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Title:
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Date:
2017-03-01

Citation:
Pollard, A., Burchell, J. L., Castle, D., Neilson, K., Ftanou, M., Corry, J., Rischin, D., Kissane, D. W., Krishnasamy, M., Carlson, L. E. & Couper, J. (2017). Individualised mindfulness-based stress reduction for head and neck cancer patients undergoing radiotherapy of curative intent: a descriptive pilot study. European Journal of Cancer Care, 26 (2), https://doi.org/10.1111/ecc.12474.

Individualized Mindfulness-Based Stress Reduction for Head and Neck Cancer patients undergoing radiotherapy of curative intent: A descriptive pilot study

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Grants: This research was supported by a grant from *beyondblue*© (grant number: Couper 6509).

Received Date : 17-Jun-2015

Revised Date : 18-Jan-2016

Accepted Date : 22-Jan-2016

Article type : Original Article

Abstract

People with Head and Neck cancer (HNC) experience elevated symptom toxicity and co-morbidity as a result of treatment, which is associated with poorer psychosocial and quality-of-life outcomes (QoL). This Phase I study examined whether an individualised Mindfulness-Based Stress Reduction (IMBSR) program could be successfully used with HNC patients undergoing curative treatment. Primary aims were to explore feasibility, compliance, acceptability and fidelity. Secondary aims were to determine whether a) participation in the intervention was associated with changes in post-intervention mindfulness and, b) post-intervention mindfulness was associated with post-intervention distress and QoL. Nineteen HNC patients participated in a 7-session IMBSR program with pre and post-test outcome measures of psychological distress, depression, anxiety and QoL. Primary aims were assessed by therapists or participants. Mindfulness, distress and QoL were assessed using self-report questionnaires at pre- and post-intervention. Longer time spent meditating daily was associated with higher post-intervention mindfulness. After controlling for pre-intervention mindfulness, there was an association between higher post-intervention mindfulness and lower psychological distress and higher total, social and emotional QoL. This study offers important preliminary evidence than an IMBSR intervention can be administered to HNC patients during active cancer treatment. A randomised controlled trial is warranted to confirm these findings.

Keywords: Head and Neck Cancer, Mindfulness, Psychological, Quality-of-life.

Internationally, head and neck cancers (HNCs) are the sixth most common type of cancer in the world (Parkin et al. 2005), and demonstrate a 5-year survival rate of approximately 60% (Jemal et al. 2002). HNCs include cancers arising in the nasal cavity, sinuses, lips, mouth, salivary glands, throat or larynx (Luckett et al. 2011). Although treatment may be of curative intent, it is always complex and burdensome, involving a 6-7-week radiotherapy regime that may be augmented by concurrent chemotherapy, surgery, support and rehabilitation services, especially dietetic support (Howren et al. 2013). The experience of receiving radiation treatment can be both uncomfortable and anxiety provoking. Radiation treatment for HNC involves the use of precisely focussed external beams, and thus requires patients to be secured under a mask covering the face and head region, and occurs on most days over a 6-7 week period. Common, and frequently severe, toxicities of HNC treatment arising from radiation/chemotherapy and surgery include fatigue, pain, nausea, dry mouth (xerostomia), altered swallowing (dysphagia), and an inflamed oral cavity (mucositis). Significant challenges during treatment and recovery include weight loss and deconditioning associated with alterations in eating and swallowing, difficulties with speaking and breathing, and facial disfigurement (Allison et al. 2004; Luckett et al. 2011). Toxicity effects are frequently cumulative during the course of treatment and for several weeks following treatment completion, and many patients will experience significant and distressing acute side effects for several months. Not all toxicities can be reversed, thus it is not uncommon for survivors of HNC to live with chronic functional impairment for many years following treatment (Kissane et al. 2013). It is evident that HNC patients experience high rates of psychological distress compared to other cancer types, with adverse impacts of treatment affecting everyday functioning (Lydiatt et al. 2009).

