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UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES
SCHOOL OF HEALTH SCIENCES

A RANDOMISED CONTROLLED TRIAL EVALUATING THE EFFECT OF MINDFULNESS-BASED STRESS REDUCTION (MBSR) ON MOOD, QUALITY OF LIFE AND WELLBEING IN WOMEN WITH STAGES 0 to III BREAST CANCER

by
Caroline Jane Hoffman

Doctor of Philosophy

August 2009

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

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A RANDOMISED CONTROLLED TRIAL EVALUATING THE EFFECT OF MINDFULNESS-BASED STRESS REDUCTION (MBSR) ON MOOD, QUALITY OF LIFE AND WELLBEING IN WOMEN WITH STAGES 0 to III BREAST CANCER

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The aim of the study was to determine whether and to what extent mindfulness-based stress reduction (MBSR) has any effect on mood, disease related quality of life, wellbeing and endocrine symptoms in women with stages 0 to III breast cancer.

The study chiefly used a randomised controlled trial design. Eligible participants had previously attended a day centre, Breast Cancer Haven in London, which offers support, information and complementary therapies for women. Eligibility was based on ending hospital treatment for breast cancer no less than two months and no more than two years previously (N=229). Consenting participants were randomly assigned to either an immediate intervention or wait-list control group. Participants completed the Profile of Mood States (POMS) (primary outcome measure), Functional Assessment of Cancer Therapy –Breast (FACT-B) and –Endocrine (FACT-ES), including their trial outcome indices (TOI) and World Health Organisation Five-Item Wellbeing Questionnaire (WHO-5) as well as a short proforma to obtain qualitative data.

Two hundred and fourteen women, (mean age 49 years) completed the study, (a 93% response rate). Intention-to-treat between-group analysis showed that after the intervention, participants in the MBSR group, compared to controls, had statistically significantly improved scores on POMS Total Mood Disturbance at both eight weeks with MBSR group mean (SD) of 30.02 (31.60) compared to controls 47.81(39.81) (95% CI for difference -27.44 to -18.14, $p<0.001$) and 12 weeks mean (SD) of 29.83 (34.19) compared to controls 45.43 (35.51) (95% CI -25.01 to -6.20, $p<0.001$). Significant improvements were also found on all POMS subscales – anxiety, depression, anger, vigour, fatigue and confusion. Significant improvements were also found on a range of FACT dimensions: FACT-B, -ES, -B TOI, -ES TOI, and physical, emotional and functional wellbeing subscales, as well as on the WHO-5 Wellbeing Questionnaire. Qualitative findings revealed that participants found themselves to be more mindful and key themes included being calmer, centred, at peace, connected and more confident; being more aware; coping with stress, anxiety and panic; and accepting things as they are, being less judgemental of myself and others.

The generalisability of these findings will be limited to those women attending Breast Cancer Haven with stages 0 to III breast cancer.

MBSR was effective in improving mood state, quality of life including endocrine symptom and wellbeing in female breast cancer survivors (diagnosed with stages 0 to III breast cancer).

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Declaration of Authorship

I, Caroline Jane Hoffman

declare that the thesis entitled

An evaluation of the effect of mindfulness-based stress reduction (MBSR) in women with stages 0 – III breast cancer

and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- none of this work has been published before submission.

Signed: ……..

Date:…….

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Definitions, abbreviations used

Adjuvant chemotherapy: Chemotherapy given after surgery
AH: POMS anger-hostility subscale
Adj'd: Adjusted
BCN: Breast care nurse and breast care nurse specialist
BDI: Beck Depression Inventory
CB: POMS confusion-bewilderment subscale
CD: Compact disc
CI: Confidence interval for difference
CRUK: Cancer Research United Kingdom
DCIS: Ductal carcinoma in situ
DD: POMS depression-dejection subscale
EORTC QLQ-30: European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire
EWB: FACT endocrine wellbeing subscale
FACIT: Functional assessment of chronic illness therapy
FACT: Functional assessment of cancer therapy
FACT-B: FACT breast-specific subscale
FACT-B TOI: FACT-B trial outcome Index
FACT-ES: FACT endocrine-specific subscale
FACT-ES TOI: FACT-ES trial outcome Index
FI: POMS fatigue-inertia subscale
FWB: FACT functional wellbeing subscale
ICD-10: Classification of mental and behavioural disorders which forms a major depression inventory
Intervention group: Treatment group
Ipsilateral lymph nodes: Lymph nodes located on the same side of the body (as the cancer)
MBSR: Mindfulness-based stress reduction programme
Metastases: Transmission of pathogenic microorganisms or cancerous cells from an original site to one or more sites elsewhere in the body, usually by way of the blood vessels or lymphatics
MIDs: Minimally Important Difference scores
MOS SF-36: Medical Outcomes Study (MOS) short form. 36 item questionnaire (SF-36)
p: level of probability
PWB: FACT physical wellbeing subscale
N: total number of subjects in a study

n: number of subjects in the sample

NCSI: National Cancer Survivorship Initiative

Neoadjuvant chemotherapy: Chemotherapy given prior to surgery

NHS: National Health Service

N-K cells: Natural Killer cells

POMS: Profile of Mood States

PSA: Prostate Specific Antigen

r: correlation coefficient

R^2 : Coefficient of determination

RCN: Royal College of Nursing

SCL-90-R: Hopkins Symptom Checklist, 90 item, revised

SD: standard deviation

SF-36: Short-Form 36

Sig: significant

SOC: Sense of Coherence questionnaire

SPSS: Statistical Package for Social Sciences

SR-RP: Stress reduction and relaxation programme

SWB: FACT social wellbeing subscale

T1: Study evaluation time point at -2 to 0 weeks

T2: Study evaluation time point at 8 to 10 weeks

T3: Study evaluation time point at 12 to14 weeks

TA: POMS tension-anxiety subscale

T-cells: Thymus-dependent lymphocytes (white blood cells)

TMD: Total Mood Disturbance

UMass: University of Massachusetts, Worcester, Massachusetts, USA

VA: POMS vigour-activity subscale

VAS: Visual Analogue Scale

Visitor: term for patients attending Breast Cancer Haven

WHO-5: World Health Organisation 5-item wellbeing questionnaire

USA: United States of America

Chapter 1. Introduction

This introduction gives an overview of the thesis and outlines the background and rationale for undertaking the research study. The overall aim was to determine whether and to what extent mindfulness-based stress reduction (MBSR) has any effect on mood, disease related quality of life, including endocrine symptoms, and wellbeing in women with stages 0 to III breast cancer in the intervention (treatment) group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

In undertaking this PhD, the clinician-researcher was clear from the outset that she wanted to research an intervention that had potential to benefit the population under study and that was in line with strategic thinking and guidelines at a national level for improving care and self-management for the increasing numbers of breast cancer survivors.

This research took place over a period of high level development when the Department of Health and National Health Service formally recognised the unmet physical and psychological needs in people with cancer (*NHS Cancer Plan* Department of Health 2000) and in cancer survivors (*NHS Cancer Reform Strategy* Department of Health 2007). The Government is currently looking at ways to improve the lives of people living with a diagnosis of cancer (*National Cancer Survivorship Initiative* Department of Health 2009), the outcomes of which are to be implemented by 2012.

In wishing to find new ways to meet the needs of breast cancer survivors, this research has the potential to help those living with this chronic disease. In the UK, one in three people are diagnosed with cancer in their life time and two million people are living with a diagnosis of cancer at any one time. Over 45,000 women are diagnosed with breast cancer each year in the UK, nearly 17% of all cancer diagnoses, and 550,000 are living with this diagnosis, 2% of the total female population and 12% of the female population over the age of 65 years. For many, breast cancer is now a chronic illness with 80% of patients living for five years, 70% living for ten years and 64% for twenty years (Cancer Research UK 2008a). Women over the age of 50 account for 80% of breast cancers (Cancer Research UK 2008a) and they may require support to help them cope with the demands of this chronic and potentially life-threatening illness. Not knowing for certain who will ultimately survive breast cancer can be difficult for those diagnosed and finding approaches that will support them is important.

Treatments for breast cancer can include surgery, chemotherapy, radiotherapy and endocrine therapy, which have a range of physical and psychological sequelae that can last months and even years beyond the period of hospital treatment (Meeske et al 2007,

Schou et al 2005). Symptoms such as anxiety (van't Spijker et al 1997), depression (Bower 2008), pain (Poleshuck et al 2006), fatigue (Meeske et al 2007) and insomnia (Lis et al 2008) can reduce quality of life affecting the lives, not only of the person with cancer, but of those around them. Hospital staff, including breast care nurses, are often stretched (Royal College of Nursing and Breast Cancer Care 2004) and generally focussed on supporting those being diagnosed, making treatment choices, undergoing treatment or returning with a recurrence of cancer.

Services available for psychological support, complementary therapies and education for breast cancer survivors, including the development of self-management skills to cope better, are currently a limited postcode lottery often provided by non-government funded agencies with centres around the UK such as Breast Cancer Haven, Macmillan funded centres and Maggie's Cancer Caring Centres. Due to the pressures of health services spending, NHS provision of these services in the future is uncertain.

The clinician-researcher has been working in the field of complementary and supportive cancer care since 1993, both in the NHS and voluntary sector, and prior to that introduced and researched complementary therapies in an NHS intensive care setting as early as 1987. Over that time, she was involved in both the development and delivery of complementary therapy services and had a growing interest in interventions that would provide self-management skills to those affected by cancer, recognising the need to assist people in finding appropriate skills to help themselves in the management of their illness and their lives.

Over the last 30 years, the worldwide interest in and research of new approaches of psychological support, complementary therapies and self-management, has risen dramatically, in many instances, pioneered in the cancer community. One of the more novel approaches used to support those living with cancer is the cultivation of mindfulness. It is through the clinician-researcher's personal practice of mindfulness and the first hand experience of its benefits that led her directly to explore the possibility of researching this intervention for those with living with breast cancer.

Mindfulness, bringing attention and awareness to each moment in a non-judgemental way, is 'a way of being', a way of living one's life (Kabat-Zinn 1990). Its origins are most clearly described in Buddhist philosophy but have been used as part of psychological approaches including cognitive-behavioural therapy. In its secular form, mindfulness can be taught via a systematic eight-week MBSR programme. This course, developed by Professor Jon Kabat-Zinn from the University of Massachusetts in 1979, and has begun to be researched in a variety of health, social and educational settings to date, including in

women with breast cancer. MBSR involves the formal and informal practice of mindfulness and gives a way of understanding reactions to perceived stressors in life including reactions via thought, emotions and bodily sensations. Increased awareness of and reactions to stressors can help people diagnosed with cancer make changes to behaviour which can reduce stress (Speca et al 2000). The programme includes weekly classes and CDs for home practice.

This thesis reports on a clinical study that took the form of a pragmatic randomised controlled trial evaluating the effectiveness of MBSR on mood, quality of life including endocrine symptoms, and wellbeing in women diagnosed with stages 0 – III breast cancer compared to controls, and included a four-week follow-up period.

The study took place in 2005 and 2006 at Breast Cancer Haven in London, one of now three centres belonging to a registered UK charity offering free support, information and complementary therapies to those affected by breast cancer working in an integrated manner with the NHS. The clinician-researcher, trained in a range of complementary therapies and formerly working in an NHS complementary cancer service, developed the model of services at Breast Cancer Haven in 1999. A two-year period spent in cancer rehabilitation in the NHS from 2001-2003, enabled the clinician-researcher to do some service development with mindfulness and to commence her PhD before returning again to work at Breast Cancer Haven. From an initial search of the literature, the researcher found that the world centre of excellence for MBSR was at the University of Massachusetts, USA. Thanks to a Florence Nightingale Foundation grant, she completed the professional training programme there in 2004 and has since had the support of experts in the field of mindfulness research from USA, Canada, the Universities of Oxford, Cambridge and Bangor to help support the development of the study. Clinical supervision for the duration of the data collection was provided by a senior MBSR teacher trainer at the University of Massachusetts.

Chapter two critically reviews the background literature, placing the study in the current health care context, examining the physical and psychological needs of breast cancer survivors, existing forms of support, and gaps in service provision. It gives a rationale for the development of self-management skills for breast cancer survivors and for choosing MBSR as the self-management intervention under evaluation in this study. This context is important to understand in terms of how the research might fit in with existing services and provide additional value for breast cancer survivors.

To help further understand the approach under evaluation, MBSR, chapter three defines mindfulness, describes its origins and provides a conceptual overview. The mechanisms

of mindfulness are then discussed, the range of mindfulness-based programmes including their similarities and differences. The underpinnings of MBSR teaching are explored and measurement tools for evaluating mindfulness discussed. An overview of MBSR clinical research is given with particular emphasis on studies performed in cancer and breast cancer. In the examination of those studies, strengths, weaknesses and research gaps are indentified, some of which the current study aimed to address. By understanding previous research evaluating mindfulness, it enabled the clinician-researcher to perform a study which addressed some of the limitations of previous MBSR studies.

The methodology and methods of the current study found in chapter four, include philosophical versus pragmatic perspectives, the rationale for the chosen methodology, ethical considerations including the tensions of being a clinician-researcher, the research aims, hypotheses and research questions. The design of the study is given including the sample, setting and recruitment, randomisation, controls and blinding and liaison with medical staff. The research instruments are then discussed including the rationale for choosing these particular tools. The validation of the instruments is outlined as well as the rigour and validity of methods. The delivery of the pilot study, including preparations for teaching MBSR, is discussed and the nature of the clinical supervision received. The MBSR intervention is described. Finally, the methods of data collection and analysis are proposed. Having a careful design for the study and taking a methodical approach to each aspect of the research enabled the clinician-researcher to perform as rigorous a study as she could.

Following this, chapter five, gives the findings of the research, starting with the profile of the sample including demographic data, information about breast cancer and treatments received. The results of each hypothesis to be tested are then discussed in turn, starting with the primary outcome measure, mood, followed by secondary outcomes, quality of life, including endocrine symptoms, and wellbeing. From this approach, the way the results link to the underlying research questions can be seen. Predictors of outcomes are identified followed by an analysis of results from the qualitative data. This shows which variables had an impact on the results presented and the qualitative data analysed gives further breadth to information gathered in the study that would otherwise have been missed from the quantitative data alone.

The discussion of the current findings in their full context is found in chapter six. Key findings, factors which may have influenced these findings and key qualitative findings are also included. There is a comparison of current findings and how they extend, reinforce or challenge those from other related studies. The study's strengths and limitations are discussed in detail including generalisability and transferability. This chapter enables the

research results to be put in context of other related literature as well as highlighting elements of the study which have been performed well and where weakness exist. All this information helps the reader to see the overall quality and value of the research and its application to the wider research and healthcare context including any potential benefits to breast cancer survivors.

In conclusion, chapter seven summarises key findings and overall outcomes of the study as well as limitations and makes suggestions for future research in the field of MBSR and breast cancer. The conclusions are important as they give the clearly distilled endpoint for the work in its wider context. The ability to look at the key limitations and how these could be addressed gives a guide to possible future studies that could develop research to further improve the lives of women with breast cancer.

Chapter 2. Background literature review

2.1 Introduction

This chapter will set the scene and review the background literature for this research study starting with information about the incidence of breast cancer and survivorship issues. The existing literature evaluating the psychological and physical impact of the disease on those affected by it will be examined and appraised in key areas, particularly stress, mood, quality of life, including fatigue, pain, insomnia, menopausal symptoms and wellbeing. The chapter will then look at existing national policies and identifies current methods and interventions available to support survivors of breast cancer to meet these needs. The potential of self-management to help address these needs will be examined. The reasons for evaluating mindfulness-based stress reduction (MBSR) in this context and how it might help will then be discussed.

2.2 Literature search strategy

The literature search focused on publications in English and indexed as human studies in MEDLINE (R) 1996 to July 2008, AMED 1985 to July 2008, CINAHL 1982 to July 2008, EMBASE 1996 to July 2008 and PsycINFO 1996 to July 2008. The primary inclusion criteria were indexing by or discussion of breast cancer. Other terms used are listed below. Excluding studies reported in other languages was thought to be appropriate as the majority of the breast cancer and mindfulness communities report their studies in English. Studies of distant metastatic (Stage IV) breast cancer alone were excluded as this population is not included in the study. Qualifying publications were those indexed by “breast cancer” and one or more of the following terms: quality of life, pain, anxiety, depression, mood, anger, fatigue, social, menopause, hot flushes, insomnia, relationships, job stress, work stress, self management.

The large number of qualifying publications was reduced by focussing on reviews, RCTs and qualitative studies. Quantitative studies with small sample size, or lacking control groups were excluded due to lack of rigour in study design. Reports of studies of women currently undergoing breast cancer treatment were only retained if follow-up data post treatment was presented. From the initial searches a selection of the most relevant articles was then made with priority given to the most recent publications. Where recent work referred to relevant earlier publications these were included in the review. This principle was followed in other searches (See Appendix 1).

2.3 Incidence of breast cancer

Information compiled by Cancer Research UK (2008a, 2008b, 2008c) provides the following statistics about breast cancer incidence. Breast cancer is the most common cancer in the UK and in 2005 there were 45,947 new cases of breast cancer diagnosed, 99% of these were in women. Breast cancer risk is strongly related to age, with more than 80% of cases occurring in women over the age of 50. The highest number of breast cancer cases diagnosed is in the 50 to 69 age group. Very few cases of breast cancer occur in women in their teens or early 20s, however breast cancer is still the most commonly diagnosed cancer in women under 35. By age 35 to 39 almost 1,500 women are diagnosed each year. Breast cancer incidence rates increase with age, with the greatest rate of increase prior to the menopause; this supports a link with changing hormonal status (Cancer Research UK 2008a). Comparing these figures to the general population of women in the UK where the average age of menopause is 52, it can be seen that separating out symptoms which might be related to natural menopause versus the side effects of breast cancer treatments such as chemotherapy or radiotherapy can be a confounding factor to researching this group.

A substantial proportion of the breast cancer diagnoses made in developed countries can be explained by factors which influence exposure to oestrogen (Key et al 2001). Risk is increased by early menarche, late menopause, and obesity in post menopausal women whilst prospective studies show that higher levels of endogenous hormone estradiol are associated with increased risk. Childbearing reduces risk, with greater protection from early first birth and a larger number of births whilst a protective effect from breast feeding is likely. Both oral contraceptives and hormonal therapy for menopause cause slight increased risks which decrease with the cessation of usage. Alcohol increases risk whilst physical activity may be protective. Genetic mutations can increase risk but this is around 5% of all breast cancers (Key et al 2001).

The incidence of breast cancer has been increasing for many years in economically developed countries. In Britain, the age-standardised incidence of breast cancer per 100,000 women increased from 74 in 1975 to 123 in 2005. Over the twenty five year period 1981-2005 the incidence rate increased by 57%. The highest risk of breast cancer is in the developed world with migrants from low to high risk countries acquire the risk of the host country within two generations (Cancer Research UK 2008c). An estimated 550,000 women are alive in the UK having received a diagnosis of breast cancer (Cancer Research UK 2008b).

2.4 Stages of breast cancer

Breast Cancer is a complex illness which may involve different presentations and pathways that progression of the disease may follow. Symptoms may range from none that are obvious from physical examination through to, for example, bone pain in the presence of spinal metastases. An overview of the stages are described below in Table 2.1, see National Cancer Institute (2009) for a more detailed description.

Table 2.1. Stages of breast cancer

Stage	Tumour size (T)	Lymph node in affected by breast cancer (except where otherwise stated) (L)	Metastases in distant organs (M)
0	In situ	No	No
1	<2cm	No	No
2A	<2cm	Metastases in ipsilateral lymph nodes	No
2A	2 - 5cm	No	No
2A	Not visible	Metastases in ipsilateral lymph nodes	
2B	<5cm	Metastases in ipsilateral lymph nodes	No
2B	>5cm	No	No
3A	Not visible	Metastases in ipsilateral lymph nodes fixed or matted	No
3A	<5cm	Metastases in ipsilateral lymph nodes fixed or matted	No
3A	>5cm	Metastases in ipsilateral lymph nodes may or may not be fixed or matted	No
3B	Fixed to skin or chest wall	Lymph metastases may or may not be present, may be fixed or matted if present	No
3C	Any size	Lymph node involvement: could be present in ipsilateral, axillary, mammary and/or supraclavicular	No
4	Any size	Lymph nodes may or may not be affected but spread to other organs, some of all of liver, lung, bone or brain	

2.5 Impact of breast cancer

The impact of breast cancer on overall health, quality of life, psychological and physical functioning has been discussed at great length in the literature. In the group of ‘disease-free’ breast cancer survivors under study, there is existing evidence to show the long term effects of breast cancer and its treatments on physical, psycho-emotional and social aspects of quality of life. These effects may results from treatments such as chemotherapy and radiotherapy or the ongoing effects of endocrine treatments such as Tamoxifen or aromatase inhibitors such as Arimidex. The monoclonal antibody, Herceptin, may be useful for about 25% of women affected by breast cancer who test sufficiently positive to having the Her-2 protein. However, Herceptin can leave people with cardiac damage (Seidman et al 2002) and less harmful alternatives are being evaluated.

2.5.1 Importance of quality of life in breast cancer

Quality of life is a multidimensional construct and several psychosocial and physical factors can predict this (Lehto et al 2005). From experience researching quality of life in cancer, Fallowfield (1995) noted that in the early 1990s there was a proliferation of research papers showing the deleterious impact that both the diagnosis and treatment of

breast cancer can have on the quality of a woman's life and that there are now hundreds of tests purporting to measure health related quality of life or some aspect of it. She commented that the many psychological, social, functional and sexual problems associated with the diagnosis and treatments have been well-described in the medical literature and in the lay press and that the range of possible medical treatments may have similar outcomes in terms of responses and survival, but can produce very different effects on emotional wellbeing. She suggested that quality of life is an important measure to include in any clinical study of breast cancer and suggested a variety of measures to do this which cover a range of general health questionnaires; domain-specific measures for mood, anxiety and depression, wellbeing; and cancer-specific tests. This scope of measures used to evaluate quality of life and breast cancer make summarising the key research in this area challenging and the range of conclusions reached are quite varied across different aspects of quality of life.

