Mindfulness-based stress reduction as supportive therapy in cancer care: systematic review.

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Mindfulness-Based Stress Reduction (MBSR) as supportive therapy in cancer care: A systematic literature review

ABSTRACT

Aim

To systematically review and critically appraise the evidence on the effectiveness of Mindfulness-Based Stress Reduction (MBSR) for cancer supportive care.

Methods

A comprehensive search of major biomedical databases including Medline, EMBASE, CINAHL, PsycINFO and the Cochrane Library was conducted. Specialist complementary and alternative medicine (CAM) databases including AMED and CISCOM were also searched. Additionally, efforts were made to identify unpublished and ongoing research. Relevant research was categorised by study type and appraised according to study design. Clinical commentaries were obtained for each study and included in the review.

Findings

Three randomised controlled clinical trials (RCTs) and seven uncontrolled clinical trials were found. A lack of relevant qualitative research studies was identified. Studies report positive results including improvements in mood, sleep quality and reductions in stress. A dose-response effect has been observed between practice of MBSR and improved

outcome. A number of methodological limitations were identified. Modifications to the traditional MBSR program make comparison between studies difficult and a lack of controlled studies precludes any firm conclusion on efficacy. No adverse effects from therapy were reported in the studies.

Conclusion

Systematic searching and appraisal of relevant studies has demonstrated that MBSR has potential as a clinically valuable self-administered intervention for cancer patients. A small number of RCTs and several uncontrolled studies have been published. Further research into the efficacy, feasibility and safety of MBSR for cancer patients in the nursing context is recommended.

Keywords

Mindfulness meditation, MBSR, cancer, systematic review.

SUMMARY

What is already known about this topic

- The receipt of a cancer diagnosis and having to undergo cancer treatment can have negative implications for psychological health, physical symptoms and may also adversely affect quality of life.

- Mindfulness-Based Stress Reduction has been used with various populations to facilitate psychological and physical health but its validity in the context of cancer management has not been systematically reviewed.

What this paper adds

- Assesses current state of evidence and suggests areas for future research.

- Shows MBSR has potential as a clinically valuable intervention for cancer patients.

- Suggests Nurses can facilitate cancer patients' self-help by integrating Mindfulness-Based Stress Reduction into practice.

INTRODUCTION

The receipt of a cancer diagnosis and having to undergo cancer treatment prompts a high degree of emotional distress (Strain 1998, Derogatis et al 1983, Zabora et al 1997). It can have negative implications for psychological health, physical symptoms and may also adversely affect quality of life. One Canadian survey of 913 cancer patients found that 94% of patients experienced one or more of the following psychological and quality of life-related symptoms: fatigue (78%); anxiety (77%); depression (59%) and sleep disturbance (55%)(Ashbury et al. 1998). Estimates of sleep difficulties range between 31% and 54% (Degner et al. 1995 Savard et al. 2001), with problems reported to continue for several years after diagnosis in some cancer patients (Couzi et al. 1995, Lindley et al. 1998).

The survey by Ashbury and colleagues reported that respondents were more likely to be dissatisfied with treatment for their symptoms than for their cancer (Ashbury et al. 1998). Nurses can play a vital role in addressing this deficit by incorporating complementary therapy programmes within their nursing role in the management of care for people affected by cancer.

Complementary therapies have the potential to alleviate the symptoms and side effects of cancer treatments, and may have a positive effect on levels of distress and quality of life during treatment and rehabilitation. A growing number of nurses are practicing

complementary therapies, ensuring that a variety of supportive interventions are in place in addition to conventional medical cancer treatments. Such programmes may include the running of support groups, relaxation and visualisation training and hands on therapies (Stevensen 2001).

Reports suggest that cancer patients have a growing interest in complementary and mind-body therapies. A systematic review of surveys in 13 countries indicated that 7-64% (mean 31%) of cancer patients had tried complementary medicine (Ernst & Cassileth 1998). In 1995 70% of oncology centres in England and Wales were providing some form of complementary therapy (White 1998). A recent survey found that women chose complementary therapy in order to cure or slow down their cancer, relieve the symptoms of cancer and cancer treatment (Rees et al. 2000). In addition, cancer patients reportedly use complementary therapies as a source of psychological support and emotional help (Lynda Jackson Macmillan Centre 1998). Estimates of prevalence of use of relaxation/ meditation techniques used by breast cancer patients vary between 8.4%-41% (Jacobson 2001). Variations in reporting the use of complementary therapies may, in part, be due to differential definition of CAM therapies.