Pre-existing psychological morbidity in this population is known to be high, often associated with higher than average alcohol and tobacco use, whilst HNC patients report high rates of major depressive disorder (incidence rates: 15-50%; Howren et al. 2013; Lydiatt et al. 2009) and clinically significant anxiety (15%; Pandey et al. 2007). Elevated suicide rates also occur in the HNC population, with HNC patients being 1.5 times more likely to complete suicide than the wider cancer population (Zeller 2006). Patients are particularly vulnerable over the course of cancer treatment, with several studies indicating that levels of depression and anxiety increase in HNC patients during this period (Chen et al. 2009; Neilson et al. 2010 & 2013), whilst measures of quality-of-life (QoL) decline across

radiotherapy (Neilson et al. 2010). A previous longitudinal study by this research team found that depression increased between the commencement of radiotherapy and up to 3 weeks following, while anxiety increased between 3-weeks and 18-months post-radiotherapy, with lower physical QoL connected to worse depression and anxiety (Neilson et al. 2013).

Despite these elevated levels of distress, it has been suggested that HNC patients may be less likely to participate in or adhere to psychotherapy than other cancer patients (Luckett et al. 2011; Zeller 2006). The challenges in managing distress in this population are compounded by a lack of clear evidence that psychological interventions can be effective (Howren et al. 2013; Luckett et al. 2011). Only three studies to date have evaluated interventions delivered during the active treatment phase (Luckett et al. 2011).

Mindfulness-Based Stress Reduction

Third wave approaches, including mindfulness, view distress and suffering as both normative and appropriate responses to certain adverse situations, including cancer (Roemer & Orsillo 2010). In this context psychological distress does not represent pathology, but rather the variety of (usually adaptive) human processes and responses to adverse life events (Hulbert-Williams 2014). Traditionally, cognitive behavioural therapies (CBTs) have taken a problem-focussed approach, targeting thoughts and thought content, with the aim of correcting or minimising cognitions associated with distress. Interventions of this type require substantial patient commitment and effort and are usually highly verbal (Segal et al. 2001). In contrast mindfulness interventions are focussed on developing a) greater self-awareness and self-regulation of attention in the present moment and b) openness and acceptance of present experience (Kahl et al. 2012). The emphasis in mindfulness interventions on openness to and acceptance of experiential and psychological phenomena aims to promote greater flexibility in coping with both positive and negative aspects of individual experience, acknowledging that suffering and discomfort are components of direct experience.

Research on applications of mindfulness for the treatment of medical conditions has received increasing attention from psychosocial clinicians and researchers. Mindfulness is described as a process of bringing a certain quality of non- judgemental attention and awareness to moment by moment experience (Kabat-Zinn, 1990). Mindfulness has its origins in ancient Buddhist practice, however contemporary interest in mindfulness has been developed in a more secular medical environment, in part inspired by the Jon Kabat-Zinn's introduction of a manualised approach Mindfulness Based Stress Reduction (MBSR) (Carlson, 2012). MBSR is a manualised approach which was initially developed to treat

chronic pain and is now used more widely in the context of chronic illness to reduce psychological morbidity associated with chronic illness (Kabat-Zinn, 1998). Clinical applications for mindfulness based interventions (MBI's) have continued to evolve since that time and now extend to interventions for depression, generalised anxiety disorders, dialectical behaviour therapy and cancer treatments (Bishop, 2004; Carlson, 2012). Mindfulness training is viewed as an approach to reducing vulnerability to stress and emotional distress (Bishop et al 2004). Interventions employing mindfulness techniques therefore represent a shift in therapeutic emphasis away from cognition towards acceptance-based approaches that view suffering as a significant component of experience in cancer. Mindfulness interventions can be viewed as a form of mental training, cultivating openness to and acceptance of experiential and psychological phenomena, with the aim of promoting greater flexibility in coping with both positive and negative aspects of individual experience (Kabat-Zinn, 1990).