The importance of measuring quality of life in breast cancer patients at all stages of disease was noted by Gupta et al (2007) who found that baseline measures of quality of life before treatment (N=251), examining health and physical functioning, social and economic, psychological and spiritual, and family dimensions, gave useful prognostic information in patients with breast cancer, independent of stage of disease. They found that patient satisfaction with a health and physical subscale was significantly associated with survival ($p=0.00006$) as was satisfaction with overall health related quality of life ($p=0.00006$). Limitations of this study however were that many of their patients had advanced disease having had failed primary treatment, so the generalisability of their findings to those with early stage breast cancer is questionable. Schou et al (2005) found that quality of life was significantly lower in women with early stage breast cancer (n=161) in emotional, cognitive and social functioning ($p<0.01$) at the time of diagnosis and in cognitive ($p=0.008$) and social ($p=0.009$) functioning one year after surgery compared to the general female population (n=949). A strength of this study is that whilst multiple statistical tests were used, authors only reported those at $p<0.01$ level of significance, but a large variation in relative sample size between breast cancer group and general population may bring the generalisability of the results into question.

Evidence from the literature review, discussed further in this chapter, found that quality of life studies identified a range of physical and psychological effects from breast cancer and its treatments. There was a wide range of evidence available from reviews to uncontrolled studies. Many of the studies relevant to this literature review were conducted some time ago. Finding directly relevant studies for this review has been challenging due the scope, breadth and variable quality of published studies. These included detrimental effects on emotional wellbeing, fatigue, insomnia, depression, anxiety, menopausal symptoms and

pain to be some of the quality of life issues that effect breast cancer survivors up to years after treatment. Below are some key studies giving evidence for this.

In a large, well-conducted longitudinal survey of long term disease-free survivors of breast cancer diagnosed an average of 6.3 years earlier (N=763), Ganz et al (2002) found that not having received past systemic adjuvant therapy including Tamoxifen was associated with better functioning on several dimensions of quality of life (p=0.003), physical role functioning (p=0.02), bodily pain (p=0.01), social functioning (p=0.02) and general health (p=0.03), while past chemotherapy was a predictor of poorer quality of life (p=0.003). Limitations of this study included representation of women from only two urban locations (Los Angeles, CA, and Washington DC) and a response rate of only 61%. From a randomised trial of women with node negative breast cancer (early stage breast cancer) (n=416) compared to controls (n=421), Whelan et al (2000) found that receiving radiotherapy given following lumpectomy compared to no radiotherapy, quality of life was significantly lower (p=0.0001) and afterwards more breast symptoms were experienced, including irritation of the skin and breast pain. However after two years, there was no difference between groups as to upset caused by the appearance of the breast, skin irritation or breast pain. A limitation of this study is that a higher level of detail of quality of life was confined to the first two months of follow-up, and was not available at two years. As part of a larger study, in the assessment of stage II breast cancer patients, who were disease free and within two years post treatment (n=62), preliminary findings from Shapiro et al (2001) indicated that greater quality of life correlated with sense of coherence ($p<0.01$), marital quality ($p<0.05$), vigour ($p<0.01$), and two positive modes of control ($p<0.01$), whilst lower quality of life correlated with greater amounts of depression ($p<0.01$), state and trait anxiety ($p<0.01$), anger and hostility ($p<0.01$), and general emotional distress ($p<0.01$). They suggest that psychosocial interventions should attempt not only to reduce psychological distress but also to enhance the potential for growth and transformation, however the small sample size in this study limits the validity of the findings.

It can be seen that a number of broad dimensions of quality of life are affected in people with breast cancer and this can last over long periods of time. More discussion on the some of the individual elements of physical and psychological wellbeing affecting quality of life are discussed in the sections below.

2.5.2 Physical effects of breast cancer in survivors

This section will give more evidence from the literature on the physical effects of breast cancer and its treatments. The physical effects which are found to be problematic for survivors are fatigue, insomnia, pain, and menopausal symptoms including hot flushes.

2.5.2.1 Fatigue

Fatigue is one of the key symptoms noted as a consequence of breast cancer and its treatments (Bower 2008, Meeske et al 2007, Broeckel et al 1998, Longman et al 1996, Hassey Dow et al 1996). In early stage breast cancer, this is more a consequence of treatment, than of the disease itself (Bower 2008). The highest level of fatigue was found in survivors who had combination therapy including chemotherapy (n = 61) ($p< 0.01$) (Broeckel et al 1998), (although this is a small sample limiting the validity of the results), radiotherapy and hormone therapy (n = 322) ($p<0.03$), but this sample was mostly white, upper middle class working women (Woo et al 1998). Between 30 - 41% of breast cancer survivors suffer from moderate to severe fatigue (Ganz and Bower 2007, Bower et al 2000, Meeske et al 2007) and this can last up to 10 years (Bower et al 2007). In a large, prospective study of women with stages 0 to IIIA breast cancer, Meeske et al (2007) found evidence of long term fatigue after five years in disease free breast cancer survivors (n=1183) negatively correlated to bodily pain ($r=-0.48$), mental health ($r=-0.54$), emotional health ($r=-0.42$), physical functioning ($r = -0.36$), physical health ($r=-0.47$), vitality ($r=-0.74$), social functioning ($r=-0.60$). Poorer quality of life was also noted in role and social functioning as a result of fatigue. General health scores as measured by the Medical Outcomes Study 36-item short-form health survey (SF-36) were significantly lower for fatigued survivors than for non-fatigued survivors ($p<0.0001$). A limiting factor of this study is that it does not include a control group. Longman et al (1996) found that the number and increase in side effects in survivors (N=307), mean age 55 years, 80% of whom had stages I or II breast cancer, were moderately correlated ($p<0.001$) in a negative direction with fatigue and depression. They found that other longer term side effects may include pain (61%), anxiety (57%), difficulty sleeping (59%), swelling (49%), and depression (49%). Again this study lacked controls not enabling any comparison.

2.5.2.2 Insomnia

Insomnia is common following treatment for breast cancer (Bower 2008, Lis et al 2008, Fiorentino and Ancoli-Israel et al 2006, Meeske et al 2007), and persists after treatment ends (Hassey Dow et al 1996). It has been noted that the incidence of insomnia is three to five-fold higher in breast cancer patients than in the general population (Berger et al 2005, Bower 2008). Lis et al (2008) found that in patients with cancer (N=954), 26% of whom had breast cancer, sleep disturbance or insomnia was characterised by reduced sleep duration and intensity. Increased insomnia has also been associated with decreased patient satisfaction ($p<0.001$) and quality of life in cancer ($p<0.0001$) (Lis et al 2008). Using a single item of the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30) global quality of life questionnaire to measure insomnia is a limitation of this study.

Insomnia and sleep disturbance has been shown to have a host of psychological and medical correlates and consequences including fatigue (Fiorentino and Ancoli-Israel 2006). One of the common causes of insomnia in this population are menopausal symptoms of hot flushes and night sweats as a consequence of chemotherapy or hormonal treatments such as Tamoxifen which can last for the five year duration of the treatment. This can be in addition to the psychological sequelae of breast cancer such as anxiety and depression which may affect sleep. These are discussed in 2.5.3.2.

2.5.2.3 Pain

Pain is a possible side effect following surgery, chemotherapy and radiotherapy for breast cancer. Chronic pain following breast cancer surgery is associated with decreased health-related quality of life and is an additional source of psychological distress. In a study of women (N=95) undergoing surgery for breast cancer, only younger age ($p=0.04$) was associated with a significantly increased risk of developing chronic pain after 3 months (Poleshuck et al 2006), however in this study, risk factors for chronic pain were indentified on the basis of prospective research design, the research did not demonstrate that they were causal risk factors. Also the sample was small, mostly Caucasian, well educated and drawn from a single teaching hospital, showing limited representation of the breast cancer population as a whole.

Neuropathic pain, which is often chronic, may exceed 50% following breast surgery (Jung et al 2003) can also follow some chemotherapy agents (particularly taxanes, vinca alkaloids and the platinum agents carboplatin and cisplatin) (Jung et al 2005). Following radiotherapy for breast cancer (n=416), 33% of patients suffered pain in the brachial plexus, this figure then declined to 15% by 24 months after treatment (Whelan et al 2000). Neuropathic pain can be constant, debilitating and difficult to treat.

2.5.2.4 Menopausal symptoms

Menopausal symptoms can persist following breast cancer treatments (King et al 2000, Carpenter et al 2002, Hunter et al 2004). Many women treated for breast cancer remain on anti-oestrogen medication such as Tamoxifen or aromatase inhibitors for up to five years or have been thrown into an early menopause by chemotherapy or ovarian oblation or oopherectomy. In women with early stage breast cancer (n=305), King et al (2000) found that between three and 12 months post surgery, menopausal symptoms persisted. In a survey of breast cancer survivors (n=69) compared to age-matched healthy controls (n=63), Carpenter et al (2002) found that breast cancer survivors suffered from greater overall hot flush severity ($p<0.001$) and overall hot flush bother ($p<0.001$) compared to controls. Hot flushes were also more frequent ($p<0.001$), severe ($p<0.001$), and of longer duration ($p<0.01$) than in controls. Limitations of these results include a low response rate

of 33% resulting in small sample sizes, but authors claim the sample was representative. The controls were not case controlled, having been recruited from the population at large.

In a cross-sectional study of a sample of mostly breast cancer survivors (n=113), prescribed Tamoxifen® in Guy's Hospital in London, Hunter et al (2004) found three years post diagnosis, that 80% still suffered from hot flushes and 72% from night sweats. Compared to a normative sample (n=692), these breast cancer survivors suffered increased vasomotor symptoms ($p<0.05$). Although a small sample, authors reported that they were typical of Tamoxifen users on their database.

As can be seen from the studies mentioned above, physical symptoms in breast cancer survivors can affect women for years after surgery, chemotherapy and radiotherapy has finished.

2.5.3 Psychological effects of breast cancer in survivors

The psychological and emotional impact of breast cancer is recognised but its full extent and depth not fully understood. Women with early stage breast cancer (N=233) related directly to cancer as a health and life threat, with particular concerns about recurrence (Spencer et al 1999). Psychological distress in cancer patients has been evaluated in a large number of studies using a wide range of measures (Gotay and Stern 1995).
The evidence for psychological distress, mood disturbance, depression and anxiety as a consequence of a breast cancer diagnosis and its treatments are outlined below.

2.5.3.1 Mood disturbance and psychological distress

There is a wealth of literature describing the psychological and emotional impact of the diagnosis and treatment of cancer and breast cancer and the fact that this impact may continue into the survivorship period. In one study, Carpenter et al (2002) found that mood state in breast cancer survivors (n=69) was worse in comparison to healthy women (n=63) although these differences were not significant and other studies show lowered mood in survivors as well (Pinto et al 2002, Speca et al 2000). There are a range of influences which affect mood and psychological distress in breast cancer survivors. In a descriptive survey and using an American sample derived from the National Coalition for Cancer Survivorship of long-term survivors, mean age 50.9 years, with an average of five years and eight months post diagnosis, (N=294), Hassey Dow et al (1996) found that
a) psychological distress from fear of cancer diagnosis and treatment, and fear of recurrent and metastatic disease were problematic over time, b) family distress, sexual and family burden issues were of greatest social concern and c) uncertainty over the future plagued breast cancer survivors long-term. They found that quality of life scores improved the longer the time since diagnosis ($p=0.05$). As with many breast cancer

studies, they found few respondents were from minority or disadvantaged groups which biases their results.

When comparing health related quality of life women with early stage breast cancer (n=161) survivors compared to the general population (n=949), Schou et al (2005) found that women with breast cancer scored lower on emotional, cognitive and social functioning at diagnosis ($p<0.01$), and this persisted with cognitive ($p=0.008$) and social ($p=0.009$) functioning one year after surgery. As observed here, the psychological needs of breast cancer survivors are complex.

The main mood states discussed in the relevant literature are depression and anxiety and these are explored below. As some key studies evaluate both dimensions, these are presented together.

2.5.3.2 Depression and anxiety

Depression has been identified in the literature as a common consequence of breast cancer and its treatments (Spiegal 1996, van't Spijker et al 1997, Carroll et al 1993, Bower 2008, Fann et al 2008, Somerset et al 2004). Half of all cancer patients have a psychiatric disorder, usually an adjustment disorder with depression according to an examination of the literature by Spiegel (1996). Previously raised ideas of a prospective link between depression and breast cancer have little support (Fox 1989), however early work showing possible links between depression and lowered immunity (Herbert and Cohen 1993) may alter this stance in the future. From a meta-analysis of the literature from 1980 to 1994 on psychological and psychiatric problems in patients with cancer, van't Spijker et al (1997) found breast cancer patients (N=1151 in 14 studies) seemed to be significantly more depressed, anxious and distressed than normals ($p<0.001$). Compared with psychiatric patients, cancer patients were significantly less depressed, anxious, or distressed and breast cancer patients were less depressed than all other cancer patients. Depression was also an ongoing problem for cancer patients where the other symptoms were less so. The authors acknowledged that patients may suppress any (pre-existing) psychological problems because they have to deal with cancer, a major life event or deny the feelings as they cannot cope with them and it may be that many can adjust to cancer without professional help. In addition, they acknowledge that when measurements take place may be crucial to what is found and studies need to specify this moment. It was not possible for the authors to estimate the prevalence of psychiatric and psychological problems for the many studies that presented mean scores.

Carroll et al (1993) found that of 809 cancer in- and out-patients approached for screening using the Hospital Anxiety and Depression scale that 47.6% would warrant further

psychiatric investigation. Twenty-three percent (23.1%) had scores of 11 or greater and would be the most likely to have had anxiety (17.7%) or depressive (9.9%) disorders based on Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R) criteria (American Psychiatric Association 1987). In a review, McDaniel and Nemeroff (1993) cited the range of depression amongst cancer patients was between 4.5 to 50% and it is considered to be frequently under-diagnosed and undertreated in women with breast cancer (Fann et al 2008, Somerset et al 2004). For some, the distress of breast cancer can initiate disabling psychological symptoms and exacerbate underlying mental illness. Estimates of figures for depression in all stages of breast cancer range from 10 to 25% according to a review by Fann et al (2008) and up to 50% depending on the sample and method of assessment (Massie 2004, Burgess et al 2005). Somerset et al (2004) reviewed the literature of cancer and major depressive disorder and included 11 breast cancer studies where the incidence of major depression was 4.5 to 32% (N=2705). Fann et al (2008) acknowledged that more research is needed to understand major depressive disorder after breast cancer including symptom burden, cognition, functional status, burden on family and caregivers, and immune function as well as prevention studies and modifiers on depression such as menopausal status or hormone therapy.
In a study of women in the year after breast cancer (N=227), Schag et al (1993) found psychological distress and depressive symptoms to be typically highest in the first six months after breast cancer diagnosis and then decline over time as the initial adjustment to cancer and its treatments was made, even though those identified as being at psychological risk experience more problems of greater severity one year later. Hunter et al (2004) found breast cancer survivors (n=113) suffered more depressed mood ($p<0.05$) compared to a normative sample (n=692). Weitzner et al (1997) found increased depression, lower quality of life and increased stress is experienced by long term survivors of breast cancer (n=60) compared to low risk breast screening patients (n=93).

Anxiety is the second most prevalent psychological problem for cancer patients (Derogatis et al 1983), and Fallowfield et al (1994) found for women with stages I and II breast cancer post treatment in south east England (N=269), irrespective of surgery type, that for an appreciable minority of these patients, anxiety (n=41) and depression (n=32) persisted two and three years afterwards (n=216). Schreier and Williams (2004) found that at the start of chemotherapy or radiotherapy treatment for breast cancer (N= 48), both state and trait anxiety correlated negatively with quality of life ($r=-0.29$ and $r=-0.32$ respectively, $p<0.05$) and this persisted one year post treatment.

In an observational cohort study consisting of a series of clinical interviews with women having early stage breast cancer (N=222), (Burgess et al 2005), anxiety and depression were categorised as full, borderline or non-case at different time points. In completed data

up to five years after diagnosis or recurrence was gathered from 77% (n=170) women with early breast cancer, Burgess et al found that 48% had depression, anxiety or both in the year after diagnosis, 25% in the second, 23% in the third, 22% in the fourth and 15% in the fifth year (exact numbers are not given in the report). They found that previous psychological treatment predicted depression, anxiety or both in the period around diagnosis ($p=0.05$) and that longer term depression and anxiety were associated with previous psychological treatment ($p<0.01$), lack of intimate confiding relationship ($p<0.01$), younger age ($p<0.01$), and extremely stressful non-cancer life experiences ($p<0.01$). They found that clinical factors were not associated with depression at any time and that lack of confiding support also predicted more protracted episodes of depression and anxiety. In agreement with other studies, they concluded that it is factors relating to the person, rather than the disease or treatment, which increases risk of anxiety or depression in the year after early breast cancer is diagnosed. The findings of this study are limited as recruitment came solely from the breast patients of Guy's Hospital, London.

Anxiety and depression are important possible psychological sequelae of breast cancer as the studies above show.

2.5.3.3 Stress

Stress is a common reaction or response to any distressing life experience and the diagnosis and treatment of breast cancer can be a highly stressful and emotionally upsetting experience, full of uncertainty and fear, as Luecken and Compas (2002) found when integrating evidence from several lines of research. Stress can continue in different forms for years following diagnosis as described below. In early research looking at the relationship between stress and breast cancer, an explicit and well conducted systematic review of the literature on stress and breast cancer conducted by Nielsen and Grønbæk (2006) of articles published until 1 November 2005, after exclusions, found 13 studies on stress and breast cancer incidence and five on stress and breast cancer relapse. All of these studies were conducted in westernised countries. Differences in the way that stress was conceptualised and measured prevented authors from performing a meta-analysis to give a quantitative link between stress and breast cancer. They found no higher risk of breast cancer in large-scale registry linkage studies that addressed the effect of a major life event such as divorce or death of a child. They concluded that a build up of stressful life events might, however, be associated with a higher risk of breast cancer. They found that work-related stress and perceived stress were either not associated with breast cancer risk or with a slightly lower risk. Their conclusions reached was that stress did not seem to be an important risk factor for breast cancer incidence with the exception that stress experienced one year before the diagnosis of breast cancer might be associated with a higher risk of relapse, but more rigorous research is needed in this area.

There are reports that a severe form of stress, post traumatic stress disorder (PTSD), may exist in between 3-10% of patients with breast cancer (Andrykowski et al 1998, Cordova et al 1995). Amir and Ramati (2002) found that women (n=39) at least five years post diagnosis for breast cancer (stages I to III) and at least three years cancer free were compared to women (n=39) who had never had breast cancer matched to the experimental group by age and education. Survivors had higher rates of partial ($p<0.001$) or full ($p<0.001$) PTSD. This study was limited as the sample size was small and results from the regression analysis should be treated with caution. In addition the PSTD group was only comprised of seven women and the study would have benefitted from a longitudinal rather than cross-sectional design. In contrast to these results, in a subgroup (n=84) of a larger study examining the influence on the phase of the disease on women with breast cancer, where the group was considered stable with a median of four years post diagnosis, they experienced limited physical, mental and social consequence and were similar to the general population. These results need to be taken with caution as the participation in the study was made to coincide with medical appointments, which may be an additional source of stress for patients. It is not known whether this smaller sample is representative and there was no control group. The long-term impact of stress on breast cancer on survivors does needs more research with larger, more rigorous studies (Frost et al 2000).

Summary of physical and psychological factors

Mainly quantitative research studies were sought to provide evidence of the physical and psychological impact that breast cancer can have on quality of life, physical and psychological wellbeing, although the design of many of these reported was flawed. In stages 0 to III breast cancer survivors, there were negative effects of breast cancer and its treatments on physical, psycho-emotional and social aspects of quality of life that can last for years in some cases. Systemic adjuvant drug therapy, including Tamoxifen®, predicted poorer quality of life. Fatigue was found in 30 to 41% of breast cancer patients and was an ongoing problem and lasted for many years, particularly in those whose treatment for breast cancer included chemotherapy. Insomnia was three to five times higher in breast cancer patients than in the general population and was a common and an ongoing problem after treatment finished. Pain, particularly neuropathic pain, was found in more than 50% of women following breast surgery, lasting for long periods following treatment and could be difficult to treat. Menopausal symptoms, including hot flushes, were present in 80% of breast cancer survivors three years after treatment, particularly for those on Tamoxifen.

Psychological symptoms that affect breast cancer survivors include concerns about recurrence and the potential threat to their lives. Women with breast cancer have been

shown to have lowered mood and be affected emotionally, cognitively and socially and to be significantly more depressed, anxious and distressed than normals. There is considerable variation in the literature regarding the extent to which those with breast cancer are affected by these mood states and more research is needed to understand the relationship between them and breast cancer. Anxiety was the second most prevalent psychological condition suffered by breast cancer patients following depression. Recent estimates of those affected by depression ranged from 4.5 to 50%. A past history of psychological treatment predicted the likelihood of depression and anxiety being present in the response to breast cancer. Stress was another possible response to breast cancer which included stress responses at a more extreme level in the form of PTSD.

From the literature cited, the complexity of the issues has been highlighted and breast cancer survivors may have symptoms of one kind or another, possibly several lasting for a long time beyond the completion of initial hospital treatment. Also highlighted in the literature is the range in quality of evidence and the difficulties of researching these factors in the breast cancer population. Many trials reported were either underpowered or not explicit as to whether this calculation has been performed. It is important to see how physical and psychological needs are currently met for breast cancer survivors, so the next part of this chapter will look at the existing policies and services which aim to address these needs.

