with facial disfigurement, patients are vulnerable to poor body image. Body image concerns arising from HNC treatment have been associated with intimacy issues, stigma, reduced social contact and overall poorer health-related quality-of-life (11, 14, 15, 16).

Patients are particularly vulnerable to psychological distress over the course of treatment. Treatment for HNC is complex, involving any combination of surgery, radiotherapy and chemotherapy, as well the involvement of support services including dentists, speech therapists and dieticians (8). These treatments are often debilitating, and associated with a heavy burden of side effects including fatigue, pain, nausea, loss of taste or smell, xerostomia, dysphagia and mucositis (9). Previous studies have found that depression increases in HNC patients over the course of treatment (17, 18). The incidence of depression has been found to increase between 14-27% over the course of radiotherapy, with up to 75% of patients meeting caseness for at least mild depression in the period immediately following radiotherapy (17, 18). In addition, anxiety has been found to increase following treatment, with one study finding that 21% of patients met caseness for anxiety 18-months post-radiotherapy (19).
Psychosocial Interventions to Help Patients Living with Head and Neck Cancer

Despite suffering from high levels of distress, HNC patients may be less likely to participate in psychotherapy than other cancer patients (7, 20). The typical risk factors for HNC include being older and male, heavy alcohol use and smoking, minority status and socioeconomic disadvantage (8). These combined factors simultaneously increase the likelihood that HNC patients will suffer from distress and could benefit from psychological support and decrease their chances of seeking and adhering to a psychological intervention (7, 20). This unmet need for support is reflected in high suicide rates in the HNC population, with HNC patients being 1.5 times more likely to complete suicide than the wider cancer population and 4 times more likely than the general population (20).

The difficulties with properly managing psychological distress in the HNC population are compounded by a lack of clear evidence on what interventions are actually effective (7, 8). A recent review found that very few studies have developed and evaluated interventions for this group (7). This is particularly the case for the cancer treatment period, where only three studies to date have evaluated interventions delivered during active treatment (7). The few studies that have been conducted have provided mixed results, making it unclear which interventions are actually effective (7). There is therefore currently a gap in knowledge on how best to alleviate psychological distress in HNC patients, particularly during the vulnerable treatment period.

Mindfulness-Based Stress Reduction in Cancer Patients

Mindfulness-Based Stress Reduction (MBSR) is an ideal candidate for filling this gap in meeting the psychological needs of HNC patients. MBSR is a highly structured psychological intervention that is centred on the practice of mindfulness meditation (21, 22). Mindfulness is defined as present-moment non-judgemental awareness, and is a state-of-mind that is cultivated to prevent the suffering that can come with ruminating on the past or worrying about the future (21, 22). Traditional MBSR programs last for 8 weeks and involve 2.5-hour weekly group sessions, as well as a 6-hour retreat between weeks 6 and 7. Exercises
undertaken in MBSR programs are designed to enhance participant’s mindful awareness. They can take the form of formal practices, such as sitting meditations or gentle Hatha yoga exercises, or informal practices, where participants try to be present as they undertake routine tasks (21). The overall program aims to promote a sense of acceptance of current experience and a consequent reduction in suffering and distress (21).

MBSR is particularly well suited to the challenges faced by cancer patients (21, 22). The cancer experience is often marked by a feeling of loss of control, uncertainty, constant change and being “betrayed” by one’s body. Mindfulness gives patients the tools to deal with these feelings, allowing them to accept things the way they are, turn towards difficult emotional experiences, embrace change, and become gently reacquainted with their bodies (21, 23). A growing number of studies have examined the effect of MBSR interventions with general cancer populations, as well as specifically breast and prostate cancer patients (e.g., 24-27), although HNC patients have not been included in these studies so far. These studies overall have demonstrated that MBSR interventions can elicit significant positive changes in anxiety, stress and mood disturbance. MBSR intervention groups have also shown non-significant trends for improvement of quality-of-life, immune function, physiological arousal and resolution of sexual difficulties (28).

Evidence on the use of MBSR with other cancer populations suggests that this intervention may be a suitable alternative to current psychological treatments used with HNC patients, and have efficacy in reducing psychological distress. Moreover, mindful practice has already been recognised as a potential treatment for the specific challenges faced by the HNC population, such as difficulties with eating (29). As this was the first time such a program had been used with a HNC population undergoing active treatment, our primary aims were to see whether it was possible to administer this program in a hospital setting. Our secondary aims were to assess whether participation in the intervention had a relationship with participants’ distress and quality-of-life.
Research Questions

Primary questions in this study:

1. **Feasibility**: Are participants able to attend the majority of the MBSR sessions while they undergo radiotherapy (and possibly concurrent chemotherapy)?
2. **Compliance**: Do participants practice meditation outside of sessions?
3. **Fidelity**: Are clinicians able to adequately adhere to the MBSR manual while delivering sessions?
4. **Acceptability**: Are the patients who agree to participate significantly different from those who decline the program?

Secondary aims of the study:

1. **Change in mindfulness**: Do patient’s levels of self-reported mindfulness change over the course of the study?
2. **Psychological distress**: Does participation in this intervention have a relationship with lower psychological distress?
3. **Quality-of-life**: Does participation in this intervention have a relationship with higher quality-of-life?