Mindfulness-Based Stress Reduction (MBSR) is an evidence-based psychotherapy particularly well suited to the challenges faced by cancer patients (Carlson 2013; Fish et al. 2014; Smith et al. 2005). The cancer experience is often marked by a feeling a loss of control, uncertainty, constant change and being "betrayed" by one's body. Mindfulness-based interventions in cancer encourage people to turn towards difficult emotional experiences, embrace change, and become gently reacquainted with their bodies (Carlson 2013; Carlson & Speca 2010). Over the past decade a growing number of studies have examined the effectiveness of MBSR interventions with general cancer populations, as well as specifically breast and prostate cancer patients (e.g., Carlson & Garland 2005; Carlson et al. 2003, 2004; Speca et al. 2000). MBSR has been shown to contribute to significant positive changes in anxiety, stress and mood disturbance in cancer populations (Carlson & Garland 2005; Carlson et al. 2003; Speca et al. 2000). HNC patients have not been included in studies of MBSR so far. Several reviews report that mindfulness interventions produce a number of significant benefits including improvements in sleep quality, QoL, mood and well-being (Ott et al. 2006; Smith 2005). MBSR intervention groups have also shown non-significant trends for improvement to immune function, physiological arousal and resolution of sexual difficulties (Shennan et al. 2011). The correlation between psychological distress and treatment toxicities across HNC treatment has been well documented (e.g., Lewis et al. 2013; Rose-Ped et al. 2002). An intervention aimed at developing flexibility and tolerance in relation to treatment side effects and distress was hypothesised to be a potentially important adjunct for people undergoing treatment for HNC.

The present study

The primary aim of this project was to determine whether an individualised MBSR intervention (IMBSR) could be successfully used with HNC patients undergoing active cancer treatment. Four hypotheses were tested: a) The program would be feasible, meaning that at least 60% of patients attended a minimum of 4 sessions; b) Patients would comply with the program requirements, meaning that patients would practise mindfulness meditation outside of sessions at least 3 days per week for every week they were on the study; c) The program would be generally acceptable to eligible patients, meaning that the patients who completed the program would not significantly differ from those who declined or withdrew, and; d) Clinicians could maintain fidelity to the treatment manual, meaning that the clinicians administered at least 80% of the session content for each participant.

The secondary aim of this study was to determine whether participation in the intervention was related to levels of post-intervention mindfulness, whether the deterioration in psychological distress and QoL across treatment reported in prior studies (Chen et al. 2009; Neilson et al. 2010, 2013) was found in this population, and whether post-intervention levels of mindfulness were associated with distress and QoL.

Methods

Participants and procedure

The Human Research Ethics committee at Peter MacCallum Cancer Centre granted ethical approval to conduct this study. The sample was recruited from patients attending outpatient HNC clinics at the Peter MacCallum Cancer Centre (East Melbourne campus) between January 2013 and March 2014. All patients were undergoing radiotherapy, with or without adjuvant chemotherapy. Patients may also have received surgery prior to beginning radiotherapy. 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 but had not yet commenced. Exclusion criteria included inability to provide informed consent (including active psychosis, intellectual disability or dementia), receiving treatment for

another cancer, having another major illness which may cause distress independent of the cancer, or minimal understanding of English.

Participants also needed to be willing to attend all 7 therapy sessions. Ninety-four patients were eligible to participate (23% of the total HNC population during the study period). Of these 21 (22%) agreed to participate and 73 (79%) declined. Two of the 21 patients (10%) withdrew before completing any sessions. Participants were recruited from consecutive eligible patients prior to commencing radiotherapy. The study employed a pre-test, post-test single-group design, whereby patients completed measures before and after the completion of the intervention. As the primary aims were to explore the feasibility of the intervention, no control group was used.

Individualised Mindfulness-Based Stress Reduction (IMBSR)

MBSR is a highly structured psychological intervention that is centred on the practice of mindfulness meditation (Carlson et al. 2003; Smith et al. 2005). 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. The IMBSR intervention delivered in this study was based on the MBSR manualised program previously tested in cancer survivors (Mindfulness-Based Cancer Recovery; Carlson & Speca 2010). The IMBSR intervention was modified in order to make it suitable for HNC patients undergoing radiotherapy (Table 1). Modifications to this program were made following a series of consultations with lead psychosocial clinicians who are experts at delivering MBSR and treating cancer populations including HNCs. The major ways in which this program deviates from a traditional MBSR program, and the rationale for these changes, are detailed in Table 2. Examples of significant adaptations include the use of water instead of a raisin as the 'tasting object' in an early exercise (to accommodate oral changes), and the removal of strenuous yoga exercises, deemed unsuitable for patients with severe treatment related toxicities in the head and neck region leading to pain and mobility difficulties. Mindfulness strategies such as acceptance, tolerance of altered bodily sensations (pain and discomfort) and management of aversive experiences, were targeted specifically to the challenges and threats posed by HNC in the manualised program.