What is Mindfulness-Based Stress Reduction

Mindfulness-Based Stress Reduction (MBSR) is a specific highly structured psychoeducational and skill-based therapy package that combines mindfulness meditation (also known as vipassana or insight meditation, Ott 2004) with hatha yoga exercises

traditionally delivered as an 8 week programme with an additional 7.5 hour intensive 'meditation retreat' that is taken in silence (Kabat-Zinn 1992). Classes last 2.5 hours and are taken in groups. 45-minute audiotapes of the intervention are provided for individual daily practice (Baer 2003, Proulx 2003).

An operational working definition of mindfulness is*: 'moment-to-moment non-judgemental awareness'* (personal communication Kabat-Zinn). Mindfulness has also been defined as a Zen-like approach to meditation, in which the individual focuses completely on the activity or event occurring at that moment; mindfulness contrasts with traditional meditation, whereby the intent is to free the mind of all thought (Segen 1998). MBSR is not a "technique" for stress reduction but rather a way of being or life, to be practiced, independent of illness state (Proulx 2003, Ott 2004).

MBSR was developed by Kabat-Zinn at the University of Massachusetts Medical Centre in 1979. The intervention was intended as a training vehicle for the relief of suffering to complement medical treatments and as a model for other hospitals and medical centres to implement (Kabat Zinn 2003). Mindfulness-based programs are now offered in hospitals and clinics around the world, as well as in inner city health centres, and a range of other settings (Kabat-Zinn 2003). In 1998 it was reported that there were more than 200 clinics and hospitals using MBSR in the United States (Majumdar et al. 2002). In the UK, the Centre for Mindfulness in Bangor, Wales offers Mindfulness-Based Cognitive Therapy for stress reduction (MBCT) programmes (a variation of MBSR). Classes in MBCT are also available for people with cancer attending the local hospital.

To date there has been little uptake of MBSR in cancer settings in the UK, however Mindfulness-based programmes are slowly developing. Mindfulness-Based Cognitive Therapy (MBCT) is more commonly used in the UK (Segal et al. 2002). MBCT is similar to MBSR, the major difference being an additional three minute breathing space incorporated as part of the program. MBCT programmes are offered to people suffering depression and other psychological or psychiatric conditions in Bangor, Exeter and Oxford, Lancashire, London, Southampton both within and outside the NHS.

A planned MBSR clinical trial aims to evaluate the therapeutic effectiveness of MBSR in 240 women with breast cancer attending a day centre offering support, information and complementary therapies to people affected by breast cancer. This randomised controlled trial will be the largest of its kind to be performed in this field (Hoffman, personal communication).

Many patients desire the ability to take control of their cancer management (Cassileth 1998, Ernst and Cassileth 1998,). The practice of holistic, self-help, mind-body therapies such as MBSR are congruent with patients' needs as well as nursing values and beliefs (Orem 1985, Proulx 2003), suggesting the potential for MBSR to be integrated into nursing practice (Ott, 2004). As a patient-centred therapy, it utilises self-mastery and draws on inner resources (Majumdar et al. 2002), integrating mind and body for increased awareness as well as providing stress relief.

There are no systematic reviews focusing specifically on MBSR and cancer patients. However two non-systematic reviews of MBSR have recently been published that include cancer patients. One (Proulx 2003) failed to report any systematic assessment of methodological quality and excluded studies where only abstracts were available, with one exception. Baer (2003) conducted a meta-analysis of MBSR but failed to report a search strategy or assessment of methodological quality. Research studies with cancer patients have been published since the completion of these reviews.

AIM

This review evaluated the evidence for effectiveness (including safety and patient experience) of Mindfulness-Based Stress Reduction as a supportive cancer therapy. The methodological quality of studies was appraised and gaps in the evidence highlighted. The potential value of MBSR for clinical practice is discussed together with suggestions for future research.

Studies that focus on yoga and/or meditation individually, or include such therapies as a non-MBSR based intervention are reviewed elsewhere (RCCM website).

SEARCH AND APPRAISAL METHODS

Systematic searches of major biomedical, nursing and specialist CAM databases were carried out: Medline, Embase, AMED, CISCOM, CINAHL, PsycInfo, Cochrane Library.

A search of specialist resources included Cochrane Complementary Field Registry, and other Cochrane Specialist Registries. Search strategies were developed to accommodate the different indexing approaches used by the databases (Pilkington and Richardson 2003).