Part 2: Implications

The MBSR program trialled in this study offers a novel treatment for HNC patients, which is delivered during the vulnerable treatment period. The results of this study demonstrate that this program is attractive to eligible patients and that their ability to participate in the program is generally unaffected by the side effects of treatment. While the benefits of this program have yet to be tested in a more rigorous, Phase II trial, this program offers a promising means of supporting HNC patients through treatment and acute recovery. This is important as very few interventions have been trialled during this period of high treatment toxicity. This work therefore has implications for three main groups:
• **Mental Health Professionals:** This program, if demonstrated to be effective in a Phase II trial, will offer mental health clinicians an effective and appealing new tool to help HNC patients during radiotherapy.

• **Head and Neck Oncology Staff:** If demonstrated to be effective, this program will give HNC oncology staff an additional, powerful resource to support their patients.

• **Head and Neck Cancer Patients and Consumers:** If demonstrated to be effective, this program will give current patients a treatment option that can help them deal with the challenges of acute treatment toxicities and radiotherapy. It is also a psychological treatment option that consumers can advocate for the use of with existing HNC patients. It is an easily applied self-care option that can complement acute treatment in a vulnerable population.

**Part 3: Approach**

**Design**

The study consisted of a pilot trial design in which participants all received the intervention. Participants took part in a 7-session tailored face-to-face MBSR intervention that was conducted one-on-one with a trained therapist. Therapists adhered to a structured treatment manual that detailed which components of the intervention were to be completed in which session. Participants commenced the MBSR intervention within the first two weeks of commencing radiotherapy or chemoradiotherapy and subsequently completed sessions on a weekly to fortnightly basis thereafter. Patients completed a questionnaire pack at baseline (before beginning the MBSR intervention) and at post-intervention (immediately after completing the MBSR intervention). Patients were also asked to practice mindfulness meditation daily while participating in the intervention, and keep a diary tracking the amount of time they spent doing so.

**Participants**

Participants were recruited between January 2013 and March 2014 from the pool of eligible patients attending the Peter MacCallum Cancer Centre (Australia’s largest comprehensive...
cancer centre), East Melbourne campus. Patient eligibility for the study was assessed by their treating radiation oncologist. Patients were eligible for this study if they had a first time diagnosis of a HNC, were aged ≥ 18 years and had agreed to undertake radiotherapy with curative intent. Exclusion criteria included the inability to give informed consent (including active psychosis, intellectual disability or dementia), receiving treatment for another cancer, or minimal understanding of English.

Procedure

Patients who were interested in participating in the study were asked to complete the consent form and the baseline questionnaire. They were also assigned a therapist and given a time for the first session. Ideally, the sessions were administered in tandem with the patient’s radiotherapy schedule as shown in Figure 1. This schedule allowed patients to complete the bulk of their sessions before the acute side effects of radiotherapy manifested, but supported them throughout the entire time they were undergoing treatment. However, flexibility in this schedule was possible, allowing the program to a) fit with a patient’s already busy treatment schedule, and b) allow for that fact that most patients became acutely unwell over the course of treatment.

During the intervention, participants were asked to meditate daily, as much as this was possible given the development of acute treatment toxicities. Patients were given specific

Radiotherapy schedule

| Planning | Weeks 1-4 | Week 5 | Week 6 | Week 7 |

MBSR intervention schedule

| Session 1 | Sessions 2-5 | Session 6 | Session 7 |

Initial sessions build skills prior to onset of side-effects

Later sessions support vulnerable patients

Figure 1. Alignment of the MBSR intervention with patient’s radiotherapy schedules.
meditations to practice each week which consisted of a minimum of 20 minutes of daily recommended meditation time. Patients were asked to complete a daily diary each week recording a) whether they meditated that day; b) how long they meditated (in minutes); c) which meditations they completed; d) their current distress; e) how bothered they currently felt by treatment side effects; and f) how much pain they were currently experiencing in their mouth, throat and neck.

Following the completion of the intervention or radiotherapy (whichever happened last), participants were asked to complete the post-intervention questionnaire.

**MBSR intervention**

The MBSR intervention used in this study was adapted from a manualised group program (23) which tailors Kabat-Zinn’s (30) program to meet the challenges of cancer treatment and survival. This cancer-specific MBSR program has previously been validated with breast, prostate (25, 26) and general cancer (27) survivor populations. The intervention used in this study made further adjustments to this program in order to make it suitable for HNC patients undergoing radiotherapy (see Appendix: Table 1). Modifications to this program were made in consultation with clinicians who are experts at delivering MBSR and treating cancer populations. The major ways in which this program has been adapted from a traditional MBSR program, and the rationale for these changes, are detailed in the Appendix (Table 2).

The program consisted of 7 90-minute sessions administered one-on-one by clinical psychologists experienced in delivering mindfulness-based treatments. Sessions were run concurrently with the patient’s radiotherapy treatment, and were administered on a weekly to fortnightly basis (Figure 1).

Patients were asked to practice both formal and informal meditations daily while participating in this study. Formal meditations were given to the patients in the form of recordings on a CD or in handouts during sessions (see Table 1 for the specific meditations.
recommended each week). The therapists were supervised regularly by a clinical psychologist with expertise in MBSR.

**Outcome measures**

**Primary outcomes**

**Feasibility**

The pilot intervention was considered feasible if at least 60% of patients adhered to the program. Therapists recorded each week whether patients attended their sessions. The total number of sessions a patient attended was used to see whether patients could feasibly participate in this program during active treatment. If a patient completed 4 or more sessions they were considered to have adhered to the program. A 4-session minimum was chosen as the cut off for this criterion as the core skills in the program are taught during the first 4 sessions.