The intervention was delivered in seven 90-minute sessions administered one-on-one by clinical psychologists with training and experience in delivering mindfulness-based treatments. All therapists attended a one-day training session, conducted by an international leader in the field. The study employed a face-to-face intervention because patients were already attending the hospital for radiotherapy treatment. IMBSR sessions were run

concurrently with the patient's radiotherapy treatment, and were administered on a weekly to fortnightly basis (Figure 1), with some flexibility to time sessions around patient availability. Participants kept a diary of meditation, were provided with tip sheets, and practised both formal (CD recordings or handouts) and informal meditations daily. The therapists were supervised monthly by a clinical psychologist with expertise in MBSR.

Measures

Demographic data

A number of self-report items were used in the pre-intervention questionnaire to obtain demographic information about the patients (see Table 3).

Primary outcomes

Feasibility. Clinicians recorded whether a patient attended each session. The total number of sessions attended was summed. The minimum number of sessions was based on the fact that a patient's burden of side effects increases by the fourth week of treatment.

Compliance. Patients completed daily diaries recording whether they practiced meditation and the duration of their meditation in minutes. The minimum number of days per week spent meditating was based on that used by Bauer-Wu et al. (2008), who conducted a comparable study of one-on-one MBSR in hematopoietic stem cell transplant patients.

Acceptability. Pre-radiotherapy characteristics of the patients who declined participation or withdrew were extracted from their medical records. This included cancer histology type, gender, age, remoteness, marital status, employment status, whether they lived alone and smoking and alcohol consumption. This was compared to information provided by patients who undertook the intervention in their pre-intervention questionnaire.

Fidelity. Clinicians recorded which parts of each session they completed using a self-report checklist. This checklist was discussed during supervision.

Secondary outcomes

Degree of Mindfulness

Mindfulness was assessed using the Five-Factor Mindfulness Questionnaire (FFMQ; Baer et al. 2008), a 39-item measure of mindfulness with five subscales: non-reactivity to inner experience, observing sensations, acting with awareness, describing with words and non-judging of experience. Participants were asked to indicate how much they agreed with each item on a 5-point Likert scale (1 = Never or rarely true; 5 = Very often or always true).

Scores are derived by dividing the raw scale by the number of items in the scale, therefore each scale ranges from 1-5. For the sake of brevity, only the full mindfulness scale will be used in this paper. Higher scores indicate greater practice of mindfulness (Baer et al. 2008). The FFMQ has demonstrated acceptable internal reliability and validity (Baer et al. 2006, 2008) in community samples. The pre-intervention (α = .84) and post-intervention (α = .84) FFMQ scales demonstrated acceptable internal reliability in this sample.

Psychological Distress

Psychological distress was assessed using the 35-item Profile of Mood States-Short Form (POMS-SF; Heuchert & McNair 2012; Shacham 1983) total score. Furthermore, specific mood states were assessed using the following POMS-SF subscales: anger-hostility, confusion-bewilderment, depression-dejection, fatigue-inertia and tension-anxiety (each with 5 items). Participants are asked to indicate how much they endorse each item on a 5-point Likert scale (1 = Not at all; 5 = Extremely). Scores are calculated using a proprietary formula (Heuchert & McNair 2012), therefore score ranges for each scale are not publically available. Higher scores indicate greater mood disturbance on all scales used in this study. The POMS-SF and its subscales have generally shown good internal reliability and validity in cancer samples (Baker et al. 2002; Curran et al. 1995). The post-intervention POMS-SF scales demonstrated acceptable internal reliability in this sample (α = .78-.97).