Search terms

Terms for cancer were based primarily on those used by the Cochrane Cancer Field. The basic search terms used included:

(exp neoplasms/ or neoplas$.mp. or tumor$.mp. or tumour$.mp. or melanoma$.mp. or cancer.mp. or cancer$.mp. or malignan$.mp. or leukemia$.mp. or leukaemia$.mp. or carcin$.mp. or metastas$.mp. or sarcoma$.mp. or exp antineoplastic agents/ or chemotherapy.mp. or exp palliative care/ or exp palliative treatment/ or exp palliative therapy/ or exp terminal care/).

and

(Mindfulness or MBSR or yoga.mp or pranayama.mp. or dhyana.mp. or asanas.mp.or yogic.mp. or exp meditation or meditat$.mp. or transcendental meditation.mp).

Efforts were made to identify unpublished and ongoing research using relevant databases such as the National Research Register (UK) and Clinicaltrials.gov (US) together with

contacting experts in the field. Reference lists of relevant articles were reviewed to identify further studies.

Filtering

Potential research articles were noted for retrieval and given a preliminary 'study type' categorisation according to a flow-chart system. This process was carried out independently by two reviewers, notes were compared and in cases of disagreement these articles were also retrieved.

Relevant research was categorised by study type according to a flow-chart system developed for this project.

The basic categories used are shown in Table 1.

Table 1. Study categories for filtered citations

Systematic Review	Reviews including details of the methods used for searching and for the assessment of study quality.
RCT	randomised controlled trials
CCT	controlled clinical trials (not randomised)
UC studies	uncontrolled studies including uncontrolled clinical trials and case series (further categorised according to the study population i.e. random sample, consecutive series or 'best' series)
Case reports/studies	reports of individual cases/patients
Qualitative research	study designs with a qualitative approach (including in-depth

	interviews and focus groups)
Surveys	large scale, primarily quantitative structured approaches
Other	research studies not falling into above categories

Animal research and basic laboratory-based research were not included in the categorisation process.

Selection criteria

Types of studies

- Filtering only identified a small number of randomised controlled studies; therefore all research studies that included outcome measures were selected. In addition any qualitative studies were also included. Attempts were also made to locate relevant systematic reviews.

- No language restrictions were imposed at the search and filtering stage.

Types of participants

- Study participants with a primary diagnosis of cancer.

Types of intervention

- MBSR programmes as a specific intervention, mindfulness meditation therapy alone or mindfulness meditation as part of a modified psychological intervention. Modified MBSR programs were included to illustrate the disparity of application of MBSR in

research in the hope of highlighting issues relating to the differential application of therapy.

Types of outcome measures

- Patient self-reported measures of subjective well-being, quality of life and physical functioning (pain and mobility) and psychological measures (stress, anxiety, coping). Physical measures such as blood tests and saliva samples for tumour markers/ immunological function were also included.

Excluded studies are shown in table 2

Table 2 Excluded Studies

Author	**Study Type**	**Title**	**Reason for exclusion**
Hebert et al. (2001)	RCT	Change in women's diet and body mass following intensive intervention for early-stage breast cancer.	Outcome measures of dietary composition and body mass index
Massion (1997)	RCT	New research in psychosocial interventions for women with early stage breast cancer: The Bridges Study.	Report of an Annual Meeting, abstract only. It is unclear whether this is MBSR. No results available in the abstract.
Young (1999)	Qualitative	The experience of cancer patients practicing mindfulness meditation.	It is unclear whether this is MBSR. Insufficient detail available in the abstract.
Bonadonna (2000)	Qualitative	Experiencing impermanence: a theory of living mindfully with cancer.	It is unclear whether this is MBSR.

			Insufficient detail available in the abstract.
Santorelli (1992)	Qualitative	A qualitative case analysis of mindfulness meditation training in an outpatient stress reduction clinic and its implications for the development of self knowledge.	Not cancer patients
Mason and Hargreaves (2001)	Qualitative	A qualitative study of Mindfulness-Based Cognitive Therapy for depression.	Not cancer patients
Shuk-wah Helen Ma (2002)	Qualitative	Prevention of relapse/recurrence in recurrent major depression by Mindfulness-Based Cognitive Therapy	Not cancer patients

Data collection and analysis

All relevant studies were appraised and their methodological quality assessed. Relevant information was extracted independently by two reviewers using a standardised data extraction and critical appraisal form (DECA form). Differences were resolved by discussion and, if necessary, a third reviewer was involved. Where required, the advice of a statistician was sought. The DECA form was based primarily on a template published by the Centre for Reviews and Dissemination (CRD), following development and testing by two researchers.

Clinical commentaries

A clinician with relevant training and experience in both MBSR and nursing was asked to comment on each study focussing on the appropriateness of the intervention, clinical relevance and practical issues. A semi-structured question format was developed specifically for this. Summaries of these commentaries are provided in the tables of studies.