**Compliance**

The diaries were used to see whether patients practiced meditation every day. If a patient practiced meditation at least 3 times a week for every week they were on the study, they were considered to have complied with the program requirements.

**Fidelity**

Checklists of each session’s content were completed by therapists. If therapists completed at least 80% of the session content for each participant, fidelity was met. Therapists met for regular group supervision to ensure the program content was delivered and to discuss any obstacles.

**Acceptability**

Patient characteristics, including cancer histology, age, sex, marital status and smoking status and alcohol use were collected for and compared between those eligible patients who participated versus those who declined. The program was considered to be acceptable to eligible HNC patients if these characteristics did not significantly vary between these two groups.
Secondary outcomes:
The secondary outcomes were assessed using a combination of information gathered from the mindfulness diaries and the baseline and post-intervention questionnaires. The measures collected in these questionnaires will be detailed below.

Mindfulness
Mindfulness was assessed using the Five-Factor Mindfulness Questionnaire (FFMQ; 31), a 39-item measure of mindful awareness with 5 subscales: nonreactivity to inner experience, observing sensations, acting with awareness, describing with words and nonjudging of experience. Higher scores indicate greater practice of mindfulness (31).

Psychological Distress
Psychological distress was assessed using a number of scales. Overall psychological distress was assessed using the Profile of Mood States-Short Form (POMS-SF; 32) total score. Specific mood states were assessed using the POMS-SF subscales: anger-hostility, confusion-bewilderment, depression-dejection, fatigue-inertia, tension-anxiety and vigor-activity. Higher scores indicate greater psychological distress on all scales except vigor-activity, where lower scores indicate greater distress. The POMS-SF and its subscales have generally shown good internal reliability (α = .80-.93) in cancer samples (33).

Cancer-Related Quality of Life
Patient perceived Quality of Life (QoL) was measured using the 28-item Functional Assessment Cancer Therapy – Head and Neck module (FACT-H&N; 34). This instrument is specifically devised to evaluate the socio-emotional wellbeing and disease and treatment specific QoL of patients with Head and Neck cancer. The FACT- H&N is sensitive to fluctuations in patient level of functioning on the basis of treatment status and overall performance. The FACT- H&N evaluates patient functioning across 5 domains: physical well-being, social and family well-being, emotional well-being, functional well-being, and head and neck specific symptoms. A higher score correlates with better quality of life in that domain.
**Statistical Analysis**

**Primary outcomes:** Feasibility, compliance and fidelity were all assessed using percentages and summary statistics (e.g., means and standard deviations). Acceptability was assessed using appropriate group comparison statistics (Fisher’s exact test or independent samples t-test). The relationships between primary outcomes and side effects and pain were assessed using regression models with clustered standard errors to account for the non-independence of the outcome variables.

**Secondary outcomes:** Changes in scores between baseline and post-intervention were assessed using paired-samples t-tests. The bivariate relationships between median meditation time and self-reported mindfulness were assessed using Pearson’s product-moment correlations. The relationships between self-reported mindfulness and psychological distress and quality-of-life were assessed using multiple linear regression models, including both baseline and post-intervention mindfulness as predictors.

**Part 4: Results**

**Sample characteristics**

Nineteen participants took part in the MBSR intervention (see Appendix: Table 3). The majority of patients were male (84%), were aged 60 years or older (58%), were married or de facto (58%), had post-secondary education (58%), were employed (63%) and were living in the Melbourne metropolitan area (74%). Patients were generally diagnosed with a squamous cell carcinoma (84%). None of the patients were currently smoking, and the majority had low-risk alcohol consumption patterns (58%) and no current diagnosis of a psychological illness (84%).

The final group of participants were drawn from an initial pool of 412 HNC patients. Of these patients, 318 (77%) were ineligible to participate, with 123 (40%) patients already having commenced radiotherapy, 81 (25%) not meeting criteria due to physical or psychological illness-related reasons, 33 (10%) unable to participate due to logistics-related reasons, and
another 81 (25%) ineligible due to other reasons (such as not speaking English or declining radiotherapy). This left 94 (23%) patients eligible to participate, and all were invited to undertake this study. Of these 21 (22%) agreed to participate and 73 (79%) declined. Finally, of the 21 patients allocated to the MBSR program, 2 (10%) withdrew before completing any sessions (see Appendix: Figure 1).

**Primary outcomes**

**Feasibility**

16 participants (84%) completed at least 4 sessions of the MBSR intervention, meeting the feasibility criterion. The mean number of sessions attended across participants was 5.93. Notably, the majority of participants (11 participants, or 58%) completed all 7 sessions of the intervention (see Figure 2). These results suggest that it is feasible for patients to take part in a tailored MBSR program while undergoing radiotherapy.

![Figure 2](image-url)  
*Figure 2. Frequency of sessions attended by participants in the study. The dotted line marks the minimum number of sessions a participant needed to attend to consider the program feasible.*
However, it should be noted that those people (8, or 42%) who failed to complete all 7 sessions of intervention reported significantly higher levels of radiotherapy side effects over the course of the study than those who completed all sessions, \( Z = -2.310, \ p = .021 \). Using a scale of 0-4, where higher scores indicate greater side effects, participants who completed all 7 sessions reported a median rating of side effects intensity of 1 over the course of treatment (IQR = 1, 2). In contrast, people who completed less than 7 sessions reported a median rating of side effects intensity of 2 (IQR = 1, 3). This suggests that people who experience higher side effects during radiotherapy may have difficulty completing the entire intervention.