2.6 National policies informing supportive cancer care

In addition to the existing medical treatments for people affected by cancer, the need to offer support has been acknowledged at government level in the publication of several major policy documents including the *NHS Cancer Plan* (Department of Health 2000), *NICE Guidance on Cancer Services - Improving supportive and palliative care for adults with cancer* (National Institute for Clinical Excellence 2004) and most recently, the *NHS Cancer Reform Strategy* (Department of Health 2007).

The *NHS Cancer Plan* and its update*,* the *NHS Cancer Reform Strategy* are the key documents that set out plans and targets to improve cancer services overall. The *NICE Guidance on Cancer Services - Improving supportive and palliative care for adults with cancer* (National Institute for Clinical Excellence 2004) defined service models 'likely to ensure that patients with cancer, with their families, and carers, receive support and care to help them cope with cancer and its treatments at all stages' (p. 4) with targets to complete this work extended to December 2008 (Department of Health 2007). As a result of the *Cancer Reform Strategy*, from 2008 to 2012, there is an initiative to improve the care given to survivors entitled the *National Cancer Survivorship Initiative* (Department of Health 2009). This is echoing survivorship work already commenced in America (Rowland

et al 2006) where questions of how to deliver follow up care, who should deliver it, in what settings, and according to which guidelines or best practice models represent a new focus of research (Earle 2006). Not all people with cancer choose to welcome or embrace the term “cancer survivor” (Rowland et al 2006) and it should be questioned if this label creates a new category of patient with care needs and the associated resource implications. The period over which this care should be delivered needs to be made explicit, especially as more people are living with cancer post treatment. Earle (2006) acknowledges that the creation and communication of survivorship care plans can be time consuming and difficult and there is the question of whether there will be NHS resources available to meet these demands at a local level. At the RCN national cancer conference in 2006 where the author spoke, there was a different discussion related to hospital staff shortages and diminishing budgets and the fact that some specialist cancer nurses (BCN) were being required to work on the wards instead of performing their specialist role. This implies less time for BCN to meet the needs of non-hospitalised patients.

The *Cancer Reform Strategy* (Department of Health 2007) specifically states that

> ‘cancer patients and their families and carers may need psychological support. Commissioners should work collaboratively to ensure that good psychological support services are available throughout the cancer journey’ (p. 10).

Four key levels of psychological support have been identified in the *Cancer Reform Strategy* which are:

1. Effective information giving, compassionate communication and general psychological support
2. Psychological interventions, such as anxiety management, problem solving
3. Counselling, theoretically driven psychological interventions, such as cognitive behavioural therapy and solution focused therapy
4. Specialist psychological and psychiatric interventions (p. 76)

The intervention evaluated in this research, Mindfulness-Based Stress Reduction (MBSR), fits into level three of these categories as it is a theoretically driven psychological intervention.

In addition, the need to help people living with and beyond cancer is important and there is acknowledgement in the *Cancer Reform Strategy* that

> ‘many patients who are cured of their cancer may be left with physical or psychological effects from the diagnosis and treatment of their disease’ (p.70).

The *Cancer Reform Strategy* recognises that survivors of cancer have a range of physical, psychological, social, spiritual and financial needs. It goes on to say that frequently services do not meet these needs for patients or are poorly integrated. It acknowledges that the after effects of treatment for cancer 'can, in some cases, be long lasting and severely debilitating' (p.80). This is of particular importance as more people are living with breast cancer as a chronic condition.

In order to achieve improved quality of life for cancer survivors, the *Cancer Reform Strategy* states that 'a new National Cancer Survivorship Initiative, in partnership with cancer charities, clinicians and patients, will consider a range of approaches to improving the services and support available for cancer survivors' (p.10). This project is underway at the time of writing this thesis and the author is participating in the Assessment and Care Planning sub-group intended to help survivors get appropriate and individualised care including self-management strategies.

In addition to the above mentioned document, the *National Guidelines for the Use of Complementary Therapies in Supportive and Palliative Care* (Prince of Wales's Foundation for Integrated Health 2003) has been a useful document offering appropriate guidance and support to professionals wishing to implement complementary therapies as a form of additional support in their clinical practice.

Thus it can be seen that the UK National Health Service is now recognising the needs of cancer survivors and gaps in service and trying to find ways to offer appropriate support. This news is welcome, but, to date, in the absence of a fully implemented survivorship initiative, current levels of support need to be examined.

2.7 Existing support services for breast cancer survivors

Support for patients with breast cancer is most readily available from Breast Care Nurses and Nurse Specialists (BCN) during the diagnosis and treatment phases of the disease. There is also limited support from psychological services and complementary therapies available via some hospitals. Increasingly GP surgeries do offer psychological support and there are a number of charities which offer further help in the form of support and complementary therapies, some specifically aimed at people with breast cancer. Each of these avenues of support will be discussed in turn.

2.7.1 Breast Care Nurses and Nurse Specialists

Breast Care Nurses and Nurse Specialists (BCN) provide information and support to help patients understand their diagnoses, medical treatment for breast cancer and gain some emotional and practical support through the breast cancer journey. In a survey sent to 653

breast care nurses and completed by 272, 40% per did not feel they had sufficient numbers of breast care nurses in their area to cope with demand (Royal College of Nursing and Breast Cancer Care 2004). A Cochrane Review (Cruickshank et al 2008) reviewed five studies to evaluate the impact of the support given by breast care nurses. In three studies assessing psychosocial nursing interventions around diagnosis and early treatment they found BCN could affect some components of quality of life, such as anxiety and early recognition of depressive symptoms. In addition, perceived distress during radiotherapy was alleviated, but coping skills, mood and quality of life were not. Their impact on the social and functional aspects of the disease trajectory was inconclusive. The authors concluded that there is limited evidence to support the contention that interventions by BCN assist in the short-term with the recognition and management of psychological distress for women with breast cancer and that further research was needed.

2.7.2 Psychological and psychiatric services

Existing psychological services for people with breast cancer generally depend on the provision made in their hospital or GP surgery. Sibbald et al (1993) found psychological and counselling support exists in 31% of GP surgeries (N=1542) and that figure is likely to have risen. Often it is only those with the greatest need who receive this form of help and support. A meta-analysis of the clinical effectiveness of counselling in primary care (Bower et al 2003) revealed that counselling showed significantly greater clinical effectiveness compared to usual GP care in the short term (standard mean difference -0.28, 95% CI -0.43 to -0.13, N = 741, six trials) , but not in the longer term (standard mean difference -0.07, 95% CI -0.26 to 0.12, N = 447, four trials), but it is uncertain to what extent this kind of support would be valuable to women with breast cancer whose needs may extend over a longer period of time. Cancer Research UK (2008d) provides guidelines for those seeking counselling and psychological support but acknowledges their uneven provision. The supportive care strategy of *NHS Cancer Plan* (Department of Health 2000) commented on the value of partnerships between NHS and the voluntary sector in the provision of support and information services stating that the benefits for patients are access to clear, unbiased information and a service which meets the emotional, psychosocial and physical needs of the patient and their supporters. Patients in need of psychiatric services can access these through a referral from their GP or possibly through the secondary care provision of psychiatry via their hospital. From consulting over many years with those attending Breast Cancer Haven, the clinician-researcher found that breast cancer patients attending NHS breast clinics are not routinely offered any form of professional psychological support by the hospital.

Survivors often have to rely on social support and that of family and friends. Lewis et al (2001) in a study of breast cancer survivors (N=64), found that those able to disclose their cancer-related thoughts and feelings to significant others (engaging in higher levels of appraisal social support) showed less impact of these thoughts on quality of life compared to those who did not ($p<0.005$). This suggests that social support can mitigate the impact of traumatic life events. Andersen et al (2008) performed an RCT evaluating the impact of a one-year 26-session psychological intervention on survival or breast cancer patients (N=227). Patients were assessed post surgery and prior to adjuvant treatment. The sessions, led by two psychologists, were offered weekly for four months, then monthly for eight months. The intervention consisted of progressive muscular relaxation for stress reduction, problem solving for common difficulties (e.g. fatigue), identifying family members or friends able to provide assistance, using assertive communication for getting one's psychological and medical needs met, strategies to increase daily activity (e.g. walking, exercise), improving dietary habits (e.g. lowering fat intake), finding ways to cope with treatment side effects (e.g. nausea) and maintaining adherence to medical treatment and follow up. After a median of 11 years of follow-up, patients in the intervention arm were found to have a reduced risk of breast cancer recurrence, hazards ratio (HR) of 0.55, ($p=0.034$), and death from breast cancer, HR of 0.44, ($p=0.016$), compared to controls who received assessments only. In addition, the intervention arm had a reduced risk from death of all causes suggesting that this kind of psychological intervention improved survival. Limitations of these findings include the fact that there was no information on vital treatments such as the length of time or compliance with hormone medication which may also have affected survival.

Newell et al (2002) performed a systematic review of psychological therapies for cancer patients, providing an overview for future research of their possible benefits in both physical and psychological domains of cancer therapy. They identified 627 relevant papers that reported on 329 intervention trials. They looked at effectiveness outcomes from 34 trials, side effects outcomes from 28 trials, conditioned side effects from 10 trials and survival and immune outcomes from 10 trials. Due to the quality of the research and in many cases commenting on only one or two rigorously conducted studies, they were only able to make tentative recommendations regarding the effectiveness of psychological therapies for improving cancer patients' outcomes and suggested other approaches warranted further investigation. Some of their tentative recommendations mentioned are counselling, self-practice and group therapy for anxiety; group therapy, education and structured counselling for depression; structured and unstructured counselling, guided imagery for improving quality of life or general functional ability; group therapy for coping and control skills; counselling for interpersonal or social relationships; group therapy and cognitive behavioural therapy for targeting fatigue (Newell et al 2002).

2.7.3 Support and complementary therapies

The supportive and complementary therapy services available to people with cancer still remain a somewhat of a 'postcode lottery' with some geographical areas less well serviced than others (Macmillan Cancer Relief 2002). In these areas, often patients have to seek these therapies privately. Macmillan Cancer Relief (2002) published the *Directory of Complementary Therapy Services in UK Cancer Care: Public and Voluntary Sectors* which showed the spread of use of complementary therapies in the UK. Most provision is in hospices (36%) and hospitals (31%) with up to 20% based in the voluntary sector. Over 90% of services offer touch therapies such as massage, aromatherapy and reflexology. Relaxation and visualisation are offered in over 80% of services (Kohn 2003, personal communication). Healing and energy work including reiki, spiritual healing and therapeutic touch are also widely available in 45% of services. According to the NHS Choices website (NHS Choices 2009), it states that complementary therapies are gradually becoming more widely available on the NHS but are still quite sparse. Models of integrated healthcare have been created by individual organisations such as Breast Cancer Haven's model of Integrated Healthcare (see Appendix 2) but whilst there is a model of supportive care suggested in the *Cancer Reform Strategy* (Department of Health 2007), this does not specifically include complementary therapies.

In December 2008, The Department of Health (2008) circulated its *Manual for Cancer Services: draft complementary therapy measures - consultation version* for comment. The aim of the manual is to improve quality assurance of cancer services and enable improvement. The measures suggest that each cancer network be responsible for the quality of the complementary therapies it provides on the NHS as well as produce an annually updated list of those who practise locally or organisations who provide therapists either endorsed by the network or cited in the patient information. At the time of writing, it is difficult to know what direction these measures will take, but the author believes the scope of this task may have been underestimated and wonders who will be doing the work required to ensure the quality of service provision and how many networks will want to embark on or continue with the provision of these services in the light of the recommendations that may be made.

In a review of 26 surveys looking at complementary and alternative therapies in cancer care from 13 countries, Ernst and Cassileth (1998) found that 7-64% (N=10,284) of patients with cancer used these therapies, with an average of 31% across all studies. In a study looking at the prevalence of complementary therapy use by women with breast cancer in the South Thames region of London, Rees et al (2000) found that 22.4% (N=1023) of women diagnosed with breast cancer over the last 7 years had consulted a complementary practitioner in the previous 12 months. Of these women, 31.5% (n=714)

had done so since diagnosis. When looking at reasons for people choosing complementary therapies (n=74), they found that 80% (n=59) of women with breast cancer choosing complementary therapies for reasons other than to cure or slow down their cancer, 58% (n=43) to relieve symptoms of cancer and cancer treatment, and 34% (n=25) were to slow down or cure their cancer, but no further details were given. It was stated that 8.4% (n=60) of these women had accessed relaxation, yoga or meditation since diagnosis. The study does not report accessibility to or perceived benefits from the individual therapies, however it does report that a total of £17,000 was spent by 111 women who had accessed complementary therapies in the previous 12 months, suggesting the willingness for this group to pay for further help beyond that provided on the NHS.

2.8 Gaps in existing services for women with breast cancer

To date, providing complementary approaches that give people tools to help manage their own lives and symptoms has not been a priority in breast cancer care. Self-management practices such as meditation, yoga, Qi gong and Tai Chi are less readily available to people in the UK cancer services than touch therapies. The reason for this is that it has been chiefly nurses who developed the practice of complementary therapies in cancer since the 1980s and these nurses often chose touch therapies to work with alongside their clinical practice (Stevensen 1996).

A Cochrane review of exercise for the management of cancer-related fatigue in adults (Cramp and Daniel 2008) examined 28 studies (N=2083), 16 of which were with breast cancer (n=1172). The authors concluded that exercise can be regarded as beneficial for individuals with cancer-related fatigue during and post cancer therapy. They commented that further research is required to determine the optimal type, intensity and timing of an exercise intervention. Included in the review were a variety of forms of exercise including yoga. Included in the review was a pilot study on yoga in breast cancer by Culos-Reed et al (2006), (N=38) of whom 85% were breast cancer survivors. Using the 30-item European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30) global quality of life was improved ($p< 0.01$) and emotional function (n=18, $p< 0.05$) and decreased diarrhoea. Measuring before and afterwards, more improvements were found in mood measured with Profile of Mood States (POMS) than controls in total mood disturbance ($p<0.10$) and in the subscales of tension ($p<0.10$), depression ($p<0.10$) and confusion ($p<0.10$). From the Symptoms of Stress Inventory (SOSI), emotional irritability, gastrointestinal symptoms and cognitive disorganisation were also improved and some of the physical fitness variables also improved but not significantly. This small pilot study suggests the need for a larger more rigorous study to validate these findings.

Fenlon et al (2008) performed an RCT of relaxation training to reduce hot flushes in post menopausal women with primary breast cancer attending follow-up clinics and excluding those receiving any ongoing treatment such as aromatase inhibitors and other hormonal therapy other than Tamoxifen (N=150). They found that from one session of relaxation training plus tapes practised daily for one month, the incidence and severity of the hot flushes declined ($p<0.001$ and $p=0.01$ respectively). They concluded that whilst the incidence of hot flushes had a median decrease from four to three, the severity was also reduced which may reflect a real benefit in addition to lowered levels of distress. They did not see changes in quality of life including endocrine symptoms as measured by the Functional Assessment of Cancer Therapy – Endocrine Symptoms (FACT-ES), a tool used in the current doctoral study, although she commented that this tool was designed for people going through breast cancer treatment and the symptoms may not be sufficiently sensitive to measure quality of life issues associated with hot flushes. Three month follow-up did not show sustained results, but this may have been due to flaws in study design, as recording of the amount of relaxation performed in the follow-up period was not requested. This may have led to inadequate reporting.

This shows that there is preliminary research into the value of self management interventions but there is scope for more research and development in this area to best meet the needs for people living with breast cancer. The next section explores the value self-management in a broader context.

2.9 Self-management in health care and breast cancer

Self-management has been recently recognised as an important concept in health care with the aim that we can make patients partners in their own healthcare, empowering themselves and offering tools to live with their illness. A recent report entitled Co-creating Health produced by the British charity, The Health Foundation (2008), outlines steps being taken to help those facing long-term health conditions to self-manage. Pilot programmes are being undertaken in a diverse range of conditions such as depression, chronic obstructive pulmonary disease, diabetes and musculoskeletal pain. To date, plans to help people live with cancer and breast cancer are being developed from the impetus of the *National Cancer Survivorship Initiative* (Department of Health 2009), but these are still in progress and there is a self-management group exploring programmes for development. As many people are now living with breast cancer and the longer term side effects and psychological impact of the disease or its treatments, evidence for appropriate and valuable methods of self-management are important to establish.

2.9.1 Definitions of self-management

Self-management has been defined in a number of ways. Self-management programmes facilitate the patient's acquisition of preventative and therapeutic health care activities, often in collaboration with health care providers. Creer and Holroyd (1997) define self-management as

> 'referring to those processes, internal and external, that enable individuals to guide goal directed activities over time and across settings. Self-modulation entails modulation of thought, affect, behaviour or attention through use specific mechanisms and skills' (p.255) (adapted from Karoly 1993).

Patient education provides the basis for self-management later performed by patients, thus making them partners in their own healthcare rather than passive recipients (Creer and Holroyd 1997). Processes salient in the self-management of health problems include

1. goal selection
2. information collection
3. information processing and evaluation
4. decision-making
5. action
6. self-reaction

This earlier definition has been more recently replaced by a more generalised one from the National Cancer Research Institute's work to define self-management (Foster et al 2007). They state that there is no agreement as to the meaning of the term self-management and that it has been identified in three different ways (Koch et al 2004):
1. The medical model whereby patients receive professional support and direction and follow the given instructions to self-manage aspects of their condition
2. A collaborative model where patients seek, and are actively involved in, a relationship with health professionals facilitating choice in levels of support/management
3. A self-agency model for those who embrace self-management which includes patients planning and taking action for themselves, developing alternative lifestyle habits which helped them take control and allow the person to become self determining.
Koch suggests that self-management is related to decision making and personal accountability.

The UK's Cancer Experience Research Collaborative (CECo) (Foster et al 2007) has added to the definition of self-management in the context of supportive and palliative care, saying that it is about 'approaches used by the individual affected by cancer (or life limiting illness) and its effects to optimise living (with the illness and its effects). In the context of

this report, MBSR would be offered as part of a 'self-agency model' to empower breast cancer survivors to find ways to optimise living.

2.9.2 The impact of self-management

The impact of self-management across a range of illnesses is not yet clear and The Health Foundation (2008) has named areas of impact of self-management which include:

1. It improves health-related behaviours, and as a result, clinical outcomes
2. Due to lack of appropriate research, there is as yet uncertain impact of the relevance of self-management on health services utilisation
3. It may be that the impact of self-management on clinical outcomes varies across conditions, but again more research is needed
4. More quality of life research is needed as much of the research to date has focused on clinical outcomes.

The extent of effective forms of self-management in breast cancer are as yet largely unknown but do include collaborative interaction between patients and health care professionals, providing information, goal setting and the development of self-management skills.

There are no systematic reviews to date of self-management in breast cancer, only on non-cancer related illnesses. Even in other chronic illnesses where researchers have examined self-management programmes for longer than in cancer care, more studies are needed to establish what is effective (Warsi et al 2004). There is scant evidence in the literature of self-management programmes directed at the period following treatment for breast cancer. In one of the largest studies conducted to date, Stanton et al (2005) evaluated 558 women treated with surgery for breast cancer in a randomised controlled study involving in a 'Moving Beyond Cancer' programme. Results showed that a 23 minute peer-modelling videotape addressing challenges in four areas: physical health, emotional wellbeing, interpersonal relations, and life perspectives could speed up the recovery of energy during the early period following breast cancer treatment, particularly for those feeling less prepared. A small study evaluated a self-management programme for randomly assigned women following breast cancer (N=25) (Cimprich et al 2005) where women chose to work on a concern most related to their survivorship from: stress, fatigue, physical activity and personal relationship. This was done at two weekly intervals for seven sessions. The purpose of the sessions was to teach steps in self-regulation and address the concerns. The programme was found to be timely, relevant and to have high utility in dealing with their concerns. Damush et al (2006) found an exercise self-management programme for older survivors of breast cancer (N=34) to be efficacious for

implementing a lifestyle modification change. Clearly the small size of these two studies limits the validity of their findings.

From the literature there is clearly a need to evaluate the most effective self-management tools or programmes for breast cancer. Some patients were already seeking ways either independently or through programmes such as those provided by the breast cancer charity Breast Cancer Haven whose remit it is to provide free programmes of support, information and complementary therapies including self-management programmes to people affected by breast cancer. There was therefore scope to develop mindfulness research from some preliminary work in the field of cancer (Speca et al 2000, Carlson et al 2001, 2003, 2004, Shapiro et al 2003) as more rigorous studies were required to establish a sound evidence base in breast cancer.

2.10 Summary of literature review

Increasing numbers of women are surviving breast cancer and living with the physical and psychological sequelae. The literature identifies a number of aspects of quality of life affected by breast cancer and its treatments including fatigue, insomnia, pain, menopausal symptoms, mood disturbance, depression, anxiety and stress as some of the consequences that can persist for years. Where comparisons exist, breast cancer survivors fare worse in these areas than the general population. Currently there is little evidence to show which self-management interventions would relieve many of these symptoms and to date studies performed with breast cancer survivors in these areas are generally scant and many are performed with small sample sizes and lack rigour. To meet the ongoing needs of survivors, the provision of psychological and complementary support by the NHS and charities is uneven and currently does not meet the national demand nor has it been assessed rigorously for its effectiveness. The Department of Health and Macmillan Cancer Support are taking steps through the *National Cancer Survivorship Initiative* (Department of Health 2009) to explore methods of self-management in cancer survivors but this work is in its early stages and will be challenging at a time of increasing financial constraints. Thus further scope exists to evaluate appropriate ways to help empower interested patients, make them more self sufficient and to relieve the burden on an already overstretched health service. MBSR is one way that was considered to be worthy of further investigation.