Cancer-Related Quality-of-Life

Patient perceived QoL was measured using the 28-item FACT-H&N (List et al. 1996). This instrument is specifically devised to evaluate the socio-emotional wellbeing and disease and treatment-specific QoL of patients with HNC. 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 five domains: physical well-being (7 items), social and family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and head and neck specific symptoms (12 items). Participants indicate how much they endorse each item on a 5-point Likert scale (0 = Not at all; 4 = Very much). Scores are derived by dividing the raw scale by the number of items in the scale, therefore each scale ranges from 0-4. A higher score correlates with better QoL on that domain. The FACT-H&N has been shown to be valid in other HNC populations (List et al. 1996). The post-intervention internal reliabilities were all acceptable in the current sample (α = .78-.93).

Data Analysis

Continuous variables were assessed to see whether they met the assumptions of parametric testing appropriate for each test (e.g., independence, normality, linearity, multicollinearity). Most assumptions were met, although the small sample size meant that normality could not be accurately assessed. As such, the outcomes of the t-tests and correlations were compared with their non-parametric equivalents (Wilcoxon Rank-Sum test and Spearman's rank correlation respectively) and were not found to differ (McDonald 2014). Parametric testing was therefore considered appropriate in this study.

Feasibility, compliance and fidelity were assessed using percentages. Acceptability was assessed using appropriate group comparison statistics (two-sided Fisher's exact tests or independent samples t-tests).

Changes in scores between pre- and post-intervention mindfulness were assessed using paired-samples t-tests, and effect sizes reported using Cohen's d. The bivariate relationships between mean time spent meditating per day and pre-and post-intervention self-reported mindfulness (FFMQ) scores were assessed using Pearson's product-moment correlations, and effect sizes reported using Pearson's r. The relationships between self-reported mindfulness and psychological distress and QoL were assessed using multiple linear regression models, including both pre- and post-intervention mindfulness as predictors. The effect size reported for each model was the partial η^2 of post-intervention mindfulness on each outcome, controlling for pre-intervention mindfulness. A significance level of 0.05 was used for all significance testing. Adjustments for multiplicity were not made for the secondary outcomes on the basis that these outcomes are exploratory and are not considered confirmatory evidence (Freemantle 2001). Analyses were completed using Stata version 13.1 (StataCorp 2013).

Results

Participant Characteristics

Nineteen participants took part in the IMBSR intervention (see 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%).

Primary Outcomes

Feasibility

Sixteen participants (84%) completed at least 4 sessions of IMBSR, meeting the feasibility criterion. The majority of participants (11, or 58%) completed all 7 sessions of the intervention.

Compliance

Fifteen participants (78%) practiced mindfulness meditation at least 3 times a week for every week during the study period (compliance target 100%). While this failed to fully meet the compliance criterion, the remaining four participants (22%) met this criterion for all but one of the week of the study.

Acceptability

Study participants did not differ from those who declined or withdrew in cancer histology type ($p = .706$), gender ($p = .562$), age ($t(111) = 11.03$, $p = 0.120$, $d = 0.33$), remoteness ($p = .927$), marital status ($p = .187$), whether they lived alone ($p = 1.000$) or employment status ($p = 1.000$). However, the groups significantly differed in their frequency of alcohol consumption ($p = .002$), with those who declined or withdrew more likely to drink 4 times a week or more (48%) than those who participated (17%). In addition, there was a higher proportion of current smokers (14%) among those who declined or withdrew compared to those who participated (0%), although this difference was not significant ($p = .075$).

Fidelity

The amount of session content delivered by the clinicians was above 80% (range: 81-100%) for each participant, satisfying the fidelity criterion.

Changes in Mindfulness

Participants' mean mindfulness scores were compared between the pre- and post-intervention time points. There was no significant change in mean mindfulness scores for the whole group from pre- to post- intervention (pre-intervention: M = 3.48, SD = .06; post-intervention: M = 3.52, SD = .10; t(17) = -.475; p = .641, d = 0.09). However, levels of study participation, represented by the mean weekly amount of time that participants spent in meditation practice per day, were found to correlate strongly and significantly with post-intervention (r = .496, p = .043) but not pre-intervention mindfulness (r = .027, p = .915).

Changes in Psychological Distress and Quality-of-Life

Tension-anxiety scores significantly decreased over the course of the study; however, there was no significant change in depression-dejection scores (Table 4).

Patient's total QoL scores were significantly lower post-intervention (Table 4). Changes in QoL were largest in physical wellbeing and HNC specific symptoms, which both significantly declined across the course of the intervention.