**Compliance**

81% of participants practiced mindfulness meditation at least 3 times a week for every week they were on the study. In addition, those participants who did not meet the compliance criterion every week only failed to practice at least 3 times a week for one week of the intervention each.

Figure 3 demonstrates the median number of days a week that patients engaged in meditation. As can be seen the average number of days that participants meditated per week exceeded 3 for every week of the intervention. These two results demonstrate that, while on the study, patients were able to sufficiently adhere to the meditation requirement of the program.

In addition, we assessed whether treatment side effects and pain affected the amount of days per week that patients spent meditating. No relationship was found between the number of days per week that a participant spent meditating and their treatment side effects \( (B = -.175, \ SE = .089, \ p = .069) \) or pain \( (B = -.077, \ SE = .065, \ p = .251) \). This is illustrated in Figure 4, where the number of days patients spent meditating each week is relatively unaffected by increasing levels of side effects and pain over the course of
Figure 3. Median days spent meditating across the course of the study.

radiotherapy. This result suggests that participants are able to continue to comply with the meditation requirement of this program even when experiencing high levels of side effects and pain from their cancer treatment.

Figure 4. Relationship between treatment side effects, pain and average days per week spent meditating across the course of radiotherapy. Note that the side effects and pain scales have been doubled to make their scores comparable to the days per week variable, meaning they range from 0-8 in this figure.
Fidelity

The amount of session content delivered by the clinicians was above 80% (range: 81-100%) for each participant, satisfying the fidelity criterion. In addition, as demonstrated by Figure 5, the average percentage of content delivered per session remained high across the intervention. This suggests that it is possible for clinicians to reliably adhere to the treatment manual and deliver this intervention in a standardised fashion.

Figure 5. Average percentage of content delivered per session across the intervention.

Figure 6. Relationship between treatment side effects, pain and percentage of session content delivered across the course of radiotherapy. Note that all scales have been converted into scores out of 100.
As with compliance, we assessed whether the participant’s treatment side effects and pain interfered with the clinician’s ability to deliver the intervention. No relationship was found between the amount of session content delivered and level of side effects ($B = -.010$, $SE = .015$, $p = .531$) or pain ($B = -.005$, $SE = .015$, $p = .750$). This is demonstrated in Figure 6, where fidelity remains high even in the final weeks of radiotherapy.

Acceptability
Those patients who participated in the MBSR intervention were compared with those who declined or withdrew across a number of demographic characteristics (see Table 1).

Table 1. Assessment of the acceptability of the MBSR intervention to eligible HNC patients (N = 93).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Accepted (n = 19)</th>
<th>Declined or withdrawn (n = 74)</th>
<th>Significantly different?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancer characteristics</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cancer histology type*</td>
<td>84% SCC</td>
<td>86% SCC</td>
<td>No</td>
</tr>
<tr>
<td>16% other</td>
<td>14% other</td>
<td></td>
<td>(p = .706)</td>
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<tr>
<td><strong>Patient characteristics</strong></td>
<td></td>
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<tr>
<td>Gender</td>
<td>68% men</td>
<td>76% men</td>
<td>No</td>
</tr>
<tr>
<td>32% women</td>
<td>24% women</td>
<td></td>
<td>(p = .562)</td>
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<tr>
<td><strong>Age</strong></td>
<td></td>
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<tr>
<td>$M = 56.89$ years</td>
<td>$M = 61.12$ years</td>
<td>No</td>
<td>(p = 0.174)</td>
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<tr>
<td>$SD = 13.96$</td>
<td>$SD = 11.47$</td>
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<tr>
<td><strong>Remoteness</strong></td>
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<tr>
<td>74% major cities</td>
<td>73% major cities</td>
<td>No</td>
<td>(p = .927)</td>
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<tr>
<td>21% inner regional</td>
<td>18% inner regional</td>
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<td></td>
</tr>
<tr>
<td>5% outer regional</td>
<td>8% outer regional</td>
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<tr>
<td>0% remote</td>
<td>1% remote</td>
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<tr>
<td><strong>Marital status</strong></td>
<td></td>
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<tr>
<td>58% married or de facto</td>
<td>72% married or de facto</td>
<td>No</td>
<td>(p = 187)</td>
</tr>
<tr>
<td>42% unmarried</td>
<td>28% unmarried</td>
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<tr>
<td><strong>Lives alone</strong></td>
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<tr>
<td>26% yes</td>
<td>24% yes</td>
<td>No</td>
<td>(p = 1.000)</td>
</tr>
<tr>
<td>74% no</td>
<td>76% no</td>
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<tr>
<td><strong>Employment status</strong></td>
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<tr>
<td>63% employed</td>
<td>63% employed</td>
<td>No</td>
<td>(p = 1.000)</td>
</tr>
<tr>
<td>37% unemployed</td>
<td>37% unemployed</td>
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<tr>
<td><strong>Substance use</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Currently smoking</td>
<td>0% yes</td>
<td>14% yes</td>
<td>No</td>
</tr>
<tr>
<td>100% no</td>
<td>86% no</td>
<td></td>
<td>(p = .075)</td>
</tr>
<tr>
<td><strong>Risky alcohol consumption</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>61% low risk</td>
<td>41% low risk</td>
<td>No</td>
<td>(p = .108)</td>
</tr>
<tr>
<td>39% risky</td>
<td>59% risky</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Frequency of alcohol consumption</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11% never</td>
<td>21% never</td>
<td>Yes</td>
<td>(p = .002)</td>
</tr>
<tr>
<td>17% monthly or less</td>
<td>18% monthly or less</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22% 2-4 times a month</td>
<td>6% 2-4 times a month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33% 2-3 times a week</td>
<td>6% 2-3 times a week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17% 4+ times a week</td>
<td>48% 4+ times a week</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. SCC = squamous cell carcinoma. 2. Risky alcohol consumption is defined as consuming more than the weekly recommended limit of alcoholic drinks.
Those people who participated in the intervention did not differ from those who declined or withdrew in cancer characteristics (histology type) or patient characteristics (gender, age, remoteness, marital status, whether they lived alone or employment status).