2.11 The rationale for researching Mindfulness-Based Stress Reduction (MBSR)

In deciding which self-management tool to investigate for this doctoral research study, Mindfulness-Based Stress Reduction (MBSR) (see Chapter 3 for more details) was chosen. MBSR is a potentially empowering self-management programme where

participants play an active part in its process. It is qualitatively different from many of the complementary therapy approaches that have been used in most UK cancer care settings to date in that tools are taught and provided with a long term goal of helping people to lead happier and healthier lives and cope with them better regardless of whatever may happen in the future. MBSR therefore warranted further investigation. Therapeutic effectiveness has been chosen as a term to capture any possible benefits of MBSR with study participants. Therapeutic effectiveness is defined as the extent to which participants may find this intervention beneficial in improving quality of life in relation to physical, mental, emotional, and social and spiritual wellbeing. This generic term has been chosen so that the study may capture any aspects of potential benefit to the participants. In developing this PhD study, until performing a literature search, the candidate was previously unfamiliar with the variety of mindfulness interventions available as her own previous clinical work with mindfulness had been limited. MBSR was chosen over other mindfulness interventions for several reasons:

1. MBSR is a defined and structured 8-week programme described in detail in the book by Kabat-Zinn (1990) Full Catastrophe Living (see Appendices 3 and 4) that has been researched in a variety of health care settings since Kabat Zinn's first published study in 1982 (Baer 2003).
2. MBSR had been used in previous studies with people with cancer (Speca et al 2000, Shapiro et al 2003).
3. The clinician-researcher had a keen interest from her own experience and practice of mindfulness as well as the teaching of simple awareness of breathing techniques to cultivate mindfulness to patients with cancer and staff in a specialist cancer hospital, an area she wanted to research further in people diagnosed with cancer.
4. The clinician-researcher had the necessary prerequisites for MBSR teacher training which included a personal practice of yoga exercises and forms of sitting meditation for over 20 years and specifically mindfulness for 14 years. In addition, the clinician-researcher had some psychological support experience due to her degree and practice in the field of social work and later in supportive and complementary cancer nursing. She had previous experience of running groups of relaxation, visualisation and mindful awareness of breathing to people with cancer.
5. The clinician-researcher was granted a Florence Nightingale Foundation Scholarship for £5000 in 2003 which enabled her to complete the necessary MBSR training at the University of Massachusetts, USA outlined in Appendix 5 along with other research training and mindfulness development undertaken.

The next chapter provides a background on mindfulness, MBSR and the relevant research carried out in this field to date.

Chapter 3. MBSR background and literature survey

3.1 Introduction

This chapter will review the background information and literature relevant to the intervention under study, mindfulness-based stress reduction (MBSR). The origins of MBSR, definitions of mindfulness, theoretical and philosophical underpinnings and the history of mindfulness will be described. The conceptualisation of mindfulness, mechanisms of action in mindfulness, mindfulness-based programmes, underpinnings of MBSR teaching and measurement tools for assessing mindfulness are discussed. This chapter will also give an overview of the mindfulness research literature including clinical research into MBSR with cancer and breast cancer populations.

3.2 Origins of mindfulness-based stress reduction (MBSR)

Mindfulness-based stress reduction (MBSR) was developed by Professor Jon Kabat-Zinn, a molecular biologist with a strong personal practice of mindfulness in 1979 while working at the University of Massachusetts in Worcester, USA. The initial idea came to him when he was on a mindfulness retreat and he saw how this practice could benefit the wider community, particularly those with health problems. He commenced sessions of the programme which he called the stress reduction and relaxation programme (SR-RP) in the university's medical centre (Kabat-Zinn 1982). This later became known as MBSR.

The primary aim of MBSR is to cultivate mindfulness using techniques to enhance awareness of the present moment (Kabat-Zinn et al 1998a). The emphasis is on mindfulness as a way of being, a way of living one's life, and as a way of developing alternative generic strategies for coping with life's stresses. It is not seen as a technique for solely coping with a specific problem such as cancer, pain or mental illness. In MBSR, mindfulness practices, such as sitting and lying mindfulness meditation and mindful stretching exercises, are taught to be practised regularly as a daily discipline (Kabat-Zinn 1990).

3.3 Definition of mindfulness

Mindfulness is described by Kabat-Zinn as 'paying attention in a particular way: on purpose, in the present moment and non-judgementally (Kabat-Zinn 1994, p 4) or as he has more recently defined it more succinctly, 'moment to moment non-judgemental awareness' (Kabat-Zinn 2004, personal communication). Mindfulness was described to participants as, 'bringing attention and awareness to the present moment in a non-judgemental way'. It is a practice of non-doing or the 'practice of being'. Kabat-Zinn explains that it is the allowing of the body and mind to come to rest in the present moment, no matter what is 'on' the mind or how the body feels. It is the allowing of things

to be exactly as they are without changing anything by making judgements or reacting to the experience. Mindfulness is a way of being that is cultivated and practised, not a fixed state.

Other authors have defined mindfulness in slightly different ways, Nyanaponika called mindfulness 'the clear and single-minded awareness of what actually happens to us and in us at the successive moments of perception' (Nyanaponika1992, p 5) and Brown and Ryan defined mindfulness as 'being attentive to and aware of what is taking place in the present moment' (Brown and Ryan 2003, p 822). Baer et al (2006) bring together a number of definitions of mindfulness into a composite of bringing one's complete attention to the experience occurring in the present moment, in a non-judgemental or accepting way (Brown and Ryan 2003, Kabat-Zinn 1990, Linehan 1993, Marlatt and Kristeller 1999). The key elements of all definitions include present moment attention and awareness and acceptance or non-judgement. It is also helpful to note that the practice of mindfulness is a continual process and, as described by Kabat-Zinn and traditionally described in Buddhist texts, 'a way of being' where the mind is brought back again and again to the present moment.

Mindfulness is about 'paying attention', whether in formal practice for example sitting quietly and paying attention (mindfulness meditation) or whether in daily life. Mindfulness does not involve trying to get anywhere or feel anything special. Rather it involves allowing yourself to be where you are, to become more familiar with your actual experience, moment to moment (Kabat-Zinn 1990). Rahula comments

> 'Mindfulness or awareness does not mean that you should think and be conscious 'I am doing this' or 'I am doing that'. No, just the contrary. The moment you think 'I am doing this', you become self-conscious, and you do not live in the action, but you live in the idea 'I am', and consequently your work too is spoilt. You should forget yourself completely, and lose yourself in what you do' (Rahula 1974, p 72).

Jon-Kabat-Zinn also describes mindfulness in a wider context,

> 'it turns out that we all have, lying deep within us, in our hearts and in our very bones, a capacity for a dynamic, vital, sustaining inner peacefulness and wellbeing and for a huge, innate, multifaceted intelligence that goes way beyond the mere conceptual. When we mobilise and refine that capacity and put it to use, we are much healthier physically, emotionally and spiritually and much happier. Even our thinking becomes clearer, and less plagued by storms in the mind' (Kabat-Zinn 2005, p 7).

So it can be seen that the potential of mindfulness is contact with that which is within each person, a deep, vital and sustainable awareness of inner peacefulness which can bring wellbeing to the wider dimensions of life.

3.4 Theoretical and philosophical underpinnings of MBSR

MBSR arose out of the contemplative theoretical/philosophical ground of Buddhism. Central to Buddhist philosophy and practice is cultivating a way of being in the world that relieves suffering through knowing, shaping and liberating the mind. Mindfulness is central to this philosophy and provides a mechanism through which this can be achieved (Nyanaponika 1992). In addition, there are a variety of psychological theories and models that inform MBSR as it has become contextualised in health care. This contributes to teaching MBSR being a creative, iterative process (Santorelli 2004a). Dr Saki Santorelli, Director of the Centre for Mindfulness at the University of Massachusetts, has gathered a number of models which he suggests form the theoretical and philosophical underpinnings of MBSR and its teaching. The model or guiding principles from each of these philosophies or theories are presented in Table 3.1 (Santorelli 2004a) and demonstrate the convergence of eastern philosophy and western psychology in the MBSR programme.

Table 3.1. The theoretical and philosophical underpinnings of MBSR

(Santorelli 2004a)

Categories of models	**Source**	**Models or guiding principles**
Contemplative/ philosophical	Gautama Buddha (Hanh 1990)	Four noble truths: 1)*dukkha* (suffering), 2) the arising of *dukkha*, 3) the cessation of *dukkha,* 4) the way leading to the cessation of *dukkha.*
	Gautama Buddha (Hanh 1990)	Four foundations of mindfulness (mahasattipatana sutra) 1)awareness of body, 2)awareness of feelings, 3)awareness of thoughts, 4)awareness of mind objects
	Gautama Buddha (Rosenberg 1998)	Full awareness of breathing (anapanasati sutra)
Psychological/ stress	(Lazarus 1966, Lazarus and Folkman 1982)	'Transactional' individual personality characteristics (individual appraisal/mind) mediate external environmental factors and symptoms of stress
	Bandura (1977)	Self-efficacy. Perceived self-efficacy is defined as people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives. Self-efficacy beliefs determine how people feel, think, motivate themselves and behave
	Schwartz (1979)	The critical role of attention in health
	Shapiro and Schwartz (2000)	Intentional systemic self-regulation. This model defines attention and intention as critical to our capacity to self-regulate
	Kosoba (1980)	Psychological hardiness (resilience) concerning fluid personality factors that interact with the environment
	Antonovsky (1979,1987)	Coherence/stability (resilience) The construct of "sense of coherence" (SOC) was introduced by Antonovsky (1979, 1987) to describe a dispositional orientation, offering a way of seeing the world to enhance health.
	Segal, Williams and Teasdale (2002)	Interruption of the conditioned ruminative processes through use of mindfulness, bare attention to prevent the relapse of depression
	Karasak and Theorell (1990)	Strain/learning theory and workplace stress – control/demand theory (environmental factors in stress)
	Sapolsky (1998)	Stress physiology/neurology (mind-body/environment)
	McEwan with Lasley (2002)	Allostasis/allostatic load (resilience capacities in the body)

One of the most fundamental cornerstones of mindfulness and therefore, MBSR is described in one of the foremost of Buddhist texts called the 'Foundations of Mindfulness,' where attention is given to the body, feelings, the mind and mental objects (Rahula 1974). If followed, these foundations are identified as a way of relieving pain and suffering. These four foundations involve contemplation or awareness of body and mind and are described below (Nyanaponika 1992) with some examples.

1. Contemplation of the body
This includes awareness in every day life situations. Examples of being mindful include: mindfulness of breathing, awareness when sitting, standing, lying, walking, moving, eating, sitting or being silent.

2. Contemplation of feelings or sensations
This is the awareness of feelings or bodily sensations when present and whether they are pleasant, neutral, unpleasant or painful.

3. Contemplation of the mind
Awareness of emotions such as lust, hate, delusion, awareness of when concentration is present or not present. Awareness of these and other states of mind and being able to observe them as they occur without clinging (attachment).

4. Contemplation of mind-objects
Awareness of sense-desire, anger, laziness, agitation, worry and doubt.

From these foundations it can be seen that attention and awareness is brought to the mind and body in each moment. This is the basis of mindfulness practice. It should be noted that mindful awareness also extends to awareness of surroundings and sensations that come from the exterior such as heat, wind, rain, sights and sounds.

Mindfulness as a practice is most clearly found in the Buddhist tradition and its core concepts are shared with many traditions and philosophies including the yogic traditions, Greek philosophy, Christianity, phenomenology, existentialism and modern day works on spiritual enlightenment (Dass 1971, Tolle 1999, 2006). This cross-cutting concept of being fully present or being mindful in its fullest expression is described in Buddhism as 'liberation' of the mind or 'freedom from suffering', enabling a deep sense of serenity and peace that comes from freedom from fear. In the Christian tradition, St Paul described the experience as 'the peace of God which passeth all understanding', an experience that goes beyond the thinking mind. 'Salvation' was the term used by Jesus whilst Hindus use 'enlightenment'; awakening is also used to describe this same transformation (Tolle 2006).

In the Buddhist Therevada tradition, mindfulness is described as *sattipatana, vipassana* or insight meditation, it is part of Mahayana or Soto Zen practices as well as the yogic traditions. Known as 'the heart of Buddhist meditation' mindfulness meditation, it is extensively described in Buddhist literature. The term mindfulness originates from the Pali word *sati* (or in Sanskrit: smṛti) has its original meaning as memory, recollection or remembrance. In modern Buddhist usage, it mostly refers to the present, and as a general psychological term, it has the meaning of 'attention' or 'awareness'. In the Pali scriptures it is restricted to a kind of attentiveness that is skilful and that we refer to as mindfulness also known as 'bare attention' , an awareness of what is going on from moment to moment (Nyanaponika 1992).

It is important to note that mindfulness can be practised as a valuable self-help technique without requiring the adoption of a particular belief system. It can also be practised with accompanying values and frameworks of other religious or philosophical beliefs, for example, the non-judgemental attitude taught with the practice of mindfulness in MBSR is consistent with concept of 'loving thy neighbour as thyself' described in the Bible, Leviticus 19:18, Matthew 22:39 amongst others or loving-kindness (metta) in Buddhism.

3.5 Conceptual overview of mindfulness

Until very recently, academic literature has not provided a clear and detailed conceptual overview of mindfulness. In a well constructed view of the theoretical foundations of mindfulness, Brown et al (2007a) identified six aspects of mindfulness in its conceptualisation. Their essence of their concepts is presented here with comments from other authors:

3.5.1 Clarity of awareness
3.5.2 Non-conceptual, non-discriminatory awareness
3.5.3 Flexibility of awareness and attention
3.5.4 Empirical stance towards reality
3.5.5 Present-orientated consciousness
3.5.6 Stability or continuity of attention and awareness

More detail of these concepts is presented with additional comments is presented below:

3.5.1 Clarity of awareness

Clarity of awareness is a moment to moment clear awareness of one's changing inner or outer worlds, including thoughts, emotions, sensations, actions, or surroundings. This unbiased awareness, free from judgements and reactions, is thought to facilitate insights into reality, offering the ability to see phenomena which would otherwise have been

obscured from view. This awareness can then provide the opportunity for behaviours or reactions to be changed. This clarity of awareness has also been described as 'mindful attention' or 'mindful awareness' to one's present experience (Leary and Tate 2007) and is accessible to one degree or another through the practice of mindfulness.

3.5.2 Non-conceptual, non-discriminatory awareness

The non-conceptual nature of clear awareness is characterised by direct contact with reality, not unlike the thinking of Husserl (1859 to 1938), the father of phenomenology, who saw that in order to study the structure of consciousness, one would have to distinguish between the act of consciousness and the phenomena at which it is directed. Husserl spent a life-time working on a method for phenomenological intuiting but was unsuccessful in developing method for translating his philosophy into practice. The practice of mindfulness does provides a way which allow thoughts, emotions, sensations including sights, sounds and other experiences to be as they are through simply noticing what is there from moment to moment. Brown et al (2007a) observed that thoughts can be disentangled from cognitive content when mindful, so the activity of conceptual thought can be engaged and disengaged more as a matter of choice. Whatever the content of thoughts, they can be simply seen as 'thoughts' or events passing across the field of consciousness. Shapiro et al (2006b) described this as reperceiving, which allows the stepping back from emotions such as anxiety and to see them simply as emotional states that are arising and will in time pass away. The recognition of impermanence of mental phenomena allows a higher level of tolerance for unpleasant internal states.

3.5.3 Flexibility of awareness and attention

Attention and awareness can be altered quickly in response to any situation. Like a camera, attention and awareness can be in close up, focusing on minute detail or on wide angle, seeing the larger picture in context, giving a clearer perspective of the whole. Whilst the direction of attention is developed with the practice of mindfulness through bringing the mind back to the present moment and this requires concentration, it is not the same as concentration. This is supported by differences in brain electroencephalographic (EEG) readings (Dunn, Hartigan and Mikulas 1999).

3.5.4 Empirical stance towards reality

The empirical stance of mindfulness encourages the full or 'bare' facts to be known before judgement is made, just as the true scientist has

> 'unprejudiced receptivity for the instruction that comes out of things themselves; exclusion or at least reduction, of the subjective factor in judgement; deferring of judgement until a careful examination of the facts has been made' (Nyanaponika 1992, p 39).

Non-judgement has also been described as experiencing one's situation as it is happening without clinging to it or rejecting it (Leary and Tate 2007). Mindfulness fosters an openness, active participation and ever present curiosity to experience phenomena that arise from moment to moment which Brown et al (2007a) suggest foster a greater interest and concern for life, empathy for others and ecological stewardship.

3.5.5 Present-orientated consciousness

The benefits of being and experiencing life in the here and now are an approach that has been used in a variety of modern day psychological approaches including humanism (Rogers 1961) and gestalt (Perls 1973). The movement of the mind from thought to thought and from past to present to future serves an important regulatory purpose of protecting, maintaining and enhancing of the self, but it is easily forgotten that we exist only in the present moment with no direct experience of the past or the future (Brown et al 2007a), this only comes through reflection. Bare attention or mindfulness is concerned only with the present. It is about facing the present without trying to escape into the future or the past as it is in this space that

> 'by stepping back from things and men, one's attitude towards them will even become friendlier, because those tensions will be lacking which so often arise from interference, desire, aversion or other forms of self reference. Life will become a good deal easier, and one's inner and outer world more spacious…bare attention schools us in the art of letting go, weans us from busy-ness and from habitual interfering.' (Nyanaponika 1992, p 43).

3.5.6 Stability or continuity of attention and awareness

Mindfulness is about noticing when one is present and when one is not present. This gives the opportunity to consciously return the mind to the present again and again when the mind wanders into the past or into the future. For those who have cultivated mindfulness fully into their lives, mindfulness becomes a way of life, where ones attention and awareness is more continually present, whereas for beginners, mindful moments might be more infrequent and of much shorter duration.

Humans have an inherent capacity to be mindful (Brown and Ryan 2003; Kabat-Zinn 2003), in fact being mindful could be regarded as our most natural state, a peaceful and joyful state, free from the burden of thoughts and emotions, although the cultivation of mindfulness to its fullest and most lasting expression is not common. Even in popular literature, information about awakening to our true nature, liberation or transformation of human consciousness is being made easily accessible for those who are interested (Tolle 1999, 2006). It can be argued that being fully aware in the present moment is the only real

control available as it is from there that it is possible to control one's reactions to life events. In terms of dealing with what is subconscious or unconscious, in relation to mindfulness practice from moment to moment,

> 'We cannot know what we don't know, and yet, by pausing, and noticing, we may begin to see patterns which function automatically (unconsciously) more easily. As we develop the capacity to be curious about our mental and emotional formations, we can gain clarity on the constructions we take as reality. Many people discover as (mindfulness) practice deepens over time, that there is more lucidity in dreaming as well as waking experience. This is another avenue for investigation into unconscious material' (Meleo Meyer 2008, personal communication).

Through this process of pausing, noticing what is happening from moment to moment, it allows deeper investigation of things which might at first be taken at face value.

3.6 Other elements of mindfulness

Authors have tried to identify particular components, models or elements of mindfulness which have been included below:

1. Shapiro et al (2006b) identified three axioms of mindfulness: intention, attention and attitude that match Kabat-Zinn's definition of mindfulness where he refers to it as

> 'paying attention in a particular way: on purpose, in the present moment and non-judgementally' (Kabat-Zinn 1994, p 4)

Shapiro et al (2006b) comment on the axioms as follows: intention ('on purpose') – attention ('paying attention') – attitude ('in a particular way').

2. Bishop et al (2004) suggest a model of mindfulness consisting of two components involving 1) self-regulation of attention so it is maintained on immediate experience, thereby allowing for increased recognition of mental events in the present moment, 2) the adoption of a particular orientation towards one's experience in the present moment, an orientation that is characterised by curiosity, openness and acceptance.

3. Diminished self-talk, quieting the self chatter, the running flow of mental commentary (Leary and Tate 2007).

4. The concept of non-doing is important in the practice of mindfulness is that there is no trying to do or to experience anything in particular whilst maintaining mindful attention (Leary and Tate 2007).

5. Self- regulation enables systems to maintain stability of functioning and adapt to change. Shapiro and Schwartz (2000) claim that intention and attention function to enhance these feedback loops and create health:
Intention – attention – connection – regulation – order – health
Shapiro et al (2006b) suggest that intentionally cultivating non-judgemental attention leads to attention which leads to connection, leading to self-regulation and greater order and health. Attending to the information contained in each moment can be done through the process of reperceiving.

6. It has been suggested (Brown et al 2007a) that clinically orientated conceptualisation of mindfulness, as in MBSR, can confound the description of the phenomenon with the methods through which it is fostered. Intention and compassion (inviting a kindly and non-judgemental attitude towards the self) whilst practising mindfulness have been highlighted.

3.7 The relationship between meditation and mindfulness

The term meditation is often misconstrued and misunderstood. Whilst this term is used, often in relation to the 'sitting practice' of mindfulness, it conjures up many different images in people's minds depending on their previously experience. Frequent misconceptions about meditation include mentally trying to shut off or get away from the present moment and trying to stop thoughts and feelings arising, or trying to reach some higher spiritual plane.

To learn any form of meditation, the first step is the development of concentration. The practice of mindfulness presupposes concentration to maintain steady attention, this adds stability to the observation of thoughts and feelings in a non-reactive way (Hanh 1991, Nyanaponika 1992, Kabat-Zinn 1990). However, it differs from concentration forms of meditation, such as Transcendental Meditation® (TM®) which uses the internal repetition of a sound or mantra, because rather than restricting attention to one object, mindfulness emphasises detached observation, from one moment to the next, of a constantly changing field of objects of awareness such as the breath, thoughts passing through the mind, emotions that arise, sensations in the body and sounds that come to the ears, just as they happen.