Relationship of Mindfulness to Post-Intervention Distress

When statistically taking into account participants' pre-intervention levels of mindfulness, post-intervention mindfulness had a significant negative relationship with both total psychological distress and each of the POMS-SF subscales except fatigue-inertia (Table 5). In each case, higher levels of post-intervention mindfulness were related to lower post-intervention psychological distress, including depression-dejection and tension-anxiety. Each of these relationships had a large effect size (Cohen 1988).

Relationship of Mindfulness to Post-Intervention Quality-of-Life

Similarly, when statistically taking into account pre-intervention mindfulness, participant's post-intervention mindfulness had a significant positive relationship with a number of QoL measures (Table 5). Specifically, higher post-intervention mindfulness was related to higher total QoL, social wellbeing and emotional wellbeing. Again, each of these significant relationships had a large effect size.

Discussion

The present study describes an original report of a pilot psychological intervention for HNC. Few studies have attempted to address the challenges faced by HNC patients during active treatment, and this study is the first to demonstrate that MBSR, a promising treatment for distress in other cancer types, may be suitable to help these patients cope with treatment-related distress. In our study, a tailored individualised intervention (IMBSR) was shown to be acceptable for HNC patients undergoing radiotherapy. Participants did not differ significantly from decliners with the exception that participants reported less alcohol use. There was good adherence to the intervention, with the majority of participants attending all sessions of the IMBSR program, despite undergoing almost daily radiation therapy over a treatment period of 6 weeks. There was high compliance to the home meditation practice requirement of the program when compared to similar studies (Bauer-Wu et al. 2008). The adherence and compliance is especially significant in light of the increasing toxicity burden faced by patients as they progress through the course of radiotherapy. Our psychologists were able to deliver the intervention, however future research should incorporate more rigorous fidelity checks. It is noteworthy that patient compliance and clinician fidelity were maintained across the intervention, despite the high levels of toxicity that HNC patients are known to experience by the end of the treatment period (Allison et al. 2004; Luckett et al. 2011).

While the results failed to demonstrate a significant increase in the average reported levels of mindfulness for the entire group, the results did demonstrate that increased time spent in meditation practice per day was associated with a greater degree of post-intervention mindfulness. In turn, higher levels of post-intervention mindfulness were associated with lower levels of post-intervention distress and improved QoL, particularly social and emotional QoL. While these results are suggestive, due to the study design it is not possible to ascertain whether there are causal links between the time participants spent meditating, post-intervention levels of mindfulness, and post-intervention psychological distress and QoL. Future research should aim to establish whether practising daily meditation as part of an IMBSR program can improve emotional regulation and psychological self-management in HNC patients undergoing radiotherapy, as seen with MBSR used in other cancer settings (Carlson & Speca 2010; Carlson 2013).

As expected, physical, functional and HNC-specific QoL significantly declined over the course of the intervention (Table 4), corresponding to the effects of treatment toxicities documented in other studies (Lewis et al. 2013; Neilson et al., 2013; Rose-Ped et al. 2002). However, social and emotional QoL did not decline. Moreover, post-intervention mindfulness scores were significantly positively correlated with post-intervention social and emotional QoL, indicating that practice of mindfulness may ameliorate the impacts of treatment on the social and emotional components of QoL in HNC. However, as stated above, further research is required to establish whether there is a causal link between mindfulness practice and these QoL components.

This study replicated previous findings that anxiety scores decrease over the course of radiotherapy (Neilson et al. 2010, 2013). However, in contrast to findings from previous studies which have noted that depression scores increase over the course of HNC treatment (Chen et al. 2009; Neilson et al. 2010, 2013), the expected deterioration in mood did not emerge. What is more, higher post-intervention mindfulness scores were associated with lower scores of depression. We hypothesise that participation in the program might have mediated or buffered patient experiences of physical and psychological deterioration usually associated with radiotherapy. Lastly, this study appears to validate that an individualised approach to MBSR in cancer may have merit.