However, the two groups significantly differed in the frequency with which they consumed alcohol, with around 50% of patients who did not participate in the intervention consuming alcohol 4 or more times per week at the time that treatment was beginning (Figure 7). In addition, the majority of participants who declined or withdrew (59%) had risky levels of alcohol consumption at the beginning of treatment (defined as consumption above the weekly recommended limit) compared to those who participated (39%), although this difference was not significant. Finally, none of the patients who participated were currently smoking at the beginning of treatment, compared to 14% of those who declined, although this difference was again non-significant.

These findings suggest that the MBSR intervention is broadly acceptable to HNC patients who are scheduled to undergo radiotherapy. However, it appears that patients who have higher levels of alcohol and tobacco consumption may be less likely to participate in this program.

![Graph showing frequency of alcohol consumption](image)

**Figure 7.** Frequency with which HNC patients consumed alcohol, comparing those who participated in the study versus those who did not.
Secondary outcomes

Changes in Mindfulness

Participants’ mean mindfulness scores (as assessed by the Five Factor Mindfulness Questionnaire, or FFMQ; see Part 3) were compared between the baseline and post-intervention timepoints (Figure 8). Although Total Mindfulness increased over the course of the study (baseline: $M = 3.50$, $SD = 0.26$; post-intervention: $M = 3.60$, $SD = 0.43$), this change was not large or significant ($t(14) = -0.596$, $p = .561$). Specific mindfulness subscales, especially Observing Sensations and Non-reactivity to Inner Experience, showed a larger increase over the course of the study, although these changes were again non-significant (Observe: $t(14) = -1.067$, $p = .304$; Nonreact: $t(14) = -0.747; p = .468$). These findings offer preliminary evidence that this intervention may be able to increase mindfulness for the people who participate, but the small sample makes it difficult to see this trend clearly.

In addition, the median amount of time that participants spent meditating per week correlated moderately to strongly with the mindfulness scales at post-intervention, but not baseline, suggesting that greater amounts of participation in our program increased participants’ levels of mindfulness (Table 2). In particular, overall mindfulness and the Observing Sensations subscale increased strongly with the amount of time participants spent practicing per day.
Table 2. Relationship between median time spent meditating and baseline and post-intervention self-reported mindfulness (N = 19).

<table>
<thead>
<tr>
<th>Mindfulness Scale</th>
<th>Average Time Spent Meditating Per Day</th>
<th>Correlation with baseline mindfulness</th>
<th>Correlation with post-intervention mindfulness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full scale</td>
<td>0.011</td>
<td>0.576*</td>
<td></td>
</tr>
<tr>
<td>Observe</td>
<td>0.140</td>
<td>0.689**</td>
<td></td>
</tr>
<tr>
<td>Describe</td>
<td>-0.050</td>
<td>0.184</td>
<td></td>
</tr>
<tr>
<td>Awareness</td>
<td>-0.130</td>
<td>0.218</td>
<td></td>
</tr>
<tr>
<td>Non-judge</td>
<td>0.043</td>
<td>0.302</td>
<td></td>
</tr>
<tr>
<td>Non-react</td>
<td>-0.038</td>
<td>0.367</td>
<td></td>
</tr>
</tbody>
</table>

* p < .05, ** p < .01

Psychological Distress

Participants’ levels of psychological distress (as assessed by the Profile of Mood States – Short Form, or POMS-SF; see Part 3) were assessed before and after taking part in the MBSR intervention (Figure 9). The changes in psychological distress were modest and non-significant for most scales, with the exception of vigour which significantly declined (baseline: $M = 6.13$, $SD = 1.38$; post-intervention: $M = 3.60$, $SD = 1.03$; $t(14) = 2.227$, $p = 0.043$). This is in contrast to previous studies where depression has been found to increase substantially over the course of radiotherapy (17; 18).

Figure 9. Changes in psychological distress scores between baseline and post-intervention.
When statistically taking into account participants’ pre-intervention levels of mindfulness, there were a number of significant relationships between post-intervention mindfulness and psychological distress (see Appendix: Table 5). Higher Total Mindfulness and Acting with Awareness were both related to lower Total Psychological Distress, Anger, Confusion, Depression, Fatigue and Anxiety. Additionally, Non-judging of Inner Experience was related to lower Total Psychological Distress, Anger, Confusion, Depression, Fatigue and Anxiety. These results suggest that changes in participant’s mindfulness scores over the course of the intervention are associated with better psychological functioning and lower distress at the end of the intervention. This implies that the intervention has the potential to help HNC patients manage their psychological distress over the course of radiotherapy. This includes depression and anxiety, which, as discussed in the introduction to this report, is a major psychological issue faced by HNC patients during and after radiotherapy.