According to Segal et al (2002) the doing/driven mode is goal orientated, motivated to reduce the gap between how things are and how we would like them to be; our attention is devoted to a narrow focus on discrepancies between desired and actual states. In contrast, the way of being, as fostered in mindful awareness and attention, is not motivated to achieve particular goals. This has two implications. Firstly there is no need for constant monitoring and evaluation of 'How am I getting on with meeting my goals?'

Secondly there is no need to emphasise discrepancy-based processing. Instead the focus of the being mode is 'accepting' and 'allowing' what is, without any immediate pressure to change it. As counter-intuitive as it may seem, it is through this process of acceptance and non-doing that changes happen, that insight and understanding is experienced.

Coupled with mindfulness, concentration gives rise to a non-discursive, non-analytical, direct experience of the object of attention. For example, patients who are able to identify anxious thoughts as 'thoughts', rather than as 'reality', report that this alone helps to reduce their anxiety and increases their ability to encounter anxiety-producing situations more effectively (Kabat-Zinn et al 1992). Brown and Ryan (2003) argue the value of mindfulness in improving psychological wellbeing. The development of insight may result and the possibility of choosing responses most called for by the situation rather than those reactively driven by fear, habit or long-standing training (Santorelli 2000).

3.8 Mechanisms of action in mindfulness

The mechanisms of action of mindfulness that might explain how mindfulness skills can lead to symptom reduction and behavioural change have been suggested by Baer (2003) to include exposure, cognitive change, self-management, relaxation and acceptance. These will now be discussed below.

3.8.1 Exposure

Mindfulness requires bringing attention to whatever comes into the field of awareness, where preferred or not, whether pleasant or unpleasant. Using the example of pain, Kabat-Zinn (1982) comments that mindfulness requires focusing on unpleasant and painful sensations when present, discouraging avoidance, distraction, escape or absorption in another object of attention. This can help the person cope with the physical and emotional experience of pain (Kabat-Zinn 1982, Kabat-Zinn et al 1987). This principle can be applied to any other physical sensation, thought or emotions such as anxiety (Kabat-Zinn et al 1992) that arises as a means of relieving its severity. It has been shown that other methods are not as effective in reducing pain symptoms in comparison to mindful observation, acceptance based protocols. Eifert and Heffner (2003) found that in response to pain, mindful observation (acceptance) was less avoidant behaviourally and those practising mindful observation reported less intense fear and cognitive symptoms and fewer catastrophic thoughts compared to controls using diaphragmatic breathing; Gutiérrez et al (2004) found a higher tolerance to pain with a mindful acceptance-based protocol compared to controls focussing on changing pain related thoughts and feelings. There is no evidence that mindfulness has been compared with other distraction techniques such as relaxation and visualisation evaluated by meta-analyses for cancer pain (Devine 2003), so it is not possible to comment further on their relative effectiveness,

but it would seem that research to compare the effectiveness of mindfulness with relaxation and visualisation may be helpful.

3.8.2 Cognitive change

The practice of mindfulness can lead to changes in thought patterns and in the way that thoughts are viewed (Baer 2003). No matter the content of thoughts, they may be seen as 'just thoughts', events passing across the field of awareness. Again with the example of pain, Kabat-Zinn (1982) suggests that this is achieved by the momentary uncoupling of the sensory component of pain from the affective and cognitive aspects, creating a detached observation. He comments that with practice, a person might develop an attitude of detached observation towards a sensation when it becomes prominent in the field of awareness, and to observe, with a similar detachment, the cognitive processes (mental label of pain), seeing them as 'just thoughts' which then label the sensation as painful. Emotions can be treated in the same manner, emphasising the shift in perception available to both mental and emotional levels through mindfulness.

3.8.3 Self-management

The fact that coping skills may be promoted as a result of the mindfulness skill of improved self-observation has been noted by some authors (Baer 2003). As an aid to the reducing the risk of a recurrent episode of depression, Teasdale et al (2000) suggest that patients can learn to become more aware of negative thoughts and feelings at times of potential relapse/recurrence so that they learn to disentangle those thoughts and feelings from ruminative depressive processing (Nolen-Hoeksema 1991). In the context of mindfulness practice, these principles of self observation and disentanglement have been applied as self-management tools to a wide variety of conditions including pain (Kabat-Zinn 1982), anxiety (Kabat-Zinn et al 1992), binge eating (Kristeller and Hallett 1999), mood and stress in cancer outpatients (Speca et al 2000), sleep disturbance in breast cancer (Shapiro et al 2003). The fact that mindfulness practice is a form of self-management is a key component to its possible application in coping with symptoms and managing everyday life more effectively.

3.8.4 The relationship between relaxation and meditation

The relationship between meditation and relaxation is quite complex (Baer 2003). It is recognised that meditation can induce a relaxed state but it is not its sole or primary objective of mindfulness practice. Benson (1975) coined the term 'relaxation response' while utilising a simple meditation when trying to help those with moderate chronic sympathetic arousal. Others have continued to discuss this relationship between different forms of meditation and the relaxation response (Shapiro 1984). With mindfulness, participants are taught to keep their minds present by repeatedly bringing their attention

and awareness to the present moment in a non-judgemental way each time they realise that the mind is no longer present. Indeed, this may be the mechanism by which relaxation is achieved.

3.8.5 Acceptance

Acceptance is taught as an alternative to avoidance as part of the process of change in mindfulness and is one of its foundations (Kabat-Zinn 1990). It is also part of other newer psychological therapies such as Acceptance and Commitment Therapy described in 3.10.3.2 where events or symptoms such as anxiety are experienced fully and without defence (Hayes et al 2006). Acceptance is seen as central to this process of change and can be viewed as the springboard from which it happens. Baer (2003) comments that treatment programmes which involve mindfulness include acceptance of pain, thoughts, feelings, urges, or other bodily sensations, cognitive or emotional events without trying to change, escape or avoid them.

3.9 Distinctions in the conceptualisation of mindfulness

It is noted however that the identification of processes by which mindfulness affects emotions and behaviour is clouded by the multifaceted nature of mindfulness. In addition, mindfulness has been viewed as a 'monolithic construct', coming from a single source, rather than as an experience that emerges from the simultaneous confluence of some combination of distinct elements (Leary and Tate 2007). Brown et al (2007b) raise the issue of the similarities and differences of mindfulness, self-awareness and self-focused attention. They conclude that mindfulness represents an open unbiased awareness of and attention to inner experience and manifest action. This is in contrast to focusing on the concerns and biases of self-centred thought in the case of self-awareness and self-focused attention.

Brown et al (2007b) also distinguish mindfulness from self-control in terms of their ultimate ends. They note that in western cultures, there is ongoing, effortful regulation of goals and a focus on achievement in life, a form of self-control. Unlike this, mindfulness is the awareness of the ongoing demands put on by the self, including the attempts to exert self-control. Awareness of this distinction may ultimately help people decide whether self control is in their best interests in any given situation.

3.10 Mindfulness-based programmes

3.10.1 The need for mindfulness-based programmes

The shift from doing to being is learned process for most people which is why there is a need for mindfulness based programmes. Brown et al (2007a) identify a further need because certain phenomena can remain hidden from consciousness as they represent

threats to self-concept or to aspects of self that are ego-invested. It is only possible to change behaviours or attitudes that people are aware of.

3.10.2 The range of mindfulness based interventions

There are a number of mindfulness based interventions which have developed over recent years. MBSR is the most frequently cited (Baer 2003) but there are others and it is important to understand the distinctions between them and other approaches which are similar. Table 3.2 identifies these and there is a summary of each one to follow.

Table 3.2. Mindfulness and related interventions

Interventions based on mindfulness training
Mindfulness-Based Stress Reduction (MBSR)
Mindfulness-Based Cognitive Therapy (MBCT)
Mindfulness-Based Art Therapy (MBAT)
Other interventions incorporating mindfulness training
Dialectical Behavioural Therapy (DBT)
Acceptance and Commitment Therapy (ACT)
Relapse Prevention

3.10.2.1 Mindfulness-Based Stress Reduction (MBSR)

Mindfulness-Based Stress Reduction (MBSR) was developed by Kabat-Zinn (1982) in 1979 in a behavioural medicine setting for people with a range of chronic, painful and stress-related conditions. Currently, around the world, the MBSR programme is conducted as courses of six to 10 weeks for groups of up to 30 participants who meet weekly for 1.5 - 2.5 hours (see Table 4.4 for comparison of classroom sizes and times offered in MBSR and cancer studies to date). In addition, a day of mindfulness practice of six to eight hours, is usually offered in week six of the programme. Either daily, or six days out of seven, home mindfulness practice is part of the course with four 30 - 45 minute CDs provided. Components of home practice are:

1) a mindful bodyscan (done lying down if possible, bringing attention and awareness to different parts of the body),
2) mindful gentle lying yoga stretches are given to teach mindful awareness whilst moving
3) a mindful sitting meditation practice
4) mindful gentle standing yoga stretches.

In addition, participants practise mindfulness during daily activities such as eating and walking.

For a summary of the eight week MBSR programme taught in this study, see Appendix 3 and for a description of the MBSR programme as taught each week, see Appendix 4.

3.10.2.2 Mindfulness-Based Cognitive Therapy (MBCT)

Mindfulness-Based Cognitive Therapy (MBCT) is an 8-week programme integrating some aspects of Cognitive Behaviour Therapy (CBT) for depression (Beck et al 1979) with components of Kabat-Zinn's MBSR programme (Teasdale et al 1995, 2000). MBCT is a manualised programme created by Segal, Williams and Teasdale (2002). Aspects of CBT included in MBCT are mainly those designed to facilitate decentred views such as 'thoughts are not facts' and 'I am not my thoughts'. Unlike CBT, there is little explicit emphasis in MBCT on changing the content or specific meanings of negative automatic thoughts, rather in changing the awareness towards them. MBCT focuses on teaching people to become more aware of thoughts and feelings and to relate to them as 'mental events' from a decentred perspective, rather than as aspects of self or as true reflections of reality. It is this mechanism applied to depressive thoughts that can help prevent relapse of depression (Teasdale et al 2000). According to Kabat-Zinn (2004, personal communication), when taught well, there is a 95% overlap between MBSR and MBCT.

3.10.2.3 Mindfulness-Based Art Therapy (MBAT)

Mindfulness-Based Art Therapy (MBAT) is conceptually rooted in the principles of self-regulation theory (Leventhal et al 1992) which provides a foundation for understanding reactions to perceptions of physical and emotional wellbeing. MBAT is designed to provide specific skills for cultivating self-regulation in a format that is not confined to verbal processing alone. In addition to the skills already provided by MBSR, art therapy as part of MBAT provides concrete tasks for expressing representations in a tangible and personally meaningful manner, designed to complement the MBSR curriculum. The process orientation in mindfulness and art making in MBAT supports in the transformation of perceived threats enabling more adaptive coping (Monti et al 2006).

3.10.3 Other interventions incorporating mindfulness training

3.10.3.1 Dialectical Behavioural Therapy (DBT)

Dialectical Behavioural Therapy (DBT) was developed by Linehan (1993) and is a multifaceted approach to the treatment of borderline personality disorder. It is based on the idea that reality consists of opposing forces as proposed by the dialectical view of the world. The relationship between acceptance of oneself and one's life and the paradoxical opportunity this creates for change is central to DBT. Mindfulness skills are taught in DBT as part of the process of acceptance and change. DBT is run as a year-long weekly skills group and has other elements including interpersonal effectiveness, emotional regulation and distress tolerance skills.

3.10.3.2 Acceptance and Commitment Therapy (ACT)

Acceptance and Commitment Therapy (ACT) comes from clinical behaviour analysis (Hayes, Strosahl and Wilson 1999). ACT is part of the cognitive behavioural therapy (CBT) tradition, although it has notable differences from CBT. The primary ACT components are challenging the control agenda, using acceptance, where

> 'acceptance involves the active and aware embrace of those private events occasioned by one's history without unnecessary attempts to change their frequency or form, especially when doing so would cause more psychological harm' (Hayes et al 2006, p 7).

In ACT, acceptance is not an end in itself, but more as a method of identifying appropriate further action. Other aspects of ACT include cognitive defusion, (which attempts to alter the undesirable function of thoughts rather than trying to alter their form, frequency or sensitivity to a situation), self as context, committed action, values, and contact with the present moment (Hayes et al 2006). Common foundations with mindfulness include the teaching of a separate observing or witnessing self that can watch thoughts, emotions and body sensations. In addition, this observation comes without judging or changing the experience (Hayes and Pierson 2005). It does not include formal practices of mindfulness or meditation (Baer 2003).

3.10.3.3 Relapse Prevention

Relapse prevention is a cognitive-behavioural treatment package created to prevent relapse in people who suffer from substance abuse developed by Marlatt and Gordon (1985). It employs mindfulness (Marlatt et al 2004) as a way to help cope with urges to use substances. Participants are encouraged to accept the constantly changing experiences of the present moment in contrast to addiction, where there is an inability to accept the present moment and a persistent seeking of the next 'high' associated with the addiction. Mindfulness allows the observation of urges, their acceptance and adaptive coping.

3.10.4 Similarities to and differences from Cognitive Behavioural Therapy (CBT)

The mindfulness, cognitive and cognitive behavioural approaches share an emphasis on noting sensations and thoughts without viewing them as catastrophic and the use of stress-inducing situations as triggers to engage new behaviours. Unlike many health promotion and cognitive-behavioural approaches, mindfulness training focuses solely on cultivating inner resources and awareness of cognitive processes, identifying thoughts as 'just thoughts', or emotions to be 'just emotions'. In addition to this, mindfulness neither includes the evaluation of thoughts as rational or distorted nor tries to change the ones

deemed irrational as is done in CBT. Mindfulness does not have a clear and specific goal such as changing a specific thinking or behavioural pattern as does CBT, in mindfulness thoughts are simply observed 'as thoughts', in a non-judgemental way, and rather than goal setting, an attitude of non-striving is adopted. Teasdale et al (1995), in analysing mindfulness and mindlessness and its effect on the prevention of depressive relapse, proposed that cognitive therapy involves a more active 'coping and controlling stance' towards the thoughts and emotions that arise than does mindfulness, which in contrast allows things to be as they are, observing them as they pass across the field of awareness.

3.11 The underpinnings of MBSR teaching

The teaching of MBSR was started at the University of Massachusetts and that centre has remained the world leader and developer of that programme. It provides programmes for teacher training, ongoing professional supervision and more recently accreditation for teachers. Saki Santorelli, D.Ed, the current Director for the Center for Mindfulness at the University of Massachusetts has proposed the following theoretical underpinning of MBSR teaching (Santorelli 2004a), see Table 3.3.

Table 3.3. The theoretical underpinning of MBSR teaching

Educational	Palmer (1998)	Inner landscape of teachers
	Friere (1998)	Education as liberative
	Winnicott (1965)	Holding environment enabling safety for person to then take responsibility for self
	Kegan (1982)	A model of adult psychological development where development consisting of six "equilibrium stages": The object of each stage is the subject of the preceding stage.

(Santorelli 2004a)

3.11.1 Elements in teaching mindfulness

There are three elements involved in the teaching of MBSR which are interwoven throughout the eight weeks which are as follows

1. Practice of mindfulness – teaching by example, as far as possible being mindful and giving space in the teaching for mindfulness to occur
2. Didactic teaching – giving direction and instruction to guide the course
3. Group process – sharing of experiences and learning process between participants and teacher

3.11.2 The five stages in the 8-week MBSR programme

Stage I – meeting yourself – in the present moment

Stage II – perception – ways of seeing

Stage III – meeting the world – attachment and aversion

Stage IV – self and others – in relationship - assertiveness or passive/aggressive

Stage V – how that shapes our lives – how we take mindfulness into the world

In the formal practice of mindfulness, when thoughts, emotions, or bodily sensations arise, they are observed in a non-judgemental way and participants are instructed not to become caught up in their content, (Kabat-Zinn 1982) rather to take a decentred view on situations, noticing how thoughts, emotions and bodily sensations are transient and ever changing. For example, instructions about managing thoughts might include them being observed as passing across the field of awareness like 'clouds moving across the sky on a Summer's day'. Thoughts, emotions and sensations are viewed as events rather than an integral part of the person. When the attention wanders from the present, once this is recognised, then mindful awareness has been regained and attention is returned to the present moment. In practising mindfulness, observing the breath or the rise and fall of the abdomen as breathing happens naturally, are often used as an anchor for the mind to come back to in the present moment.

3.11.3 The process of the cultivation of mindfulness in sitting meditation

To begin the practice of mindfulness, flexibility of the mind to observe each moment is achieved by first concentrating on one primary object (often the successive movement of inbreaths and outbreaths), until attention is relatively stable. After this, over a period of time, the field of objects of attention is allowed to expand systematically, finally to include all physical and mental events as they occur in time. In mindfulness practice, nothing is considered a distraction (not even the wandering of the mind), this is another thing to be observed each time it happens, just like everything else. The process engaged in by adopting this stance towards self-observation is referred to in the meditation literature variously as bare attention (Nyanaponika 1992), choiceless awareness, shikan-taza (Japanese for just sitting), and 'just like this mind' (Kabat-Zinn 1982).

3.11.4 Requirement of mindfulness teachers to practise mindfulness

From the Buddhist tradition of teaching mindfulness, it is generally regarded as a essential requirement of teaching mindfulness interventions including MBSR, MBCT, MBAT that the teachers practise mindfulness themselves in their own lives. This is considered a vital aspect to understand the process of mindfulness and allows the teacher of mindfulness to teach 'from the inside out'. The understanding of mindfulness and wisdom of teachers or therapists may be conveyed by example and in ways that are not yet understood. Early MBSR groups led by individuals who lacked personal experience tended to be ineffective (Rosch 2007). Details of the training undertaken by this candidate can be found in Appendix 5. This training was considered to bring the researcher to a level of competence to teach MBSR at a professional level.

3.12 Measurement tools for evaluating mindfulness

Finding sound methods to assess mindfulness are necessary to measure how the practice of mindfulness may lead to the reduction of symptoms and improvements in wellbeing (Baer 2007). There are now five recently developed measures to assess mindfulness:

1. Freiburg Mindfulness Inventory (FMI) (Buchheld, Grossman and Walach 2001)
2. Mindful Attention and Awareness Scale (MAAS) (Brown and Ryan 2003)
3. Kentucky Inventory of Mindfulness Skills (KIMS) (Baer, Smith and Allen 2004)
4. Cognitive and Affective Mindfulness Scale (CAMS) (Feldman, Hayes, Kumar, Greeson and Laurenceau 2007)
5. The Mindfulness Questionnaire (MQ) (Chadwick, Hember, Mead, Lilley, Dagnan, unpublished, 2005)

Baer et al (2008) comment that the instruments, except the Kentucky Inventory of Mindfulness Skills (KIMS), are designed to capture multiple trait-like components of mindfulness including attention, awareness, opening, letting go, non-judging, acceptance and non-aversion, but do not measure them separately and give only a total score. The KIMS provides subscale scores for each of the four mindfulness skills (observing, describing, acting with awareness, and accepting without judgement).

Baer et al (2008) note that all these mindfulness measures use self-report methods to assess a general tendency to be mindful in daily life and have more recently shown significant correlation with each other and promising psychometric characteristics (Baer et al 2006). However, differences in the content and structure of the mindfulness measures suggest a lack of consensus among researchers about whether mindfulness should be conceptualised as a multifaceted construct and if so, how the separate facets should be defined and operationalised, and how many there should be. The current study did not use one of these tools to measure mindfulness despite being aware of the existence of the published scales, as at the time of developing this study, the validity and reliability of the measures had not been externally confirmed, which has been the subject of ongoing work (Baer 2006, 2008).

3.13 Overview of MBSR clinical research

To identify relevant literature to inform the background of the study, a search was carried out following the strategy. The following databases were search: AMED, British Nursing Index, CINAHL, Ovid MEDLINE(R), PsycINFO. The search strategy used the keywords of mindful$ and MBSR and the search was limited to the English language from 1980 -2004.

The depth and breadth of mindfulness research in health care settings has been developing steadily for over 25 years. The best kind of clinical research evidence is

defined by Straus et al (2005) as research which investigates the efficacy and safety of therapeutic, rehabilitative and preventative regimes. They comment that finding new evidence from clinical research can replace existing therapeutic methods with new ones that are more accurate, efficacious and safer. The widespread use of hierarchies of evidence that grade research studies according to their quality have brought attention to the fact that some studies are more trustworthy than others but they have also led to misconceptions and abuses (Glasziou et al 2004) in the sense that different types of research questions require different types of evidence. Systematic reviews are always preferred to viewing single randomised controlled studies and meta-analyses of these reviews where applicable. Qualitative studies can also be included in reviews. Case reports can be of interest but with limited value. A problem with hierarchies of evidence is the collapsing of multiple dimensions of quality (design, conduct, size, relevance and so on) into a single grade possibly ignoring other elements such as the validity of measurements and issues of blinding to assessments, absolute and relative effect sizes (Glasziou et al 2004).

It is the aim of this review to identify the most robust research available in MBSR and evaluate it to inform the structure and content of this study In this review, there will be four levels of mindfulness research discussed based on a generally accepted hierarchy of evidence (Petticrew and Roberts 2003):

1. Meta-analyses and reviews
2. Randomised controlled trials (RCTs) in a range of health care settings
3. RCTs and uncontrolled studies in people with cancer
4. RCTs and uncontrolled studies in people with breast cancer
5. Qualitative studies

3.13.1 Meta-analyses and reviews

In the most complete scientific review of mindfulness to date, Baer (2003) employed meta-analytic techniques to quantify findings and make comparisons between mindfulness studies. She evaluated 19 empirical studies of mindfulness-based interventions including MBSR and Mindfulness Based Cognitive Therapy (MBCT) in a variety of clinical conditions which included anxiety, eating disorders, major depressive disorders, fibromyalgia, psoriasis and cancer. These studies had sample sizes ranging from 16 to 142, mean age of participants ranging from 38 to 50 years.