MAIN RESULTS

- No systematic reviews relating specifically to cancer patients
- No Cochrane reviews were located
- No reviews were located on the DARE (Database of Abstracts of Reviews of Effects) database

Recently published non systematic reviews of MBSR include (Bishop 2002, Baer 2003, Proulx, 2003). None focus specifically on MBSR for cancer.

Randomised controlled trials

- 2 published randomised controlled trials of MBSR (Speca et al. 2000, Shapiro et al. 2003). The follow up to Speca is reported in Carlson et al. (2001).
- 1 (ongoing) RCT of Mindfulness-Based Art Therapy (Monti 2002 not yet published)

Uncontrolled trials (7 in total)

- 4 published uncontrolled trials (Saxe et al. 2001, Majumdar et al. 2002, Carlson et al. 2003, Carlson et al. 2004).
- 2 uncontrolled trials not yet published (Spahn 2003, Bauer-Wu et al.2004)
- 1 uncontrolled trial dissertation, for which only the abstract was available (Altman 2001)

Qualitative studies

- There were no qualitative studies. However 2 clinical studies contained a qualitative element in the study design (Majumdar et al. 2002, Bauer-Wu et al., not yet published).

Other studies

- There were no surveys specifically on MBSR use
- No observational studies were found.
- No case reports were located

The evidence

All clinical trials located are presented in table 3, together with comments on their methodology and clinical relevance. Trials are also further discussed in narrative form in order to illustrate differences between studies and in an attempt to assist in highlighting the issues to be addressed in future research.

It was not considered appropriate to combine the results of studies due to variation in the interventions and in the outcomes measures.

Table 3. Summary of clinical trials in MBSR for cancer patients

Study	Study design	Sample	Inclusion criteria	CAM Tx	Control Tx	Outcome measure(s)	Results	Methodology comments	Clinical comments
Bauer – Wu et al. (2004) Not yet published Abstract only.	UCT Unknown recruitment and sampling	N= 20 Age range unknown, mean age 51 years. Hospital inpatients.	Unknown, cancer diagnosis undergoing stem cell/ bone marrow transplants.	45 minute Mindfulness meditation on a 1:1 basis, 1-2 times a week throughout hospitalisation. Audio CD provided	No control group	Psychological and physical symptoms VAS. Heart and respiratory rate, HADS, brief POMS, Symptom Experience Scale. Qualitative data Feasibility data.	Statistically significant differences for relaxation, pain, happiness, comfort, heart rate, and respiratory rate	Abstract only . 9% refusal, 15% lost to follow up. Ethics board committee is not mentioned.	Appropriate intervention, outcomes and follow up. Mindfulness meditation as opposed to MBSR .
Carlson et al. (2004)	UCT Recruitment by volunteers and invitation.	N =59 outpatients Age range not stated (Mean 54.5 years)	Stage 0, I or II breast cancer or localised prostate cancer outpatients (TNM diagnostic criteria), Aged >18. ≥3 months since surgery.	MBSR program 90 minute weekly group sessions for eight weeks 3 hour silent retreat. Audiotape provided	No control group	POMS, SOSI, EORTC QLQ-30, health behaviours questionnaire (including hours of sleep and sleep quality). Blood and saliva samples for cortisol, DHEAS, melatonin.	Significant improvements in QoL ($t=-2.23$, $p<0.05$), stress ($t=3.23$, $p<0.01$ and sleep quality. No significant improvements in mood disturbance or immuno-stimulation.	29% lost to follow up. Compliance, missing values and co-interventions adequately reported ethics board approval unkown. Multiple statistical testing and over-interpretation of results	Appropriate intervention, outcomes and follow up. Lack of longer-term follow up
Carlson et al. (2003)	UCT Same as above	N =59 age range not stated (Mean 54.5 years)	As above	As above	No control group	Same as above and Blood samples for cell counts. No saliva samples taken.	Same as above No significant improvements were seen in the overall number of lymphocytes or cell subsets	As above 29% lost to follow up	As above
Shapiro et al. (2003)	RCT Not powered or blinded	N= 63 Tx= 31N Ct=32N	Sex (female only), age (18-80), English speaking, stage II breast	Weekly 2 hour MBSR sessions for 6 weeks. Six hour silent retreat	Various stress management activities	Sleep diary Pre-and post-measures of POMS, BDI, STAI, FACIT-	No significant relationship found between sleep efficacy and MBSR	Randomisation method and other methodological factors unknown.	Appropriate intervention, control, outcomes and