**Quality-of-life**

Similarly, changes in participants’ quality-of-life were assessed between baseline and post-intervention (Figure 10). The FACT-H&N subscales that measured participants’ physical functioning (i.e., physical function and HNC specific wellbeing) significantly decreased over the course of radiotherapy, reflecting the burden of treatment toxicities and pain. However,
scales that reflected social support (social wellbeing) and emotional processing (emotional wellbeing) did not change over the course of the intervention.

As with psychological distress, the relationship between post-intervention quality-of-life and mindfulness was assessed while statistically taking into account participant’s baseline levels of mindfulness (see Appendix: Table 6). Again, acting with awareness was one of the main predictors of post-intervention quality-of-life, predicting higher wellbeing across all domains except HNC Specific Symptoms. In addition, overall mindfulness and/or non-judging of inner experience was related to total quality-of-life, social wellbeing and emotional wellbeing. These results suggest that changes in mindfulness over the intervention have the ability to improve HNC patient’s quality-of-life at the end of radiotherapy, especially their social and emotional functioning.

**Discussion**

The results of this study demonstrate that HNC patients are interested in participating in a structured, mindfulness-based intervention while they undergo radiotherapy. In addition, the patients who did undertake this intervention were able to complete an acceptable amount of sessions and meditation practice for the program to be considered successful. Clinicians were also able to sufficiently adhere to the therapeutic manual for the program to be reliably administered across patients.

Moreover, the preliminary results from this study suggest that participation in this program may lead to lower levels of psychological distress and higher social and emotional wellbeing. This is an important result, given that previous studies have found that depression increases over the course of radiotherapy for HNC patients (17, 18) and that HNC treatment is associated with poorer quality-of-life (11, 14, 15, 16).

There are two findings from this study that suggest that alterations to our intervention may be necessary for it to more fully benefit HNC patients undergoing radiotherapy. The first is the finding that patients with heavier substance use at the beginning of treatment are less
interested in participating in the intervention. This suggests that these patients may be using alcohol and tobacco to cope with their diagnosis and treatment, which is unhelpful given that these substances increase the risk of recurrence of HNC (35). In the future, particular attention could be paid to discussing the benefits of participating in such a program with these patients, stressing that it is an alternative to these maladaptive coping strategies. Secondly, the finding that patients who suffered from a heavier burden of side effects had difficulty completing all 7 sessions of the intervention is of interest. Alterations to this program are planned (see Part 6) which will make it easier for very sick patients to complete all 7 sessions.

Overall, the results of this study highlight that this is a promising intervention to help HNC patients cope with the emotional stress of radiotherapy and/or chemotherapy. This study also highlighted ways in which the intervention can be strengthened in order to improve its appeal to HNC patients and the ability of patients to fully complete the program. We are currently writing up the results of this study for publication.

Part 5: Additional Resources


Part 6: Future Research

We intend to apply for an NHMRC Project Grant during the 2015 granting round to seek funding for a Phase II Randomised-Controlled Trial of this intervention. This will allow the
promising secondary outcomes of this study, namely that it has the potential to improve psychological distress and quality-of-life, to be rigorously tested. In designing the RCT, we plan to incorporate the findings from the pilot study in several ways:

- As indicated in Figure 2, 123 HNC patients (30% of all screened patients) were not recruited to the study due to having already commenced radiotherapy. With a greater number of therapists and research assistants available, these patients could have been approached to undertake this study, essentially doubling the number of eligible patients. This greatly increases the pool of patients available to complete the intervention in a larger trial.

- Revisions to recruitment will be made, where particular attention will be paid to those with heavy current alcohol or tobacco use to see whether their acceptance rates can be increased.

- Some changes to the intervention will be made to increase the likelihood of patients with a heavy burden of side effects completing all 7 sessions. This will include reducing down the content of the last 3 sessions to the core, essential elements.

References


APPENDIX
Table 1. The seven MBSR sessions and their corresponding content.

<table>
<thead>
<tr>
<th>Session</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction to Mindfulness</td>
<td>Patients are introduced to the basics attitudes and ideas underlying mindfulness practice. They are introduced to meditation. Patients set a goal they wish to get out of therapy. The mindfulness diary and home practice of meditation is introduced. <em>Homework:</em> body scan and informal meditation.</td>
</tr>
<tr>
<td>2. Breathing and Body Sensations</td>
<td>The patient is introduced to breathing meditations. The role of perception in how we experience the world is discussed through examining our experience of pain and pleasant events. Further mindfulness theory is introduced through the awareness triangle. <em>Homework:</em> sitting meditation and/or body scan, and informal meditation.</td>
</tr>
<tr>
<td>3. Stress and Unpleasant Events</td>
<td>The mechanisms of stress are explained, as well as how mindfulness can change the way we respond to stress. Our relationship with aversive events is explored. Moving meditations are introduced. <em>Homework:</em> sitting meditation and/or moving meditation, and informal meditation.</td>
</tr>
<tr>
<td>4. Acceptance and Avoidance</td>
<td>The role of avoidance in emotional suffering is explained, and mindfulness-based tools are taught to help cope with unchangeable aversive experience. Difficult emotions are explored. <em>Homework:</em> sitting meditation and/or moving meditation, and informal meditation.</td>
</tr>
<tr>
<td>5. Cultivating Beneficial States of Heart and Mind</td>
<td>The role of thoughts in suffering is explored. Patients are introduced to more advanced forms of mindfulness meditations to encourage feelings of strength and resilience. <em>Homework:</em> sitting meditation, moving meditation and/or imagery meditation, and informal meditation.</td>
</tr>
<tr>
<td>6. Deepening and Expanding</td>
<td>Participants build on the learnings from previous sessions to begin practicing meditation without guidance, as well as more advanced forms of meditation which are designed to cultivate feelings of love, kindness and compassion. Further tools are taught for dealing with stressful situations. <em>Homework:</em> sitting meditation, metta meditation and/or moving meditation, and informal meditation.</td>
</tr>
<tr>
<td>7. Moving into the World</td>
<td>The program is reviewed, and whether the patient feels they accomplished their goals is discussed. Patients discuss ways they can continue their mindful practice without the support of therapy. Patients write a letter to themselves, which is posted to them 3 months after they complete the intervention.</td>
</tr>
</tbody>
</table>
Table 2. Modifications made to the MBSR program used in this study that differ from a traditional MBSR program.