The three most rigorous studies in the analysis are discussed in the paragraphs below. All of these had comparison groups and conducted between group analysis on their results.

The effect size (Cohen's *d*) was calculated for each study, it is the difference between baseline and follow up scores divided by the standard deviation of baseline scores (Kazis et al 1989). The purpose of calculating effect size is to determine whether a change in health status is statistically significant and to permit comparison with other instruments, interventions, or studies. These effect sizes were then averaged across dependent measures within studies, giving a single post treatment effect size for each study. Post treatment effect sizes ranged from 0.15 to 1.65, mean was 0.74, (SD = 0.39). When each of these 15 effect sizes was weighted by sample size, the overall effect size was 0.59, a medium effect. Baer (2003) concludes her review saying that as the term 'stress reduction' implies, mindfulness-based stress reduction is designed to reduce suffering and improve health and wellbeing and to be broadly applicable to many problems.

Teasdale et al (2000) evaluated (N=132) MBCT (n=63) with treatment as usual (n=69) for patients between depressive episodes. They found that MBCT helped prevent relapse in those who had previously had one previous recurrence (*d*=0.60). Goldenberg et al (1994) evaluated MBSR with fibro-myalgia patients (n=79) compared to TAU (n=24) or wait list (n=18), evaluating pain, sleep other symptoms (*d*=0.42). Speca et al (2000) evaluated MBSR in cancer patients (n=90), mood and stress were evaluated (*d*=0.60).

The results from Baer's meta-analysis suggest that these mindfulness interventions have found at least a medium-sized effect (around 0.5) with some effect sizes falling within the large range (0.8 upwards). This was considered to be a conservative estimate due to poor reporting in some studies, where mean and standard deviations or significance levels (p values) were not given.

Because of the way these studies were reported, the clinical significance of the changes reported is difficult to assess. However these results suggested that on average, in studies where participants had mild or moderate psychological distress, as a result of mindfulness training, their levels of distress were brought into or close to the normal range. Lack of control groups and small sample sizes were the main limitations of studies used in this analysis. The authors concluded that mindfulness-based interventions may help alleviate a variety of mental health problems and improve psychological functioning. Five studies with group designs using random assignment were reviewed here (Astin 1997, Kabat-Zinn et al 1998b, Shapiro et al 1998, Speca et al 2000, Williams et al 2001). All show MBSR to be more effective that waiting-list or treatment-as-usual-control groups. The study by Speca et al (2000) study involved patients with cancer and will be discussed in more detail later in this literature review.

Two other authors, Proulx (2003) and Bishop (2002) have performed general reviews of mindfulness literature. Proulx (2003) performed an integrative review of 21 mindfulness studies in both clinical and college-based settings. Seven studies (37%) had small sample sizes and were considered pilot or exploratory. Only two studies (Williams et al 2001, Teasdale et al 2000) had a sufficient sample size calculated to ensure adequate power. Her conclusions state that further research is clearly needed, including larger, randomised studies with comparison treatment control groups. She also suggests that to support the implementation of MBSR programmes, more expanded studies are needed in the areas of clinical efficacy, cost efficiency, health promotion and long-term durability. Bishop (2002) performed a review of the literature within the medical and social sciences of MBSR. His method of review and search strategy are not stated in the paper, but appears limited as he only reviewed four controlled studies and seven uncontrolled studies, all of which were more rigorously evaluated by Baer (2003) in her meta-analysis. Bishop (2002) concluded that MBSR seems to hold promise as a potentially effective treatment option that may assist some patients to self-manage stress and mood symptoms in the face of their illness.

In summary, the outcomes of meta-analyses and reviews conducted prior to the commencement of the current study showed promising results from the research trials evaluating mindfulness as an intervention across a variety of health care settings. Many studies were limited by small sample sizes, lack of controls and inadequate reporting. There was an increasing amount of evidence to suggest that mindfulness approaches are having some clinical effects, particularly with mild to moderate psychologically based health conditions. The recommendations from these reviews suggested that further investigation was warranted.

3.13.2 MBSR randomised controlled trials in a range of health care settings

The randomised controlled trials mentioned below were all included in the review by Baer (2003) so they will be discussed in brief in this section. MBSR research, excluding studies relating to people with cancer, has demonstrated improvements in physical and psychological parameters in relation to chronic pain (Kabat-Zinn 1982, Kabat-Zinn and Burney 1985, Kabat-Zinn et al 1987), anxiety (Kabat-Zinn et al 1992, Miller et al 1995), fibromyalgia (Kaplan et al 1993), increased sense of control and reduction in psychological symptoms (Astin 1997) and psoriasis (Kabat-Zinn et al 1998b).

Astin (1997) evaluated MBSR in a wait-listed controlled trial of medical students and Kristeller and Hallett (1999) performed a pre-post intervention in people suffering from binge-eating disorders. Both authors suggest that the emphasis on mindfulness on

accepting and trusting present moment cognitive, affective and bodily experiences may have a positive effect on sense of control leading to greater psychological health and enhanced ability to cope with life experiences.

Many of these early trials have methodological flaws, including lacking matched control groups and the use of small sample sizes which emphasises the need for more rigorously conducted trials. These conclusions once again suggest the need for more rigorous research to be performed in future studies.

3.14 MBSR research in cancer care

A systematic review on the effectiveness of MBSR as supportive therapy in cancer care (Smith et al 2005, 2006a) identified three randomised controlled trials (see Table 3.4, p 72) and seven uncontrolled clinical trials (see Table 3.5, pp 73 to 75) and found a lack of any relevant qualitative research. Qualitative research could help address the issues surrounding the experience of participating in MBSR and practising mindfulness and how that impacts health and wellbeing for those affected by breast cancer. More detail and discussion of these studies is found in the next section of this literature review. The findings of the review by Smith et al (2005, 2006a) were that studies reported positive results in mood, sleep quality and reduction in stress. In addition, a dose-response effect was observed between increased practice of MBSR and improvements in outcomes. They conclude that lack of controls in many studies precludes any firm conclusion on efficacy and recommend that further research examines the efficacy, feasibility and safety of mindfulness interventions for cancer patients in the nursing context.

3.14.1 Controlled studies of MBSR in cancer outpatients

There were two randomised controlled studies in MBSR in cancer care published prior to the commencement of this study, the first with cancer outpatients (Speca et al 2000), and a six month follow up of this study which is uncontrolled (Carlson et al 2001) and a study evaluating MBSR and its effects on sleep women with stages II breast cancer (Shapiro et al 2003). These papers will now be discussed in detail.

Speca et al (2000) used a randomised wait-list controlled clinical trial evaluating the effects of a seven week MBSR programme of 1.5 hours per week plus home meditation practice on mood and symptoms of stress in cancer out-patients. A convenience sample of people suffering from all types and stages of cancers was taken. The modal stage of cancer for participants was Stage II. No power calculation for sample size is made explicit in the report and 90 out of an initial 109 patients completed the study, 38 of whom had breast cancer (the largest subgroup). Measurement tools used were Profile of Mood States (POMS) and the Symptoms of Stress Inventory (SOSI) pre- and post-intervention.

Results of the treatment group showed a 65% reduction in total mood disturbance as measured by POMS post intervention on Total Mood Disturbance (mean 14.7, SD 29.8, $p<0.01$) and subscales of depression (mean 8.4, SD 8.9, $p<0.05$) anger (mean 6.1, SD 5.1, $p<0.05$) and confusion (mean 3.2, SD 4.8, $p<0.05$) compared to a reduction of only 12% in the control group (mean 32.9, SD 33). Change scores were calculated by subtracting the scores at Time 1 from Time 2, therefore negative scores represent improvement. Significant POMS change scores in the treatment group for Total Mood Disturbance were -24.1 ($p<0.001$), subscales of Tension-Anxiety -4.8 ($p<0.001$), depression-dejection -6.2 ($p<0.01$), anger-hostility -3.9 ($p<0.01$), and confusion -2.5 ($p<0.01$).

A reduction of 30.7% (mean 68.9, SD 40.4, $p < 0.001$) in stress symptoms as measured by SOSI was found in the treatment group compared to controls which improved by only an 11.1% (mean 97.6, SD 54.0). SOSI total change scores in the treatment group were -31.3, ($p<0.01$), with the treatment group subscales of habitual patterns change score -5.2 ($p<0.01$) and emotional irritability -3.7 ($p<0.05$). In addition to this, time spent in meditation correlated with reductions in mood disturbance. There were correlations between attendance, mindfulness practice and stress reduction ($r=0.30$, $p<0.05$) and ($r=0.253$, $p<0.10$) respectively. There was also a correlation between total meditation time in minutes and was improved total mood disturbance ($r= 0.393$, $p<0.01$). The best predictor of improvements for stress symptoms was found to be the number of sessions attended, which accounted for 13.2% of the variance in total change scores ($F(2,43)=3.11$, $p<0.05$).

This was a generally well-conducted and reported study except for lack of evidence of a power calculation. Clinically the results are interesting as the kinds of changes in awareness and perceptions available through MBSR are demonstrated in the significant change scores in habitual patterns and emotional irritability. However, one change in the MBSR programme which has been modified in the absence of a day of silent retreat in week six of the programme offered to participants and that the audiotapes provided for home practice were sensate-focused relaxation induction and a guided meditation, missing out home practice instruction on the mindful stretches (yoga) which is generally given as part of a standard MBSR programme. In addition, the programme ran over seven weeks, not 8 and the weekly session time was only 1.5 hours. Table 4.4 compares classroom times offered by Speca compared to the current research and other relevant studies.

A six months uncontrolled follow up study by Speca et al (2000) was reported by Carlson et al (2001). This follow up was achieved by the completion of postal questionnaires by 54 (60.7%) of the 90 patients. Using paired sample t-tests for the period of time from the post intervention scores to follow-up, a shift towards improvement in mood states (POMS) was found but none of these improvements were statistically significant. Of note, the most improvement occurred on the subscales measuring depression, anxiety and anger (emotional irritability on the SOSI). This is important as these are among the most frequently reported problematic psychological symptoms identified by a randomly selected sample of cancer patients from three centres, where over one third met diagnostic criteria for depression and anxiety (Derogatis et al 1983). The SOSI total score reflected a small reduction in overall stress scores experienced by participants but were not significant. This follow-up study lacks a control group and there was no mention of any co-interventions used by the participants that may have influenced the study outcomes.

These studies by Speca et al (2000) and Carlson et al (2001) are the most rigorously reported studies of MBSR and cancer patients published to date in that they meet most of the standards of the Consort statement (Moher et al 2001) for reporting studies adequately except for those mentioned in the earlier such as not reporting confidence intervals. It was the POMS scores reported by Speca et al (2000) that informed the power calculation for the current study. They suggest that future studies might help pinpoint the post effective aspects of this intervention, however this suggestion was not thought to be feasible to do in the study for reasons of time and resources.

At the time of developing the current study, there was an ongoing randomised pilot study of Mindfulness-Based Art Therapy (MBAT) in 96 cancer patients (Monti and Peterson 2002) where patients were randomly assigned to MBAT experimental group or non-intervention control group. The intervention group received eight weekly meetings of 2.5 hours. At the end of the eight weeks, the patients in the control group crossed over into the experimental intervention arm for an additional eight weeks. Pre- and post-intervention measures included health related quality of life (SF-36), psychological distress (SCL-90) and coping (COPE). The long-term goal of the study was to collect sufficient data to determine the overall efficacy of this promising intervention and to identify which patients are particularly likely to benefit from MBAT. Due to the inclusion of art therapy into the mindfulness programme, the confounding factors make it difficult so know how the results that might come from this study could inform the further development of the current study.

3.14.2 Controlled studies of MBSR and breast cancer research

There was only one published study regarding the use of MBSR in women with breast cancer before the current study commenced. Shapiro et al (2003) undertook an

exploratory randomised controlled study examining the effects of the MBSR intervention in relation to sleep disturbance in women with stage II breast cancer (N=63). Justification for choosing women with stage II breast cancer was the fact that this group of women experience a great deal of distress due to their diagnosis, treatment and fear of breast cancer recurring or of metastases. Whilst it is possible that choosing this group of women may help restrict variables, this argument could apply to any stage of breast cancer from 0 to III.

The MBSR intervention in this programme offered six weekly classes of two hour duration and a six hour silent retreat. Participants received mindfulness training in sitting meditation, body scan, progressive movement of attention through the body, yoga stretches designed to enhance greater awareness and to balance and strengthen the musculoskeletal system.

The control group were able to 'freely choose' which stress management techniques to engage in each week (e.g. talking to a friend, exercise, or taking a warm bath). Participants received a workbook including support, resources available in the community, poetry and a diary for journaling, were asked to monitor the stress management activities in which they engaged and to record the amount of time in a daily diary.

Measurement tools used in this study included sleep diaries which enabled sleep efficiency and sleep quality to be calculated, Profile of Mood States (POMS), Beck Depression Inventory (BDI), Penn State Worry Questionnaire (PENN), the Spielberger State-Trait Anxiety Inventory (STAI), the Functional Assessment of Cancer Treatment – Breast (FACT-B), the Shapiro Control Inventory (SCI), and Sense of Coherence (SOC). All the variables were reassessed within one-week pre-and post-intervention and at three and nine month follow-up.

Some limitations of this study were that no details were given of how the required sample size was estimated or whether a power calculation was performed. No details of the randomisation process or whether there was adequate concealment of allocation and masking were given. The reporting of this paper was inadequate as there are no results reported regarding any changes on the individual scales used pre- and post-treatment, no means, standard deviations or CI are reported. Only results from a hierarchical regression model using the computer programme SAS PROG GLM was reported. Unfortunately it was not possible to measure the individual changes of each measurement tool from the information presented.

Significant between-group differences were reported at baseline in the measurements of depression, trait anxiety, worry, positive sense of control, quality of life and sense of coherence. The authors attributed this to informing patients of their random assignment to either the experimental or control group prior to the collection of baseline data. The Cronbach's alpha of this of these six affected variables was 0.91, showing great internal consistency amongst them. On the basis of the significant between-group differences at baseline, authors decided to treat the groups as non-equivalent in the analysis.

Of participants, 86% (n=54) completed post assessment data, (28 controls and 26 MBSR), 65% (n=41)) completed 3 month follow-up (23 control and 18 MBSR), and 78% (27 control and 22 MBSR), completed nine month follow-up. Of the 30 women who commenced the MBSR, 84% (n=26) completed at least four of the seven sessions, and 80% (n=24) completed five or more.

Results using regression analysis suggested that both MBSR and 'free choice' control participants (who chose their own stress management techniques such as talking to a friend, reading a book, taking a bath), showed significant improvement in sleep diary quality measures, although neither group showed statistically significant improvement on sleep efficiency which was 0.89 at baseline and 0.915 after treatment. Sleep quality did not improve when baseline distress was controlled, nor were there differences between experimental conditions. After controlling for baseline distress, the main linear effect of time on degree of feeling rested after sleep was significant and negative ($\beta = -1.678$). This showed that feelings of being refreshed after sleep decreased over time for both groups. They did not find any significant relationship between sleep quality and the amount of mindfulness practice.

Shapiro et al (2003) found that participants who practised mindfulness at home did get greater improvements in feeling refreshed after sleep (*df* 1,34, *F*-value 8.37, Pr > *F* 0.007), suggesting that benefits came, not just from attending classes but also additional practice at home. This is in spite of the fact that the average amount of reported daily practice was just five minutes, which is below what is considered optimal for MBSR (which is thought to range from 30 to 45 minutes (Kabat-Zinn 1990)), but suggested as 30 minutes by Shapiro et al (2003) in this paper. The number of months passed since last medical treatment significantly improved sleep efficiency as well (*df* 1,33, *F*-value 4.64, Pr>*F* 0.039).

As the only randomised study published to date performed with women with breast cancer, the gaps in reporting of results adequately in Shapiro et al's paper mean that it is difficult to build another study based on the results given here. It is stated in the paper that this study was part of a larger one, but when this reference was followed-up to the study

centre, there was no further information that could be obtained (National Institute of Health) and in a later discussion with the author, this was confirmed (Shapiro 2006a, personal communication). Lack of the use of any standardised sleep measures also limits the rigour of this study and results need to be treated with caution.

3.14.3 Uncontrolled studies of mindfulness in cancer care

The six uncontrolled studies of mindfulness in patients with cancer (see Table 3.5) have revealed research in the following areas: stem cell/bone marrow transplants (Bauer-Wu et al 2008), breast and prostate cancer (Carlson et al 2004, Carlson et al 2003), evaluating fatigue and role function in cancer out-patients (Spahn et al 2003), in a German sample of cancer out-patients (Majumdar et al 2002), with cancer out-patients (Altman 2001a) and men diagnosed with prostate cancer and their partners (Saxe et al 2001) (see Table 3.5). As can be seen in Table 3.5, due to the limited nature of these studies either through small sample sizes, lack of controls or inadequate reporting, some findings from these studies of mindfulness in cancer care were positive giving justification for further and more rigorous research to be performed in this area.

3.14.4 Summary of MBSR research conducted prior to current study

Earlier MBSR studies showed some benefits with significant results being reported for stress, mood, relaxation, pain, comfort, quality of life and sleep quality. Many of them had the limitation of being small, uncontrolled pilot studies so their results need to be viewed with caution. The number of MBSR studies in cancer and breast cancer was very small but do show some positive results whilst also being limited methodologically. These studies informed the development of the current study mostly from their gaps, for example, a power calculation was performed in the current study to ensure adequate sample sizes. Also randomisation and controls were put in place as was reporting of statistics to include means and standard deviations, significance level and confidence intervals. It was the intention of the current research to learn from these studies and to perform a more rigorous study evaluating the effectiveness of MBSR in mood, quality of life and wellbeing in women with breast cancer.

Table 3.4. Controlled mindfulness studies in cancer populations

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Speca et al (2000)	RCT Sample from volunteers by invitation	N=109 (90 completed) Treatment n=53, controls n= 37, outpatients	Any patient having received a confirmed diagnosis of cancer at any time was eligible	Seven x 90 minute weekly sessions of MBSR plus home practice	Wait list controls	Profile of Mood States (POMS), Symptoms of Stress Inventory (SOSI)	Significant between group differences on mood ($p<0.001$) and stress ($p<0.01$). Significant correlations between attendance, practice and stress reduction $r=0.30$, ($p<0.05$) and $r=-0.253$, ($p<0.10$) respectively	Appropriate randomisation by table of numbers. Not blinded. 17% lost to follow up, adequate measures of compliance.	Appropriate intervention, control and follow up, no day of silent retreat
Monti and Peterson (2002)	RCT	Unknown number of participants	Age >21, diagnosis of cancer or cancer recurrence	Eight x 2.5 hour weekly mindfulness-based art therapy (MBAT) sessions	Usual care crossed over to receive MBAT after trial	Short-Form-36 (SF-36), Symptom Checklist -90 Revised (SCL-90-R), COPE	No findings reported by 2005	Insufficient information for full appraisal. Study ongoing, co-interventions of art therapy	Limited details preclude a detailed appraisal. Unknown relative effect of art therapy
Shapiro et al (2003)	RCT	N=63	Women only, age 18 -80, English speaking, Stage II breast cancer diagnosis	Six x 2 hour weekly sessions of MBSR plus six-hour silent retreat	A variety of stress manage ment activities	Sleep diary. POMS, Beck Depression Inventory (BDI), Spielberger State Trait Anxiety Inventory (STAI), Functional Assessment of cancer threrapy – Breast (FACT-B)	No significant relationship found between sleep efficacy and MBSR practice. A positive relation between MBSR practice and time ($\beta = +0.339$)	Randomisation method and other methodological factors unknown. Not blinded, 12% controls and 16% treatment group lost to follow up. Ethics not mentioned.	