			cancer diagnosis.			B and others.	practice. A positive relationship between MBSR practice and time (β=+.339).	12% Ct and 16% Tx lost to follow up. Ethics not stated	follow up. Some missing data.
Spahn et al. (2003) Abstract only ongoing study	UCT	N = 24 1 male, 23 female. Different cancer diagnosis and stage.	Inclusion criteria unknown	60 hour MBSR program over a 10 week period. Exercise, diet, behavioural and self care techniques, CAM.	No control group	Self reported EORTC-LQ 30 and Fatigue Assessment Questionnaire(FAQ) .	No improvement in overall QoL. A significant improvement in role function and fatigue were shown. *No statistical data reported.*	Complete data were available for 18N only. 25% lost to follow up and 8.3% missing values for FAQ data ethics not reported	Appropriate intervention and outcomes measures. Insufficient information to assess in detail. Co-interventions
Majumdar et al. (2002)	UCT	N= 21, aged 22-62 Patients had multiple conditions including cancer	Program open to all interested providing they were not currently psychotic or suicidal.	Weekly sessions for 2.5 hours of MBSR for 8 weeks, plus 7 hour silent retreat. Audio tapes provided.	No control	Five questionnaires for physical symptoms, quality of life and well being. Post-intervention telephone interviews and questionnaire.	Statistically significant changes in emotional, general and physical well-being ($p \leq 0.001$-$p \leq 0.047$). and QoL ($p \leq 0.001$-$p < 0.002$).	refusals=2N Co-interventions and compliance unknown. Ethics committee not mentioned. Participants paid for the course themselves.	Appropriate intervention, follow up and outcomes measures. Small sample size. Qualitative data of clinical value.
Monti (2002) ongoing study abstract only	RCT Unknown method of randomisation or sampling. Not blinded	N=96 Variety of cancer types	Aged >21, diagnosis of cancer or cancer recurrence.	Mindfulness-Based Art Therapy sessions. 2.5 hours for 8 weeks.	Usual care crossed over to receive MBAT after trial	SF-36, SCL-90-R and COPE	No findings reported as yet.	Insufficient information for full appraisal. Study ongoing. Co-interventions of Art-therapy	Limited details preclude a detailed appraisal. Unknown relative effect of art-therapy .
Altman (2001) Dissertation abstract	UCT	Unknown number of participants	Cancer outpatients, no further details reported.	4 week MBSR program. No details provided.	No control group	Physiological measures of heart rate, blood pressure and respiration rate. Unknown when measured.	Unknown results. No statistical data reported. Results suggested to be positive for stress reduction.	Abstract only. A lack of statistical outcomes measures.	Appropriate but short intervention. Outcomes measures are of limited clinical relevance.
Carlson et al. (2001)	Uncontrolled outcomes study follow up to	N= 54 (all patients had undergone the intervention)	As in Speca 2000	As in Speca 2000	No control group	POMS and SOSI measures taken at 6 months post-intervention.	Mean POMS TMD reduced from 17.4 to 10.7. Small but non significant decreases were observed in	39% Lost to follow up. Compliance, ethical approval, handling of	Appropriate intervention, outcomes and follow up.

	Speca 2000.						SOSI scores.	missing values, co-interventions unknown.	
Saxe et al. (2001)	UCT recruitment by referral	N= 10 men and their partners	Diagnosed adenocarcinoma of the prostate, post-prostatectomy with increasing levels of PSA on ≥ 2 sequential tests.	12 weekly classes of 3-4 hours duration. Plant base diet and MBSR course.	No control group	Pre and post measures of diet, weight and level of physical activity and PSA levels.	PSA rate on increase decreased in 8N. Estimated mean doubling time increased from 6.5 months to 17.7 months(95% CI).	Not a controlled study, small sample size. Differential; conditions for the assessment on some patients' assays.	Co-interventions of diet and exercise preclude evaluation of effectiveness of MBSR.
Speca et al. (2000)	RCT Randomisation adequate Not blinded. Sample from volunteers and by invitation. (see Carlson 2001)	N= 109 (90 completed) Tx= 53 Ct= 37 outpatients	Any patient having received a confirmed diagnosis of cancer at any time was eligible.	Seven, 90 minute weekly sessions of MBSR program plus home practice.	Wait list controls	POMS and SOSI	No significant between group differences on mood or stress. Significant correlations between attendance, practice and stress reduction ($r= 0.30$, $p < .05$) and ($r= -0.253$, $p < .10$) respectively.	Adequate randomisation by table of numbers. 17% Lost to follow up Adequate measure of compliance. ITT analysis performed.	Appropriate intervention, control, outcomes and follow up. No silent retreat.