<table>
<thead>
<tr>
<th>Modification</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery is in an individual, not group format</td>
<td>As this program was designed to be administered concurrently with radiotherapy, a group format was not possible (36). In addition, this format increases the flexibility of the program for patients suffering from treatment side-effects (22).</td>
</tr>
<tr>
<td>7 sessions were delivered, rather than 8</td>
<td>One session was removed to reduce the burden on patients undergoing active treatment for cancer. In addition, radiotherapy for HNCs generally lasts for 7 weeks, meaning 7 sessions fit better with patient’s radiotherapy schedules (36).</td>
</tr>
<tr>
<td>Sessions were 60-90 minutes, rather than 2.5 hours</td>
<td>The individual format meant that sessions could be shorter that with traditional MBSR. In addition, the shorter sessions reduced the burden on patients and allowed them to fit the program within their other hospital appointments (36).</td>
</tr>
<tr>
<td>Silent retreat was omitted from the program</td>
<td>The individual format meant that this component of MBSR was not possible (36).</td>
</tr>
<tr>
<td>Yoga exercises were modified to moving meditation exercises.</td>
<td>Patients undergoing active treatment for HNC are often in poor health, suffering from side effects such as nausea. In addition, these patients often have other physical impairments such as feeding tubes or healing surgery wounds (18). As such, traditional yoga was considered too intensive for this population. However, patients with a current yoga practice were encouraged to continue as far as it was feasible.</td>
</tr>
<tr>
<td>Characteristic</td>
<td>n</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>----</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
</tr>
<tr>
<td><strong>Age</strong></td>
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</tr>
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<td>20-39</td>
<td>3</td>
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<tr>
<td>40-49</td>
<td>1</td>
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<tr>
<td>50-59</td>
<td>4</td>
</tr>
<tr>
<td>60-69</td>
<td>8</td>
</tr>
<tr>
<td>70+</td>
<td>3</td>
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<tr>
<td><strong>Cancer histology type</strong></td>
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</tr>
<tr>
<td>SCC</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td><strong>Cancer treatment/s</strong></td>
<td></td>
</tr>
<tr>
<td>Radiation therapy only</td>
<td>3</td>
</tr>
<tr>
<td>Chemo + radiation therapy</td>
<td>5</td>
</tr>
<tr>
<td>Surgery + radiation therapy</td>
<td>9</td>
</tr>
<tr>
<td>Surgery + chemo + radiation</td>
<td>2</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>Married or defacto</td>
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</tr>
<tr>
<td>Not married</td>
<td>8</td>
</tr>
<tr>
<td><strong>Lives alone</strong></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>5</td>
</tr>
<tr>
<td>Not alone</td>
<td>14</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Secondary or lower</td>
<td>8</td>
</tr>
<tr>
<td>Post-secondary</td>
<td>11</td>
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<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>12</td>
</tr>
<tr>
<td>Unemployed or retired</td>
<td>7</td>
</tr>
<tr>
<td><strong>Income (annual household)</strong></td>
<td></td>
</tr>
<tr>
<td>$0-15,599</td>
<td>0</td>
</tr>
<tr>
<td>$15,600-36,399</td>
<td>7</td>
</tr>
<tr>
<td>$35,400-78,000</td>
<td>7</td>
</tr>
<tr>
<td>$78,001 or more</td>
<td>5</td>
</tr>
<tr>
<td><strong>Remoteness</strong></td>
<td></td>
</tr>
<tr>
<td>Major city</td>
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</tr>
<tr>
<td>Inner regional</td>
<td>4</td>
</tr>
<tr>
<td>Outer regional</td>
<td>1</td>
</tr>
<tr>
<td><strong>Currently smoking</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19</td>
</tr>
<tr>
<td><strong>Alcohol consumption</strong></td>
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</tr>
<tr>
<td>Low risk</td>
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</tr>
<tr>
<td>Risky</td>
<td>8</td>
</tr>
<tr>
<td><strong>Current psychological illnesses</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>16</td>
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</tbody>
</table>
Figure 1. CONSORT diagram demonstrating the recruitment and participation processes in this study.
Table 4. Means, standard deviations, ranges and internal reliabilities of the secondary outcome measures at Times 1 and 2 (N = 19).