Table 3.5. Uncontrolled mindfulness studies in cancer populations

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Bauer-Wu (2003 Dissertation abstract)	Uncontrolled study	N=20, mean age 51	Bone marrow /stem cell transplants	45 minute mindfulness meditation audio tape given 1 to 2 times per week, individually based	None	Profile of Mood States (POMS), Hospital Anxiety And Depression Scale (HADS), physical and psychological Visual Analogue Scale, qualitative data	Significant improvements in relaxation, mean difference 1.7 to 2.6 ($p<0.0001$ to 0.031); pain, mean difference 1.3 to 3.1 ($p<0.0002$ to 0.031); comfort, mean difference 1.8 to 3.0 ($p<0.0003$ to 0.0002)	Small sample size, no randomisation, no confidence intervals. Only abstract available	Appropriate clinical intervention, outcomes and follow up. Mindfulness tapes rather than MBSR
Carlson et al (2004 and 2003)	Uncontrolled study	N=59, 49 women and 10 men. Mean age 54.5 years	breast cancer (stages 0 to II), localised prostate cancer, > 3months post surgery	MBSR 8- week programme 90 minutes each and a three hour silent retreat. An audiotape was provided from home practice for the body scan and meditation.	None	EORTC QLQ-30, (Quality of life measure) POMS, Symptoms of Stress Inventory (SOSI), Blood samples measuring immune function	Significant improvements in Quality of life (t=-2.23, $p<0.05$), stress (t=-3.23, $p<0.01$) and sleep quality. (Cortisol levels were found to normalise (Carlson et al 2003))	Small sample size, no randomisation, no confidence intervals, inadequate reporting, 29% lost to follow up.	Appropriate clinical intervention, outcomes and follow up. Lack of longer term follow up

Table 3.5 Uncontrolled mindfulness studies in cancer populations (continued)

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Spahn et al (2003) abstract only	Uncontrolled study	N=24, 23 female (12 with breast cancer). and 1 male	Not known	60 hours over 10 weeks which includes elements of MBSR, exercise, diet, behavioural change techniques and self-care strategies	None	EORTC QLQ-30 and FAQ (fatigue scale)	EORTC QLQ-30 found no significant changes. Significant improvements in role function at workplace and home in the study population (p<0.01). Fatigue measured by VAS improved significantly (p<0.02) and on fatigue subscales (p<0.01).	25% lost to follow up, no controls, Small sample size, no randomisation, no confidence intervals, inadequate reporting and no mention of co-interventions	Appropriate interventions and outcome, insufficient information to assess co-interventions
Majumdar et al (2002)	Uncontrolled study	N = 21, adults, some with breast cancer in remission	Open to all interested if not psychotic or suicidal	8-week MBSR 2.5 hours per week plus 7 hour day in week 6	None	German versions of Hopkins Symptom Checklist SCL-90-R, General Condition (ALL), Sense of Coherence (SOC), FLZ (quality of life in German)	Emotional wellbeing and physical wellbeing increased significantly pre- to post-treatment (p<0.001 and p<0.047) showing some within-subjects effect size. Overall psychological distress/GSI/ quality of life also showed significant improvements (p<0.001 and p <0.002).	Small sample size and lack of controls, Small sample size, no randomisation, no confidence intervals, co-interventions and compliance not known	Appropriate intervention, follow-up and outcome measures. Some qualitative data of clinical value

Table 3.5 Uncontrolled mindfulness studies in cancer populations (continued)

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Altman (2001a) dissertation abstract	Uncontrolled study	Not known	Cancer outpatients	4-week stress reduction programme which included breathing, mindful meditation and yoga stretching	None	Heart rate, blood pressure, respiratory rate. Measurement times not known	No statistical results presented. Report suggests that the brief therapy model can be useful in reducing stress	No statistics presented, abstract only, unknown sample size, no randomisation, no confidence intervals.,	Appropriate but short intervention, outcome measures are of limited clinical relevance
Saxe et al (2001)	Uncontrolled study	10 men and their partners	prostate cancer with increasing levels of prostate specific antigen (PSA)	12 weekly classes of 3 to 4 four hours duration which included dietary and cooking instructions and MBSR.	None	Pre and post measures of diet, weight, levels of physical activity and PSA levels were taken. PSA rates decreased in eight men	The estimated mean doubling time for the PSA reading increased from 6.5 to 17.7 months.	Small sample size and lack of controls, co-intervention of diet and cooking instruction, it is not possible to say what benefits can be attributed to MBSR	Co-interventions of diet, exercise and cookery classes preclude evaluation of MBSR

3.14.5 More recent studies of MBSR to Spring 2008

To update the literature a new literature search was carried out following the same strategy as before but with different dates.

The following databases were search: AMED, British Nursing Index, CINAHL, Ovid MEDLINE(R), PsycINFO. The search strategy used the keywords of mindful$ and MBSR and the search was limited to the English language from 1990 to April 2008, 96 different references were found to match these search terms. Research papers evaluating mindfulness in a health care setting were then selected with particular attention given to identifying any new studies in a cancer or breast cancer and with the endocrine symptoms such as hot flushes.

3.14.6 More recent non-cancer related mindfulness studies

From reviewing the more recent literature, MBSR and related programmes have a growing evidence base of a research quality that is improving over time. MBSR is showing some positive results with people suffering from a wide range of health conditions including psycho-endocrine-immune response in HIV (Robinson et al 2003), as an adjunct to outpatient psychotherapy (Weiss et al 2005), reduced symptoms after organ transplant (Gross et al 2004), hot flushes in menopausal women (Carmody et al 2006), eating disorders (Smith et al 2006b), fibromyalgia (Grossman et al 2007), depressive symptoms in fibromyalgia (Sephton et al 2007), generalised social anxiety disorder (Koszycki et al 2007), chronic lower back pain (Morone et al 2008), MBCT was found helpful with anxiety and depressive symptoms (Evans et al 2008). These results of these early studies are encouraging but many of these studies were done with lack of adequate power or controls.

3.14.7 More recent cancer related studies

As a result of this review, a further seven mindfulness studies in patients with a mixture of cancer or pre-cancer types and a further study with those suffering from menopausal symptoms have been indentified as shown in Table 3.6. Of these studies, only one is a randomised controlled trial (N=111) (Monti et al 2006) and one non-randomised comparison group study (N= 104) (Garland et al 2007). Amongst the others there are five other uncontrolled pilot studies with small sample sizes (Abercrombie et al 2007, Carlson and Garland 2005, Carlson et al 2007, Carmody et al 2006, Soulsby et al 2007) and one qualitative study (Mackenzie et al 2007). In the most recent controlled study of MBSR and early breast cancer patients who did not have chemotherapy (N=75), Witek-Janusek et al (2008), found that MBSR participants had better immune function and quality of life, lower cortisol levels and increased coping effectiveness than the control group, but these results did not reveal statistically significant between group differences. This study is limited by its small sample size and lack of randomisation of participants.

Results for many of the studies show positive results indicating improvements in sleep quality and showing a relationship between reduced stress and improved sleep (Carlson and Garland 2005), improved immunity (Carlson et al 2007), reduction in non-cancer related hot flushes in menopausal women (Carmody et al 2006), greater improvements in mood and stress from MBSR compared to healing arts (Garland et al 2007) reductions in stress, quality of life and mental health from mindfulness-based art therapy (Monti et al 2006), and improvements in wellbeing, anxiety, vigour and depression from Mindfulness-Based Cognitive Therapy (MBCT) (Soulsby et al 2007). In summary, these studies with mixed cancer, pre cancer and symptomatic populations show promising early work in many areas but many have methodological limitations. None of them duplicate the current study.

A qualitative grounded theory study (Mackenzie et al 2007) was conducted with participants attending an MBSR drop-in group (n=9) for an average period of 2.8 years. All participants had previously completed the 8-week MBSR course. Following recruitment, each participant took part in a two-hour semi-structured interview with the same researcher. Following the completion of the interviews, a focus group was held with seven of the nine original participants and three of the MBSR group facilitators. Data was transcribed then analysed using QSR N6 computer programme. Codes were compared and discussed by two researchers then verified by a third. A focus group was used to check the validity and trustworthiness of the results and the manuscript shared with participants before submission. Themes which emerged included opening to change (through participating in MBSR and the consequences of that), self control (including self-awareness, both mentally and physically), shared experience (between group members), personal growth (a powerful way of coming to terms with their personal situation) and spirituality (the secular non-doctrinal stance of MBSR allowed personal reflection on spiritual and religious stances). This conclusions of this study suggested that further qualitative research in this field would be valuable.

Table 3.6. Further studies conducted in cancer and related symptoms since the development of the current doctoral study

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Abercrombie, Zamora and Korn (2007)	An uncontrolled pilot study	Low income multi-ethnic women with abnormal pap smears, (N=51) 41 English speaking, 11 Spanish speaking	Convenience sample of multi-ethnic low income women with abnormal pap smears	Six x 2-hour weekly MBSR classes, no expectation regarding home practice. Classes taught in English and Spanish	none	STAI, Self Compassion Scale (SCS)	10 (20%)women did not attend classes at all, 28 (54%) dropped out by the 2-month follow up. Eight women completed the programme and analysis was done on this number. STAI – no significant difference pre and post. SCS showed no main effect of time on scores. Favourable written evaluation on MBSR (n=5)	Pre and post MBSR data were available for only 8 women. Pre and post measures compared, no control group	Difficulties with recruitment inspite of incentives – child care offered, $10 for each class attended
Carlson and Garland (2005)	Uncontrolled study	Mixed cancer outpatients accrued from a waiting list for MBSR programme at a cancer centre (N = 63, 49 women, 14 men) (breast cancer 59%)	No restrictions placed on type or stage of breast cancer or on prognosis	MBSR eight week x 90 min per week, 3 hour silent retreat in week 6.	None	Pre and post measures of Pittsburgh Sleep Quality Index (PSQI), SOSI, POMS	Overall sleep disturbance significantly reduced (PSQI) ($p<0.001$), sleep quality improved ($p<0.001$), significant reduction in stress (SOSI) ($p<0.001$), mood disturbance (POMS) ($p=0.001$),fatigue ($p<0.001$)	No control group, small sample size	Increased sleep quality great benefit to patients with cancer. Interesting correlation between increased symptoms or stress and increased sleep disturbance

Table 3.6. Further studies conducted in cancer and related symptoms since the development of the current doctoral study (continued)

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Carlson, Speca, Faris and Patel (2007)	Uncontrolled study	Breast cancer (n= 49) and prostate cancer (n=10)	Inclusion Breast cancer stages 0 – II, early stage (localised) prostate cancer. Minimum of 3 months since surgery. Exclusion – if less than 3 months since chemo- or radio-therapy	MBSR Eight week x 90 min per week, 3 hour silent retreat in week 6.	None	EORTC QLQ-30, POMS, SOSI. Immune markers: CD3, CD4, CD8, CD56, Stress measured via salivary cortisol	Pre and post MBSR: No significant changes with POMS TMD. Significant changes with stress (SOSI), ($p<0.001$) maintained during follow up, average cortisol significant decrease (continued during follow up and period reductions of Th1 pro-inflammatory cytokines ($p<0.001$)	No control group, small sample size – lack of power calculation. Large number of outcome measures and multiple statistical comparisons. Risks of Types I and II errors	Isolated blood pressure measures always difficult to interpret. Helpful suggestions of possible improvement of immunity and stress levels.
Carmody, Crawford and Churchill (2006)	A pilot study of mindfulness-based stress reduction for hot flushes in a non-cancer population	15 women volunteers with a minimum of 7 moderate or severe hot flushes per day	Women suffering from at least moderate hot flushes	Eight x 2.5 hour weekly classes of MBSR, one day of mindfulness, home practice of body scan, stretches and sitting meditation six days per week	none	Hot Flushes log, Hot flush-related daily interferences scale, Women's health initiative insomnia rating scale, Hopkins Symptom Checklist (SCL-90-R), Perceived Stress Scale, Toronto Mindfulness Scale,	18 women consented to the study, 15 attended and 13 completed MBSR. Median hot flush scores decreased 39% over 11 weeks of assessment. Diary entries and interviews concurred. Median home practice during intervention 58 mins per day (45m requested), declined to 35m/day during follow up	No control group, practice log included	Preliminary evidence of feasibility and efficacy of MBSR in supporting women experiencing severe hot flushes, warrants further investigation

Table 3.6. Further studies conducted in cancer and related symptoms since the development of the current doctoral study (continued)

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Garland, Carlson, Cook, Landsdell and Speca (2007)	Non-randomised comparison study comparing MBSR with healing arts (HA)programme	(N=104) cancer outpatients, MBSR n=60, HA, n= 44.	Informed of programme through usual clinical practice by posters and pamphlets	Eight x 90 minute weekly MBSR sessions plus one 3-hour silent retreat	Healing arts group as a comparison	Post traumatic growth inventory-Revised (PTGI-R), Functional Assessment of Chronic Illness Therapy-Spiritual Wellbeing (FACIT-Sp), SOSI, POMS.	From both programmes, increase in post traumatic growth, MBSR showed greater improvements on SOSI and POMS than HA.	Pre and post measures compared, no between group analysis, no control group without intervention	Appropriate interventions and application to the real world giving choice between interventions
Mackenzie, Carlson, Munoz, Speca (2007)	Qualitative study Grounded theory	Mixed cancer outpatients (n=9) of which breast cancer (n=4)	Selected on involvement in an ongoing MBSR weekly drop in group and capacity to provide relevant information	Attending weekly MBSR drop in group for eight weeks	Not applicable	Semi-structured interviews and focus group post MBSR course	Five major themes emerged: 1) opening to change 2) self-control 3) shared experience 4) personal growth 5) spirituality	Limited generalisability beyond existing sample from this type of enquiry	Participants had been attending group post MBSR programme for 1-6 years

Table 3.6. Further studies conducted in cancer and related symptoms since the development of the current doctoral study (continued)

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Control group	Outcome measures	Results	Methodological Comments	Clinical Comments
Monti, Peterson, Kunkel, Hauck, Pequignot, Rhodes and Brainard (2006) updated from Monti and Peterson (2002)	RCT	Women with a variety of cancer diagnoses (N=111)	4 months – 2 years from a cancer diagnosis or cancer recurrence	Eight x 2.5 hours weekly Mindfulness-based art therapy (MBAT)	Wait-list control group	Symptoms Checklist-90-Revised (SCL-90-R), Medical Outcomes Study Short-Form Health Survey (SF-36)	84% completed pre- and post-measures. Deceases in symptoms of distress(SCL-90-R): overall GSI p<0.001) and some subscales: anxiety, depression, hostility. Significant improvements in key aspects of health related quality of life (SF-36) – general health (p=0.008), mental health p(<0.001)	30 minutes home practice x 6 days per week. ITT analysis	74 participants were in active cancer treatment during the study – either as chemo-, radio-therapy or outpatients
Soulsby, Morrison, Stuart, Parry, Williams (unpublished 2007)	Uncontrolled study	Mixed cancer patients: breast cancer (n=6), haematology patients (n=26), and relatives (n=11)		Eight week MBCT	None	Pre and post measures of POMS, HADS, WHO (5-item) Wellbeing Questionnaire	For patients only wellbeing improved (p<0.001), POMS tension-anxiety, vigour, depression and HADS anxiety improved (p<0.05)	Small sample – pilot only	Does show that MBCT is acceptable with patients with cancer and their relatives

3.14.8 More recent studies of MBSR and breast cancer

There were two further published MBSR studies undertaken since the initial literature review (see Table 3.7) involving women with breast cancer by Dobkin (2008) and Tacón et al (2004, 2005). Dobkin's study was an uncontrolled, mixed methods study (N=13) which found improvements in stress, mindfulness and palliative coping. In addition, from the qualitative data, themes arose in the areas of acceptance, mindfulness control, taking responsibility for change, spirit of openness and connectedness. The qualitative data from Dobkin's study revealed new insight into the way mindfulness has helped and despite very small numbers, significant quantitative results were positive.

Tacón's uncontrolled study (N=30) showed significant reductions in state anxiety, decreases in reactive coping, improvements in helplessness-hopelessness and anxious preoccupation. These more recent studies did not however surpass the need for the current study which has been able to provide information from this population in a more rigorous way.

Table 3.7. Further studies conducted in breast cancer since the development of the current doctoral study

Study	Design	Sample	Inclusion criteria	Mindfulness Intervention	Con-trol group	Outcome measures	Results	Methodological Comments	Clinical Comments
Dobkin (2008)	Mixed methods study, un-controlled	women post treatment for breast cancer (N=13), recruited from two university affiliated hospitals – all but one completed treatment for breast cancer within the last two years	Completed medical treatment for breast cancer	MBSR (no further details given)	none	Pre and post MBSR Focus groups Centre for Epidemiologic Studies Depression Scale, (CES-D), Medical Symptom Checklist (MSCL), Perceived Stress Scale (PSS), Sense of Coherence (SOC), Coping with Health Injuries and Problems (CHIP), Mindful Attention and Awareness Scale (MAAS),	Stress decreased (p=0.008), mindfulness increased (p=0.028) as did palliative coping (p=0.095) Themes arising 1) acceptance 2) regaining and sustaining mindful control 3) taking responsibility for what could change 4) spirit of openness and connectedness	Small sample size for quantitative results so caution needed with their interpretation. No longer follow up period.	Insight into process underlying benefits often reported following participation in MBSR
Tacón, Caldera, Ronaghan (2004, 2005)	Un-controlled study	Women with breast cancer (N=30), self selected volunteers, mostly white upper middle class females	Diagnosed with breast cancer and approved by physician	Eight x 1.5 hour weekly sessions of MBSR, no silent retreat	None	Spielberger State-Trait Anxiety Inventory (STAI), Problem-focused styles of coping (PF-SOC), Mental Adjustment to Cancer (MAC)	Post MBSR: STAI - significant reductions in state anxiety ($p<0.001$), PF-SOC - decreases in reactive coping ($p< 0.001$), significant differences in the suppressive style ($p< 0.05$). MAC: helplessness-hopelessness and anxious preoccupation improved post intervention (($p<0.01$). Mindfulness practice continued at 6mo follow up	Small sample size, no control group, 5 women receiving surgery, chemotherapy or radiotherapy at the time of the study, 53% on oral medication.	Appropriate clinical intervention, emphasis on application of mindfulness during cancer treatments - chemotherapy and radiotherapy.

3.15 Summary of the MBSR chapter

This chapter has reviewed the origins of mindfulness including its history, philosophy and practice. Recent detailed work regarding the conceptualisation of mindfulness and the components that contribute to this have been discussed. The origins and development of MBSR programmes, the contributing elements and variations were discussed and it is worth noting here, that despite the minor variations of the MBSR programmes, at the heart of them all is the cultivation of mindfulness, non-judgemental present moment awareness. Other programmes and therapeutic methods involving mindfulness have also been discussed.

Research into mindfulness is growing with an increasingly large number of quality research papers being published each year including some early qualitative studies. However, even though more studies suggesting positive benefits to patients have been published in the field of cancer and breast cancer, with the exception of a couple, small sample sizes and lack of randomisation hinders the quality of the quantitative research and leaves scope for more rigorous work such as the current study.

3.16 Summary of the literature review

In the light of the large and increasing number of women diagnosed and treated for breast cancer in the UK each year, there is a need for self-management interventions that will contribute positively to quality of life and help them cope better with the stressors of everyday life and live with the uncertainty following breast cancer treatment. In the field of complementary therapies in breast cancer care, much of the emphasis to date has been to offer complementary treatments such as touch therapies that offer support but are not active self-management tools. There is a need to examine whether teaching this group of people tools that can help them cope better improves their quality of life.

From reviewing the literature, MBSR and related programmes have a growing evidence base of a research quality that is improving over time. MBSR is showing some positive results with people suffering from a range of health conditions including anxiety (Kabat-Zinn et al 1992), generalised social anxiety disorder (Koszycki et al 2007), eating disorders (Kristeller and Hallett 1999, Smith et al 2006b), fibromyalgia (Kaplan et al 1993, Grossman et al 2007), depressive symptoms in fibromyalgia (Sephton et al 2007) chronic lower back pain (Morone et al 2008), psoriasis (Kabat-Zinn et al 1998b), hot flushes (Carmody et al 2006), quality of life (Reibel et al 2001), psycho-endocrine-immune response in HIV (Robinson et al 2003), reduced symptoms after organ transplant (Gross et al 2004), as an adjunct to outpatient psychotherapy (Weiss et al 2005). MBCT helps with anxiety and depressive symptoms (Evans et al 2008) and major depressive disorders (Teasdale et al 1995).

MBSR has been evaluated in pre-cancer with low income women with abnormal pap smears (Abercrombie et al 2007), and with cancer (Speca et al 2000, Carlson et al 2001, Garland et al 2007, Carlson and Garland 2005, Carlson et al 2007, Soulsby et al 2007), evaluated in a qualitative study (Mackenzie et al 2007) and with breast cancer (Shapiro et al 2003, Dobkin 2008, Tacón et al 2005). In research evaluating MBSR as an intervention with people affected by cancer, there have been a number of uncontrolled studies performed and only four controlled studies. Of these, four controlled studies, one examines its effects on mood and symptoms of stress in cancer outpatients (Speca et al 2000), the second evaluates the effects of Mindfulness-Based Art Therapy with cancer patients (Monti et al 2006), the third (Garland et al 2007) compares MBSR to a healing arts programme, whilst the only controlled study with women with breast cancer evaluates the effects of MBSR on sleep disturbance (Shapiro et al 2003).

Whilst results from many of these studies suggest some positive outcomes, there are methodological weakness in many of these studies including lack of controls, small sample sizes, lack of statistical power, inadequate methodological and statistical reporting leaving issues of randomisation and blinding unknown and a failure to report confidence intervals in studies where statistically significant results are reported. The lack of rigour in many of these studies means that results need to be viewed with caution, but also create the opportunity for more rigorous research work to be done to evaluate this potentially valuable clinical intervention.

In reviewing the studies reported using mindfulness, one apparent important but apparent issue is the minor variations and adaptations of the MBSR programme made by each teacher to best meet the needs of their population in the given circumstances. This will always be a confounding factor, making exact comparisons across studies more difficult to interpret but inevitable as programmes are adapted to be appropriate to different populations and settings.

The current study evaluating MBSR in women with breast cancer aimed to address some of the gaps in knowledge for women with breast cancer and find out whether a further more rigorous study could discover the extent to which MBSR might be an effective self-management tool for breast cancer survivors. In designing this study, the clinician-researcher hoped to address many of the methodological weaknesses by ensuring adequate randomisation and controls, ethical considerations are reported, ensuring masking and blinding as much as possible, ensuring that the chosen sample size was informed by a power calculation and that in reporting, full disclosure was given to dropouts and reasons for that, number of questionnaires completed, all statistical tests performed

were rationalised and where appropriate mean, standard deviations and CI were reported. The format and structure of the MBSR programme needed reporting.

MBSR has previously been researched in general cancer outpatients examining mood and stress, but no study had been performed evaluating mood, quality of life wellbeing in breast cancer survivors. This was the gap that this research hoped to fill. The aims and research hypotheses and questions of the current study are given in section 4.6.

Chapter 4. Methodology and Methods

4.1 Introduction

This chapter will provide information about the methodology and methods used in this study. The philosophical perspective including the epistemology, rationale for the methodology chosen, clinician-researcher boundaries and ethical considerations are presented. Following this, the aims and hypotheses of the study, the design of the study, the measurement tools used, the rigour and validity of methods and the pilot study will be explained. The mindfulness-based stress reduction (MBSR) intervention used in the study as well as methods of data collection and analysis will be described.

4.2 Philosophical perspective including the epistemology

To fully comprehend the research process, a researcher must understand the basis for choosing particular approach, including the intended methods and methodology that govern the choice of methods, the theoretical or philosophical perspective that lies behind them and the epistemology, the theory of knowledge which informs this perspective (Crotty 1998).