Key to abbreviations

SOSI Symptoms of Stress Inventory
HADS Hospital Anxiety and Depression Scale
SF-36 Short Form-36
SCL-90 R Symptom Checklist-90
POMS Profile of Mood States
STAI, State Trait Anxiety Inventory
FACIT-B Functional Assessment of Cancer Therapy-Breast Quality of Life Instrument
EORTC-LQ-30 European Organisation for Research on Treatment of Cancer
BDI, Beck Depression Inventory

Summary of each MBSR study

RCTs

Three randomised controlled trials (RCTs) of MBSR for cancer patients were found (Table 2). Shapiro et al. (2003) randomised 63 female, stage II breast cancer patients to receive either MBSR, or to a control group who could choose their own stress management activities. No statistically significant relationship was found between group allocation and sleep efficacy, nevertheless, a statistically significant relationship was observed between reported MBSR practice and beneficial outcome over time in the MBSR group. The small sample size and between-group differences at baseline in levels of distress and sleep quality compromise the methodological rigour of this study. In addition, there is no explanation as to why 6 weeks, as opposed to the traditional 8-weeks of intervention were provided to patients. The implications of this amendment for patient outcome are unknown. Furthermore, details of the stress management chosen by the control group are not reported.

Speca et al. (2000) conducted a RCT of MBSR in cancer patients with long term follow up. 109 patients, with different types and stages of cancer (of whom 86 were women, mean age 51), were randomised to either MBSR or to a wait list control group. No statistically significant differences on mood parameters were observed between the groups post-intervention. A statistically significant positive relationship was observed between both class attendance and level of reported practice with stress reduction. This trial was not, however, powered or blinded; in contrast to the traditional program, one

day of ‘mindfulness’ training (‘silent retreat’) is missing. Results from the follow up analyses are reported in Carlson et al. (2001).

Carlson et al. (2001) report the findings from 54 patients (37 MBSR and 14 controls) who completed the 6-month post-intervention re-assessment, following the RCT conducted by Speca et al. Small but non significant between-group improvements in mood were found at six months follow-up. In the absence of follow up data from non-responders, one cannot dismiss the possibility that those who did not return the follow up questionnaires did so because they did not sustain benefit.

Monti (2002 abstract only) reports details of an ongoing randomised controlled trial of 96 cancer patients with mixed diagnoses. The intervention included Mindfulness-Based Art Therapy. Controls received usual care and crossed over to receive the intervention after trial completion. No findings are available to date. In the absence of detailed information regarding findings, only limited methodological appraisal and clinical commentary are possible. This intervention described in this study differs from the traditional MBSR program and thus the effect of the adding art therapy to the MBSR intervention is unknown. No firm conclusions can be drawn from the abstract.

Uncontrolled studies on MBSR for cancer patients

Carlson et al. (2003) conducted an uncontrolled trial with 59 cancer outpatients, who underwent MBSR training. This study assessed psychological measures, sleep quality, and is the first study to assess changes in immune system parameters (including cancer-

related cytokine production) associated with MBSR program participation. Cell counts were taken pre and post-intervention. Statistically significant improvements were demonstrated post intervention for overall quality of life, symptoms of stress and sleep quality. There were no significant differences found for mood disturbance or in the number of lymphocytes or cell subsets between pre- and post measures. Notwithstanding the positive results, the study suffers from key methodological limitations that the authors themselves identify. In the absence of a control group, no firm conclusions can be drawn from this study with regards to the efficacy of the intervention.

Carlson et al. (2004) present further findings from the same study population as Carlson et al. (2003). Further to the findings reported previously (Carlson et al. 2003), additional outcome measures of interest include the assessment of the effect of MBSR on hormone levels associated with immuno-suppression (cortisol, dehydroepiandrosterone and its sulphate (DHEAS) and melatonin). However, no statistically significant improvements for either immunological suppression or tumour remission markers were observed. Methodological flaws include the absence of a control group and multiple statistical testing.

Majumdar et al. (2002) report a study involving 21 German cancer patients with Multiple conditions including non-Hodgkins lymphoma and breast cancer who were offered MBSR training. Outcomes measures included five self-completion questionnaires (not validated for a German cancer population). All major dependent health variables (emotional well being, general physical well-being and quality of life) indicated

substantial symptom improvement following treatment. The small sample size, heterogeneous patient population and lack of control group compromises the data. Nevertheless, semi-structured interviews conducted 3 months post-intervention provide clinically relevant qualitative findings of patient self-perceived alleviation of suffering, produced either through symptom reduction, or through enhanced coping skills developed as a result of MBSR practice. It is noteworthy that the participants in this study paid for the therapy themselves, thus potentially increasing compliance and motivation to practice.