There were a number of limitations in this pilot study. First, the sample was small and may be unrepresentative of all HNC patients. Notably, the acceptability criterion demonstrated that participants reported lower alcohol and tobacco consumption than decliners. Secondly, the narrow window of eligibility imposed by the requirement to commence session 1 of IMBSR prior to commencement of radiotherapy may have unnecessarily reduced participation rates. Future research into this intervention could be more flexible in this regard. Finally, the lack of a control group and adjustments for multiplicity mean that the patterns of lower post-radiotherapy distress and higher QoL cannot be confidently attributed to the intervention.

In conclusion this study is an important preliminary step in showing that HNC patients can benefit from a structured psychological intervention integrated into HNC radiotherapy. The pilot suggests that patients can successfully learn preventive strategies before their physical symptoms become burdensome and can continue to utilise these strategies over the course of radiotherapy. These results also suggest that HNC patients, who are generally less likely to participate in psychotherapy than other cancer patients (Luckett et al. 2011; Zeller 2006) are able to be recruited and can adhere to a structured psychological

intervention and participate fully. IMBSR appears to be a viable approach for helping HNC patients manage their distress during radiotherapy, an established period of high psychological morbidity (Chen et al. 2009; Neilson et al. 2010, 2013). A Phase II randomised-controlled study of IMBSR versus treatment as usual is now needed.

Acknowledgements: This research was supported by a grant from beyondblue©

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Table 1. The seven sessions of the individualized MBSR (IMBSR) program and their corresponding content.

Session	Content
1. Introduction to Mindfulness	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. Homework: body scan and informal meditation.
2. Breathing and Body Sensations	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. Homework: sitting meditation and/or body scan, and informal meditation.
3. Stress and Unpleasant Events	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. Homework: sitting meditation and/or moving meditation, and informal meditation.
4. Acceptance and Avoidance	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. Homework: sitting meditation and/or moving meditation, and informal meditation.
5. Cultivating Beneficial States of Heart and Mind	The role of thoughts in suffering is explored. Patients are introduced to more advanced forms of mindfulness mediations to encourage feelings of strength and resilience. Homework: sitting meditation, moving meditation and/or imagery meditation, and informal meditation.
6. Deepening and Expanding	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. Homework: sitting meditation, meta meditation and/or moving meditation, and informal meditation.
7. Moving into the World	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 will be posted at some point in the future.

Table 2. Modifications in the individualised MBSR program used in this study that differ from Carlson and Speca's (2010) Mindfulness-Based Cancer Recovery program.

Modification	**Reason**
"Raisin" exercise was replaced with a bottle of water.	Patients undergoing radiotherapy for HNC often suffer from oral side effects that make swallowing difficult and painful (Allison et al. 2004; Luckett et al. 2011). As such, some patients may have been unable to ingest the raisin traditionally used in the senses exercise.
Delivery is in an individual format	As this program was designed to be administered concurrently with radiotherapy, a group format was not possible (Bauer-Wu 2008). In addition, this format increases the flexibility of the program for patients suffering from treatment side-effects (Smith et al. 2005).
7 sessions were delivered, rather than 8	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 (Bauer-Wu et al. 2008).
Sessions were 60-90 minutes, rather than 2.5 hours	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 (Bauer-Wu et al. 2008).
Silent retreat was omitted from the program	The individual format meant that this component of MBSR was not possible (Bauer-Wu et al. 2008).
Yoga exercises were modified to moving meditation exercises.	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 (Neilson et al. 2010). As such, traditional yoga was considered too physically intensive for this population. However, patients with a current yoga practice were encouraged to continue as long as it was feasible.

Table 3. Participant's pre-intervention demographic characteristics (N = 19)

Characteristic	**n**	**%**
Gender		
Male	13	68
Female	6	32
Age		
20-39	3	16
40-49	1	5
50-59	4	21
60-69	8	42
70+	3	16
Cancer histology type		
SCC	16	84
Other	3	16
Cancer treatment/s		
Radiation therapy only	3	16
Chemo + radiation therapy	5	26
Surgery + radiation therapy	9	47
Surgery + chemo + radiation	2	11
Marital status		
Married or defacto	11	58
Not married	8	42
Lives alone		
Alone	5	26
Not alone	14	74
Education		
Secondary or lower	8	42
Post-secondary	11	58
Employment status		
Employed	12	63
Unemployed or retired	7	37
Income (annual household)		
$0-15,599	0	0