<table>
<thead>
<tr>
<th>Measure</th>
<th>BASELINE</th>
<th>POST-INTERVENTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Degree of Mindfulness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five Factor Mindfulness Questionnaire</td>
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<td></td>
</tr>
<tr>
<td>Full scale</td>
<td>3.50</td>
<td>0.26</td>
</tr>
<tr>
<td>Observe</td>
<td>3.00</td>
<td>0.67</td>
</tr>
<tr>
<td>Describe</td>
<td>3.78</td>
<td>0.58</td>
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<tr>
<td>Awareness</td>
<td>3.86</td>
<td>0.47</td>
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<tr>
<td>Non-judge</td>
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<td>0.63</td>
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<td>Non-react</td>
<td>2.94</td>
<td>0.51</td>
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<tr>
<td>Psychological Distress</td>
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<td></td>
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<tr>
<td>Profile of Mood States- Short Form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full scale</td>
<td>11.5</td>
<td>17.45</td>
</tr>
<tr>
<td>Anger-Hostility</td>
<td>1.83</td>
<td>2.60</td>
</tr>
<tr>
<td>Confusion-Bewilderment</td>
<td>3.39</td>
<td>3.74</td>
</tr>
<tr>
<td>Depression-Dejection</td>
<td>1.56</td>
<td>1.85</td>
</tr>
<tr>
<td>Fatigue-Inertia</td>
<td>6.28</td>
<td>5.96</td>
</tr>
<tr>
<td>Tension-Anxiety</td>
<td>4.39</td>
<td>3.85</td>
</tr>
<tr>
<td>Vigor-Activity</td>
<td>5.83</td>
<td>5.07</td>
</tr>
<tr>
<td>Cancer-Related Quality of Life</td>
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<tr>
<td>Functional Assessment Cancer Therapy – H&amp;N</td>
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<tr>
<td>Full scale</td>
<td>3.06</td>
<td>0.38</td>
</tr>
<tr>
<td>Physical Wellbeing</td>
<td>3.33</td>
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<td>Social Wellbeing</td>
<td>3.12</td>
<td>0.76</td>
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<tr>
<td>Emotional Wellbeing</td>
<td>3.21</td>
<td>0.51</td>
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<tr>
<td>Functional Wellbeing</td>
<td>2.30</td>
<td>0.74</td>
</tr>
<tr>
<td>Head and Neck Specific Symptoms</td>
<td>3.28</td>
<td>0.60</td>
</tr>
</tbody>
</table>
**Table 5.** Regression models showing the relationship between mindfulness and psychological distress following the MBSR intervention, controlling for baseline mindfulness ($N = 19$).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model Adjusted $R^2$</th>
<th>$\beta$</th>
<th>$t$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Psychological Distress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mindfulness</td>
<td>0.283</td>
<td>-0.774</td>
<td>-2.66</td>
<td>.021</td>
</tr>
<tr>
<td>Awareness</td>
<td>0.568</td>
<td>-0.962</td>
<td>-4.34</td>
<td>.001</td>
</tr>
<tr>
<td>Nonjudge</td>
<td>0.337</td>
<td>-0.812</td>
<td>-3.02</td>
<td>.011</td>
</tr>
<tr>
<td><strong>Anger-Hostility</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mindfulness</td>
<td>0.406</td>
<td>-0.853</td>
<td>-3.22</td>
<td>.007</td>
</tr>
<tr>
<td>Awareness</td>
<td>0.486</td>
<td>-0.799</td>
<td>-3.31</td>
<td>.006</td>
</tr>
<tr>
<td>Nonjudge</td>
<td>0.371</td>
<td>-0.824</td>
<td>-3.14</td>
<td>.008</td>
</tr>
<tr>
<td><strong>Confusion-Bewilderment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mindfulness</td>
<td>0.188</td>
<td>-0.695</td>
<td>-2.25</td>
<td>.044</td>
</tr>
<tr>
<td>Awareness</td>
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<td>-0.923</td>
<td>-4.08</td>
<td>.002</td>
</tr>
<tr>
<td>Nonjudge</td>
<td>0.314</td>
<td>-0.771</td>
<td>-2.82</td>
<td>.016</td>
</tr>
<tr>
<td><strong>Depression-Dejection</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mood Disturbance</td>
<td>0.252</td>
<td>-0.768</td>
<td>-2.59</td>
<td>.024</td>
</tr>
<tr>
<td>Awareness</td>
<td>0.294</td>
<td>-0.735</td>
<td>-2.60</td>
<td>.023</td>
</tr>
<tr>
<td><strong>Fatigue-Inertia</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mindfulness</td>
<td>0.245</td>
<td>-0.735</td>
<td>-2.46</td>
<td>.030</td>
</tr>
<tr>
<td>Awareness</td>
<td>0.741</td>
<td>-1.108</td>
<td>-6.46</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Nonjudge</td>
<td>0.320</td>
<td>-0.782</td>
<td>-2.87</td>
<td>.014</td>
</tr>
<tr>
<td><strong>Tension-Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Mindfulness</td>
<td>0.300</td>
<td>-0.802</td>
<td>-2.79</td>
<td>.016</td>
</tr>
<tr>
<td>Awareness</td>
<td>0.523</td>
<td>-0.900</td>
<td>-3.87</td>
<td>.002</td>
</tr>
<tr>
<td>Nonjudge</td>
<td>0.504</td>
<td>-0.938</td>
<td>-4.03</td>
<td>.002</td>
</tr>
</tbody>
</table>

N.B. Only significant relationships have been included in this table.
Table 6. Regression models showing the relationship between mindfulness and quality-of-life following the MBSR intervention, controlling for baseline mindfulness (N = 19).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Model Adjusted $R^2$</th>
<th>$\beta$</th>
<th>$t$</th>
<th>$p$</th>
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<tbody>
<tr>
<td>Total Quality-of-Life</td>
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<tr>
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<td>.002</td>
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<tr>
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<td>4.02</td>
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<td>2.48</td>
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</table>

N.B. Only significant relationships have been included in this table.