Altman (dissertation abstract 2001) reports a 4-week MBSR intervention with cancer patients. The absence of detail on sample characteristics and the lack of reporting of statistical analyses limit the extent to which this study can be methodologically appraised. The measures (heart rate, blood pressure and respiration rate) used to assess levels of stress are of limited relevance to clinical knowledge and practice in implementing MBSR since heart and respiration rate are measures of short-term excitatory physiological state. No self-reported measures of stress or quality of life were used. In addition, the provision of only four, as opposed to the traditional eight weeks of intervention limits the ability to compare with other studies.

Spahn et al. (dissertation abstract 2003) evaluated a MBSR intervention with co-interventions of moderate exercise, a Mediterranean diet, behavioural techniques, self care strategies and complementary therapies. This is an ongoing study, for which only the abstract was available. The nature of the MBSR intervention is not fully described

and statistical data is not reported. Insufficient information thus precludes a detailed methodological appraisal. Methodological limitations include the lack of a control group, missing values and the small sample size. The impact of the modifications to the traditional intervention on outcomes is unknown.

Saxe et al.(2001) documents an uncontrolled trial of a dietary intervention in conjunction with MBSR for prostate cancer patients who had increasing levels of prostate specific antigen (PSA). All patients lost weight and the PSA rate of increase decreased in 8 out of 10 participants. However, the authors acknowledge limitations in measurement due to PSA levels being tested at different sites with different instruments. Differential conditions for PSA assessment in some patients limit both the validity of this study and the conclusions that can be drawn. In addition, it is difficult to ascertain which aspect of the intervention had an effect since this study involved a modified MBSR program with co-interventions of diet and exercise. This was a small sample and details on interventions are not provided.

Bauer-Wu et al. (personal communication) provided an abstract of a completed but unpublished uncontrolled study of cancer inpatients, undergoing stem cell/ bone marrow transplants. Patients received mindfulness meditation sessions on a one-to-one basis with a trained instructor, Statistically significant differences were found for most sessions for relaxation, pain, happiness, comfort, heart and respiratory rate. Qualitative data suggest that patients found the therapy beneficial throughout hospitalisation and post-discharge, nevertheless, live sessions were preferred to the audio CD that was provided for daily

practice. This study is of interest since it considers mindfulness meditation provided to cancer inpatients on a one-to-one basis as opposed to the full MBSR intervention in a group format. The intervention utilised is appropriate in this group of hospitalised cancer patients with advanced cancer. Such modifications draw attention to the feasibility and appropriateness of MBSR in specific groups of cancer patients. Moreover, the inclusion of qualitative data and data on feasibility provide information of clinical value with a view to planning further MBSR interventions. Since only the abstract is available, however, limited methodological appraisal was possible. A larger RCT is planned (Bauer-Wu, in communication with the author, August 2004).

DISCUSSION

The methodological limitations of the studies reported in this review included small sample sizes, limited descriptions of the randomisation process (Shapiro et al. 2003), a lack of reporting of sampling and recruitment methods (Majumdar et al. 2002, Shapiro et al. 2003), non reporting of the reasons for why participants were lost to follow up and of co-interventions (Majumdar et al. 2002, Shapiro et al. 2003) and compliance (Saxe et al. 2001, Majumdar et al. 2002 and Shapiro et al. 2003). Inadequate reporting of the specifics of the MBSR intervention (types of yoga and meditation, content of each weekly session) presents a challenge for study replication and comparison between interventions.

Outcomes measures for mood, stress, anxiety and quality of life were self-reported by the patients. The instruments used for these measures (with the exception of Majumdar et al. 2002) have been shown to be reliable and valid in cancer patients and are easily administered by nursing staff. The physiological measures used by Altman (2001) had limited application to nursing practice. Outcome measures for immunological and tumour remission parameters are of interest, nevertheless, findings so far have not shown positive results. For those studies where only an abstract was available, only a limited methodological evaluation, clinical appraisal of outcomes measures and commentary of the clinical relevance of studies to practice was possible.

MBSR is a complex multimodal intervention with mindfulness as its focus. It is impossible to determine which aspect of the intervention has the beneficial therapeutic effect. However in a pragmatic trial this does not matter (Richardson 2000). Nevertheless, this has implications when studies utilise differential application of the traditional intervention since modified MBSR interventions are difficult to interpret and compare with other MBSR studies (Proulx 2003). The literature reports MBSR interventions with variations in the number of sessions (range 4-10 weeks), session duration (range 45 minutes-2.5 hours) and content including co-interventions of art therapy, diet and other complementary therapies. The impact of such variations cannot be established in light of the heterogeneity of sample characteristics, outcomes measures and of follow up times between studies. Some studies fail to report on critical points identified in patient trajectories such as time since diagnosis and stage in cancer therapy.