$15,600-36,399	7	37
$35,400-78,000	7	37
$78,001 or more	5	26
Remoteness		
Major city	14	74
Inner regional	4	21
Outer regional	1	5
Currently smoking		
No	19	100
Alcohol consumption		
Low risk	11	58
Risky	8	42
Current psychological illnesses		
Yes	3	16
No	16	84

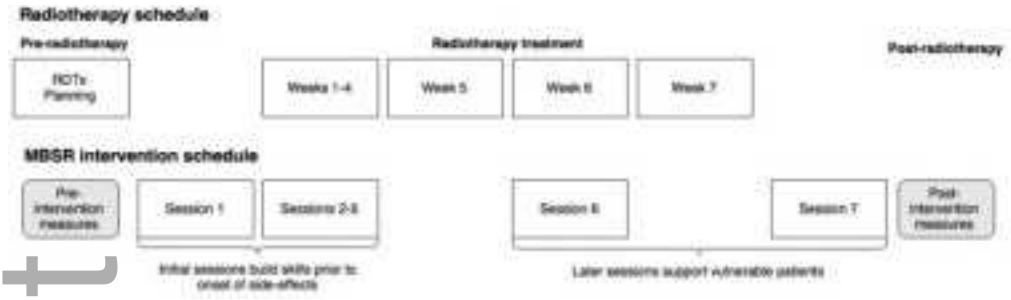
Table 4. Pre- and post-intervention quality-of-life and psychological distress scores (N = 18).

Outcome	**Pre-intervention**		**Post-intervention**		**t**	**p**	**d**
Distress Outcome (POMS-SF)	M	SD	M	SD			
Total Psychological Distress	11.39	17.50	12.78	18.39	-0.43	.672	-0.08
Anger-Hostility	1.83	2.60	1.56	2.38	0.53	.606	0.11
Confusion-Bewilderment	3.44	3.71	2.94	4.24	0.83	.417	0.13
Depression-Dejection	1.56	1.85	2.06	2.80	-0.86	.400	-0.21
Fatigue-Inertia	6.06	6.12	6.67	4.87	-0.42	.678	-0.11
Tension-Anxiety	4.89	3.83	3.28	4.48	2.20	.042	0.39
Quality-of-Life Outcome (FACT-H&N)							
Total Quality-of-Life	3.06	0.38	2.51	0.63	4.50	< .001	1.06
Physical Wellbeing	3.33	0.54	2.75	0.84	2.79	.012	0.83
Social Wellbeing	3.12	0.76	3.15	0.77	0.77	.454	-0.04
Emotional Wellbeing	3.21	0.51	3.19	0.80	0.06	.957	0.02
Functional Wellbeing	2.30	0.74	1.86	0.75	2.69	.016	0.60
HNC Specific Symptoms	3.28	0.60	1.95	0.80	6.52	< .001	1.88

Table 5. Regression models showing the relationship between post-intervention mindfulness (FFMQ), psychological distress and quality-of-life, controlling for pre-intervention mindfulness (N=18). Each row represents a separate regression model, with the outcome listed in the left column.

Distress Outcomes	β	t	p	η^2
Total Psychological Distress	-0.718	-2.56	.022	.304
Anger-Hostility	-0.803	-3.05	.008	.383
Confusion-Bewilderment	-0.664	-2.28	.037	.258
Depression-Dejection	-0.644	-2.19	.045	.242
Fatigue-Inertia	-0.616	-2.06	.057	.220
Tension-Anxiety	-0.782	-2.92	.011	.362
Quality-of-Life Outcomes				
Total Quality-of-Life	0.761	2.78	.014	.339
Physical Wellbeing	0.582	1.85	.075	.116
Social Wellbeing	0.846	3.40	.004	.343
Emotional Wellbeing	0.751	2.80	.013	.435
Functional Wellbeing	0.526	1.66	.130	.196
HNC Specific Symptoms	0.446	1.36	.180	.116

β: Post-intervention mindfulness standardised regression coefficient. η^2: Effect size coefficient (partial eta-squared) of post-intervention mindfulness on outcome, controlling for pre-intervention mindfulness.



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