Such factors would have an influence on levels of stress, coping, sleep and quality of life and these should be made explicit.

The different approaches to implementing MBSR as a supportive cancer therapy have implications for transferability. To date, however, no procedure for checking adherence to the traditional intervention format is available. In practice, MBSR has been offered to patients at any stage of the cancer journey. MBSR is intended to be flexible to meet the needs of different patient groups that accounts for some variations in length of sessions and in applications across different clinical settings. Individuals participate within their own level of capability and can substitute one mindfulness activity for another, to fulfil individual needs; for example using imagery rather than physical yoga. The provision of mindfulness meditation on an individual basis (as illustrated by Bauer-Wu et al. 2004) prompts the need for further research into the appropriateness of a group intervention and of the feasibility of certain components of the MBSR therapy for patients with different cancer stages, mobility and function, treatment schedules and with different times since diagnosis.

The feasibility of the traditional 8-week intervention structure and content with a silent retreat (from a nursing staff as well as a patient perspective) is an area that would benefit from undergoing detailed evaluation in future research. The potential of a silent retreat in a hospital setting or cancer centre is not discussed in any of the papers. A further issue of importance is the patient perception of the intervention (enjoyment, patient preference, satisfaction of the intervention/ of different components of the intervention) that elude

empirical quantitative evaluation. This element is under-evaluated and the exploration of such issues would add to the body of knowledge on MBSR as a therapy for patients and would thus assist in the implementation an MBSR intervention in clinical practice. This type of research may benefit from the application of qualitative research methodologies.

As mentioned in the introduction, MBSR is not simply a “technique” for stress reduction but rather a way of being or life, to be practiced, independent of illness state (Proulx 2003, Ott 2004). This is beneficial and has implications for the cost-effectiveness of the therapy since once learnt, patients can apply MBSR throughout their illness trajectories. Kabat-Zinn’s research on MBSR for anxiety, for example reports that 84% of participants reported continuing practice of MBSR after 3 months (Kabat-Zinn 1992), with 56% still practicing 3 years later (Miller et al. 1995). To date, only one study has included a longer-term follow up of cancer patients’ practice of MBSR (Carlson et al. 2001). This study found positive results for continued practice and maintained effect after 6 months.

The integrity of MBSR treatment implementation is stated to be enhanced through rigorous training and regular supervision of therapists, along with the use of observation, review of audio or video-taped sessions and feedback procedures (Baer, 2003: 138). There are currently no formal standards by which to assess the competency of MBSR instructors, nevertheless, the Centre for Mindfulness in Meditation has recently initiated a multistage credentialing process, teacher certification in MBSR (CMM website)

CONCLUSION

To date, studies on MBSR for cancer patients have focused specifically on psychological (mood and stress) and quality of life outcomes measures with some positive results. A dose-response effect has been observed between practice of MBSR and improved outcome for sleep (Speca et al. 2000, Carlson et al. 2001, Shapiro et al. 2003). MBSR has not been shown to produce statistically significant effects on hormone levels or on immunostimulation as measured by cancer cell counts (Carlson et al. 2003, 2004). No studies have so far specifically measured the effect of MBSR on cancer patients' physical symptoms (such as pain), or on the effect of such an intervention on the side effects that stem from cancer treatment such as nausea and vomiting.

The finding of a positive relationship between increased practice and outcome is of interest. This emphasises the importance of using appropriate measures to monitor compliance with daily practice. Studies rely on attendance reports for MBSR classes and on self-reports of practice (such as diaries) from patients that cannot be easily validated. MBSR is a quite a tough programme as it demands daily practice as well as the attendance at the 8 week programme.

RCTs on MBSR have relatively small samples and may be underpowered. However, findings from these and uncontrolled trials suggest some positive trends. Studies suffer from a number of methodological limitations. Therefore, it is clear that nurses need to consider integrating MBSR into practice in the context of methodologically rigorous

research. Research should consider the appropriateness and feasibility of MBSR for patients with different characteristics (mobility, function, time since diagnosis, stage of cancer). MBSR should be evaluated in comparison to other interventions (such as relaxation, PMR, drug therapy) as part of standard care or along with other treatment packages (Baer, 2003). Additionally, the effectiveness of different core elements of the MBSR programme (body scan, sitting meditation, yoga stretches) should be compared. In addition, qualitative data on patient expectations, commitment to practice and subjective experiences would add to the increasing body of knowledge of MBSR as a supportive therapy in cancer care.

Acknowledgements

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