The positivistic paradigm in which quantitative methodology sits, takes the stance that reality is external and knowledge is only significant if based on observed effects (Proctor 1998), that phenomena exist as meaningful entities independent of consciousness and experience and can therefore be measured by rigorous scientific research which can ascertain that objective truth or meaning. This implies that the researcher should be value free and objective as far as is humanly possible (Proctor 1998). This positivistic approach underlies the objective rigour of the randomised controlled trial (RCT) which underpins the main design of this study. Bolton (2008) argued that the epistemological principles underlying randomised controlled trials (RCTs) and evidenced based medicine in general have not received adequate attention. He clarified epistemology as meaning the principles by which RCTs are thought to reveal evidence of causal connections. He argued that

> ‘the determination of causes and RCT methodology in particular are limited by internal considerations, by their own methodological principles….Scientific methodology is not a good fit with relatively rare events involving many potential causal factors…’ (Bolton 2008, p163).

Kuhn (1990), the scientific historian and author of the seminal work *The Structure of Scientific Revolutions,* published in 1962*,* argued that what requires evaluation in scientific knowledge cannot be evaluated by ‘an individual proposition embodying a knowledge claim in isolation: embracing a new knowledge claim typically requires adjustment of other beliefs as well’ Kuhn (1990, p 6).

Despite the intended rigour of the positivistic approach, the RCT is not without its limitations and difficulties as it fits a single scientific paradigm and epistemological view which may not be held by others.

Quantitative research operates on the assumption that research should be characterised by the highest possible level of objectivity and neutrality. On the other hand, qualitative approaches which, by the nature of the methods of investigation, lack the objectivity of the positivistic approach as they rely on individual interpretations, but can offer depth and/or breadth of information and can capture personally meaningful dimensions of experience (Rapley 2003). Nesting qualitative data in a primarily quantitative study (as done in this study) mixes positivistic and interpretative paradigms and epistemologies, bringing together of two potentially 'competing' paradigms, challenging the view that research must fit into a single paradigm. The positivist research paradigm, based in the epistemological approach of objectivism, influences the quantitative methodological approach. Social constructivism and the qualitative methods are based in the interpretivist paradigm, where meanings are constructed by human beings as they live in the world they are interpreting. There have been many arguments about the possibility or impossibility of joining these two philosophical perspectives in one research approach. House (1994) referred to the difficulties found in the joining of these two approaches as a 'misunderstanding of science' and reminded readers that there is no guaranteed methodology to reach the 'promised land'. The underlying philosophical tension that exists between the positivist and interpretivist paradigms and possibilities to join them in one piece of research only highlights the complex nature of social life and the difficulties of finding precise and exact methods in the scientific search for knowledge.

4.3 Rationale for methodology chosen

All approaches to evaluating interventions have strengths and limitations, leading the researcher to find the most appropriate method depending on the particular focus of the evaluation and the interests of the different parties involved (Ingleton and Davies 2007). Cresswell et al (2004) commented that quantitative and qualitative data, used in combination, can yield a more complete and complementary analysis. In this study, the rationale for choosing a RCT will be described first, followed by that for including nested qualitative data.

MBSR, a self-management intervention, has been introduced relatively recently into the UK healthcare setting. This study tested the possible value and application of MBSR within a breast cancer context and for its generalisability. The clinician-researcher wanted to answer the research questions in a way that would obtain the strongest possible form of evidence, and still be applicable in the clinical setting. This is another reason that the main

approach was logical and positivist, characterised by the use of the RCT, which is deemed the most suitable method for evaluating cause and effect in the form of rigorously measuring the effectiveness of an intervention or a single variable in a defined patient group (Greenhalgh 2003). Muir Gray (1997) gave an interpretation of scientific evidence which rates randomised controlled trials (RCTs) as providing the strongest form of scientific evidence on which to base decision making. Others rated well-designed RCTs as second only to meta-analyses and systematic reviews of RCTs (Guyatt et al 2000, Petticrew and Roberts 2003). In a discussion about the superiority of RCTs over observational studies, the conclusion was reached that well conducted RCTs remained the gold standard for evidence of efficacy (Barton 2000, Petticrew and Roberts 2003), although well conducted mixed methods research is becoming more accepted if judged by an increasing number of studies funded (O'Cathain et al 2007).

It is recognised that in adopting the RCT as the main approach, the researcher was limited to evaluating circumscribed areas covered by the predetermined measurement tools chosen. As this study took place in a clinical setting, a pragmatic approach to this RCT was employed to measure effectiveness and the benefit that treatment produces in real life clinical situations. In a pragmatic trial, aspects of real clinical life are taken into account including the possible inability to blind and the fact that different treatments may be given to different patients. Due to the nature of the intervention, the researcher was not blinded to the different treatments given but randomisation helped take care of selection bias and all participants received the same MBSR programme. It is generally accepted that pragmatic trials should also represent the full range of health gains including quality of life (Roland and Torgerson 1998), which was addressed in this study. Using a primarily quantitative approach and limited qualitative data, meant that the clinician-researcher had to forfeit the opportunity to gain valuable depth and insight that might have been obtained by using a more in-depth qualitative approach.

At the time of developing this study, there were only a few quantitative studies published in the field of MBSR and cancer and those that were had a number of limitations. No qualitative research had been published. Of the two published controlled studies (Speca et al 2000, Shapiro et al 2003), neither reported the use of power calculations to determine sample size and sample numbers, particularly in the breast cancer study Shapiro's study was not high and there were other problems including inadequate reporting of results. It was the aim of this current study to design a more rigorous study. The CONSORT statement (Altman et al 2001b) was used as a guideline to ensure that a high degree of scientific rigour was met. The important factor was choosing the most appropriate methodology to answer the research questions and meet the research objectives (Cresswell 2003).

Another reason for choosing a pragmatic randomised controlled trial with the nesting of a small amount of supplementary interpretive qualitative data was to best answer the research questions posed in the evaluation of MBSR (see Section 4.6), a novel intervention in a relatively new population. This approach enabled the researcher to use validated tools to measure mood, quality of life and wellbeing and to see the effects of MBSR in these dimensions in women with stages 0 – III breast cancer. Using these tools enabled this research to build on that previous published and the comparisons between findings. The collection of qualitative data extended the type of information that had been gathered previously in MBSR and cancer studies, facilitating the collection of other important data not achievable through quantitative methods alone. The different types of data and so data analysis were directed at different methodological objectives. The quantitative data assessed psychological state and quality of life while the qualitative data aimed to capture the experience of mindfulness and MBSR in the population under study.

The main focus of the study was on the positivistic quantitative data with the purpose of gathering qualitative data to explore different dimensions of knowledge. The gathering of qualitative data was not done for triangulation, initiation, development or expansion although it did involve some data collection for the purposes of complementarity (Greene et al 1989), offsetting weaknesses, explanation of findings (Bryman 2006) and involving a complete integration of the two approaches (Doyle et al 2009). As a result, this cannot formally be described as a mixed methods study. Predetermined methods were used predominantly, but also some emerging methods containing both open and closed ended questions, multiple forms of data, statistical and text analysis and a pragmatic approach (Creswell 2003).

Interpretive data was collected within the qualitative approach as this values the subjective or interpretive knowledge of participants (See Appendix 16 for short proforma). Capturing open-ended qualitative data to obtain breadth of knowledge was an appropriate addition to the main quantitative design as it was intended to obtain personal views and perspectives (interpretive data) not found in the tightly regulated and contained quantitative approach, to better understand the direct experience of participating in MBSR, give insights into the interaction of women with the intervention, the benefits and challenges to the cultivation of mindfulness from the perspective of these women treated for breast cancer who participated in the study. At an explanatory level, it allowed the clinician-researcher to better understand the lived experience of those undergoing the MBSR intervention and their experience of mindfulness which could not be easily answered through quantitative methods. This data was considered important, as at the time of conducting the study there little qualitative data published relating to the experience of women with breast cancer. Obtaining some nested qualitative interpretive

data enabled the capturing of information not bound by the limitations of the format of the tools used for the quantitative data collection. It gave the opportunity to describe other dimensions beyond the rigidity of the quantitative tools. Narrative, qualitative data collected in this way from the women participants about their experience of healthcare is valid knowledge within the paradigm of interpretivism (Forbes et al 1999).

A phenomenological approach could not be pursued with the limited amount of qualitative data collected as it lacked full elaboration, so was not able to capture essences of experience, nor was it appropriate to use a grounded theory approach as there was insufficient data for theory generation.

4.4 Clinician-researcher boundaries

The role of clinician-researcher is an increasingly common one found amongst those clinicians who also undertake research within their role. In this study, the clinician-researcher was in charge of the whole research project, involved in the recruitment interview and delivered the MBSR intervention, creating possible areas of bias. It is possible that the research recruitment interview could be seen as a source of 'therapy' for participants wanting further sources of support, information and advice. Getting further support may have been a reason for participants entering a study. The therapeutic experience of the recruitment interview in the current study may have been similar to that of the qualitative research interview (Colbourne and Sque 2005). As the recruitment interview was performed pre-randomisation, it was undertaken by all potential participants. This interview was also a potential source of bias and influence for participants who had yet to decide whether or not to join the study. Performed by the clinician-researcher, this may have compromised the rigour of the study, but from a pragmatic clinical perspective ensured the safety of participants entering the MBSR programme. To minimise any possible bias, a research assistant, who was independent from the clinician-researcher offering the intervention, helped with various aspects of the study under the instruction of the clinician-researcher. She helped with the copying of materials for the intervention and facilitated data collection. She did all the distribution and collection of the main questionnaire data. The research assistant posted questionnaires out to participants at the relevant time points. The research assistant facilitated the completion of the questionnaires by participants, if needed, by speaking to them by phone at all three time points: -2 to 0, 8 to10 and 12 to14 weeks. The research assistant also contacted participants by phone if questionnaires were not received on time. She also created relevant computer spread sheets entered data onto them and worked alongside the clinician-researcher in the data analysis period to help minimise the risk of error.

4.5 Ethics

4.5.1 Ethical justification of the study

To justify the involvement of patients' time and resources in any study, it was important to establish the need for the research. In the field of mindfulness research, as in many areas of complementary medicine, more rigorous evidence was needed to prove whether or not MBSR is beneficial to women who have undergone treatment for breast cancer. This study aimed to develop this knowledge further.

Clinical equipoise, also known as the principle of equipoise, provides the ethical basis for medical research involving randomly assigning patients to different treatment arms. When clinicians become researchers, the need to recruit enough subjects for a study and retain them may conflict with the duty of promoting the welfare of patients. Unlike the uncertainty principle, where randomisation to treatment is considered acceptable when an individual researcher is genuinely unsure which treatment is best for the patient, clinical equipoise explicitly states that there must be an honest, professional disagreement among expert clinicians about the preferred treatment (Freedman 1987). Even if the clinician personally prefers one arm over the other, randomization is still ethically sound when there are other responsible and competent clinicians who disagree (Weijer et al 2000).

With MBSR, where so little research has been carried out to evaluate any potential benefits in a cancer population, there was certainly disagreement amongst clinicians as to the value of such an intervention. In recruiting participants for this study, the research interview played an important role in ascertaining whether the study was in their best interests. The clinician-researcher was constantly aware of the tension between the clinical needs of interviewees and achieving recruitment targets.

4.5.2 Other ethical considerations

Ethical consideration is important as it protects participants from any potential harm or distress that might come from participation in any study.

4.5.2.1 Ethical committee approval

This study has been given ethical approval by the Riverside Research Ethics Committee. This was granted in August 2004, REC reference number: 04/Q0401/58.
Copies of the approved Participant Information Sheets and Consent Form are found in Appendices 6 and 7 respectively. In the recruitment interview, participants were given the Participant Study Information Sheet and Consent Form to take home and a reply-paid envelope in which to return the consent form. A minimum of 24 hours was given for participants to sign the consent form but some participants chose to read the information in the Haven library following the interview and signed the consent form after that, handing

it to the receptionist to then be countersigned by the researcher and a copy was then sent to the participant. Confidentiality and anonymity of research data was assured, with all research documents kept in a locked filing cabinet for 15 years in accordance with university and charity regulations.

4.5.2.2 Withdrawal from the study

All participants were made aware of their right to withdraw from the study at any point in time. When notified of this decision, the clinician-researcher contacted the participant concerned both by phone and then in writing to thank them for their participation to date and to reassure them that it was acceptable for them to withdraw. They were also told that they were welcome to return to the Haven for further help as necessary. If the participants who withdrew were in the intervention (treatment) group, permission was requested from them to send the further two questionnaires necessary for the study. All but the first participant to withdraw agreed to this as the clinician-researcher forgot to ask the first for permission to do this.

4.5.2.3 Waiting time

There was an ethical consideration surrounding the time the control group had to wait for inclusion in the intervention, a period of about 3.5 months. The intention was that no harm or sense of neglect should come as a result of participating in the study. Control participants were not prevented from accessing other therapeutic activities at the Haven as none of these had mindfulness as their focus.

4.5.2.4 Research versus clinical need

In this study there were potential ethical dilemmas for the clinician-researcher. For example, during the pre-study interview, one participant was very distressed so the researcher recommended that she had some counselling prior to starting the study. This period of one-to-one counselling then overlapped with the start of the MBSR programme, but from a clinical point of view, it would have been unethical to deny the participant either counselling or MBSR. At the end of the 8 week programme, this participant was diagnosed with a second primary lung cancer and metastatic spread to the bones which accounted for some of her symptoms and distress before and during the MBSR programme. She did not complete the two final questionnaires but the reasons for this are not known. The clinician-researcher put the clinical needs of the participant first instead of pursuing further data collection.

4.5.2.5 Stopping procedures

The study was designed so that at the earliest opportunity, should any research information come to light which cast doubt on continued participation of the participants

during the study, that this would be discussed with individual participants for whom it was relevant, giving them the opportunity to withdraw from the study. If it became evident to the clinician-researcher or any member of the research team that, at any point during the study, a participant's physical or mental health was in danger as a result or participation in the study, then the clinician-researcher would speak to this person individually about the appropriateness of continuing with the study and if necessary make an appropriate referral for other forms of help. No interim analysis was performed on results as there was concern that this knowledge might influence the way the clinician-researcher delivered the MBSR programme to subsequent groups.

4.5.2.6 Arrangements in case of negligent and non-negligent harm

In the case of negligent harm, Breast Cancer Haven held both public indemnity insurance and employer liability insurance. The clinician-researcher held professional indemnity insurance through her membership with the Royal College of Nursing. In the case of non-negligent harm, study participants had the opportunity to contact the Chief Executive of Breast Cancer Haven or to speak to another senior member of the therapy team such as a counsellor or senior therapist, neither of whom were involved in the study.

4.6 The aims of the study, research hypotheses and research questions

Set out below are the aims of the study, research hypotheses and research questions. These were designed so that the research could either validate or refute existing preliminary evidence about the effects of MBSR as well as to develop new knowledge as to how the intervention might be helpful.

4.6.1 Research aim

The overall aim of the study was to determine whether and to what extent MBSR has any effect on mood, disease related quality of life, including endocrine symptoms, and wellbeing in women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

4.6.2 Research hypothesis

As a consequence of being exposed to MBSR, there will be an improvement in mood, disease related quality of life, including endocrine symptoms, and wellbeing of women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

4.6.3 Null hypothesis

Being exposed to MBSR has no effect on mood, disease related quality of life including endocrine symptoms, and wellbeing in women with stages 0 to III breast cancer in the

intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

The following research questions and hypotheses will be addressed:

4.6.4 Overall research question

What are the effects of MBSR for women with stages 0 to III breast cancer on mood, disease related quality of life, including endocrine symptoms, and wellbeing?

Research questions and related hypotheses to be answered by data as follows (central questions in bold):

4.6.5 Research question 1

What are the effects of MBSR for women with stages 0 to III breast cancer on mood, the effects being measured after eight weeks and again after 12 weeks?

4.6.5.1 Hypothesis 1

As a consequence of being exposed to MBSR, there will be an improvement in mood for women with stages 0 – III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

4.6.6 Research question 2

What are the effects of MBSR for women with stages 0 to III breast cancer on quality of life, including endocrine symptoms, the effects being measured after eight weeks and again after 12 weeks?

4.6.6.1 Hypothesis 2

As a consequence of being exposed to MBSR, there will be an improvement in quality of life, including endocrine symptoms, for women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks

4.6.7 Research question 3

What are the effects of MBSR for women with stages 0 to III breast cancer on overall wellbeing, the effects being measured after eight weeks and again after 12 weeks?

4.6.7.1 Hypothesis 3

As a consequence of being exposed to MBSR, there will be an improvement in overall wellbeing for women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks

4.6.8 Research question 4

What effect does participating in MBSR have on the perception of stressors relating to 1) breast cancer 2) other life events?

4.6.8.1 Hypothesis 4

As a consequence of being exposed to MBSR, there will be a reduction in the perception of stressors for women with stages 0 to III breast cancer relating to 1) breast cancer 2) other life events in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks

4.6.9 Research question 5

Is there a dose-related effect from participating in the MSBR programme on mood, disease related quality of life and wellbeing?

a) Is there a dose related effect from attending more MBSR classes?

b) Is there a dose related effect from doing MBSR home practice during the 8-week programme?

4.6.9.1 Hypothesis 5

Increased MBSR classroom attendance and mindfulness home practice hours will predict improvement in mood state, quality of life and wellbeing for women with stages 0 to III breast cancer in the intervention group, the effects being measured after eight weeks and again after 12 weeks.

4.7 Consultation with experts regarding the research design

Following a review of the current literature, it was clear that a further well conducted study was warranted to further the evidence base for MBSR. In designing the study, meetings, email and phone consultations were held with those who had previously worked, researched and published in the field of mindfulness including Dr Linda Carlson and Dr Michael Speca from Canada, Dr Shauna Shapiro, Melissa Blacker, Florence Meyer, Professor Jon Kabat-Zinn from USA, also from the UK Dr John Teasdale (Cambridge), Professor M John Williams (Oxford), Professor Paul Chadwick (Southampton), Judith Soulsby and Trish Bartley (Bangor). In this process, the adaption of and preparation for

the delivery of the MBSR intervention was discussed and the appropriate choice of measurement tools considered that would best be able to answer the chosen research questions and to advance knowledge in this field. In addition to this, choice of the study population was clarified and the appropriate timing of the intervention for this client group discussed with these experts.

4.8 Design of the study

The literature review revealed that there was a need for a well-conducted study using an experimental design so that outcomes could be compared between the intervention (treatment) and control groups.

The design of this study best fits as a phase two exploratory study as identified by Medical Research Council's Framework for the development and evaluation of RCTs for complex interventions to improve health (Medical Research Council 2000). This study is of an exploratory nature as it includes the constant and adapted components of MBSR intervention to meet the needs of the breast cancer population under study and provides a protocol for comparing this with, as far as possible, an appropriate alternative.

As there was a lot of complexity around the MBSR intervention and its delivery, a pilot study was conducted (see section 4.13). This was done primarily to establish a level of competence in its delivery for the main study. The pilot study also allowed for the testing of the supporting CDs and the practice manual as well as responses to questionnaires and any issues of concern relating to the programme raised by pilot participants. As the main questionnaires were established outcome measures, there was no need for the pilot to establish the feasibility of tools in this population, but the pilot group enabled testing of the questionnaire package as a whole to see that the measures were as easy to fill in as the designers proposed and to get an idea of how long they would take.

This study is chiefly an experimental design with pragmatic components incorporating some mixed methods, i.e. the use of both quantitative and qualitative methods. Table 4.1 illustrates the overall design of the study which is also described here from conception. The table outlines recruitment from January to August 2005 was repeated in six 12 week cycles during 2005 to 2006 to enable recruitment of the 229 participants. From 2007 to 2008 quantitative data was analysed using standard statistical tests on an Intention- to -Treat analysis. Between groups analysis was applied to descriptive statistics at all three time points: -2 to 0, 8 to10 and 12 to14 weeks. Univariate, multivariate and stepwise linear regression was performed to see the predictive effect of one variable on another. Qualitative data from the intervention group was analysed using content analysis; that from the control group was not analysed as it was collected outside the study time frame for data collection.

Table 4.1. Overall study design

Oct 2003 – Jul 2004	Development of the research proposal including three trips to University of Massachusetts, USA to develop knowledge and skills to deliver the MBSR intervention and speak to fellow MBSR researchers for intervention-specific advice on designing the study	
Aug 2004	Riverside Research Ethical Committee Approval	
Sept 2004	Approval by Breast Cancer Haven Board of Trustees	
Jan 2005	A convenience sampling method identifying suitable Haven Visitors	
Jan 2005	Study invitation sent by letter by Clinician-Researcher	
Feb – Mar 2005	Phone response by potential participants and study recruitment interviews done by Clinician-Researcher	
Feb – Mar 2005	Consented participants randomised to intervention or control group by Haven staff not involved in delivery of intervention	
Mid Apr 2005	Week 0, T1, baseline quantitative questionnaires completed and returned to Research Assistant	
Late Apr 2005	**Intervention group**	**Wait-list control group**
	Week 0 – 8 Intervention group participated in MBSR. Participants completed qualitative data at the end of the eight weeks	Week 0 – 8 wait-list control group continued with treatment as usual
End Jun 2005	Weeks 8-10, T2 quantitative questionnaires completed	Weeks 8-10, T2 quantitative questionnaires completed
	Follow up period of four weeks	Follow up period of four weeks
End Jul 2005	Weeks 12-14, T3 quantitative questionnaires completed	Weeks 12- 14, T3 quantitative questionnaires completed
Aug 2005	End of formal study and data collection period for first groups	
Sept – Nov 2005	No further involvement from intervention group	Wait-list control group participate in MBSR along with intervention group participants from the next cycle, participants completed qualitative data at the end of the course
July 2005 – Nov 2006	This recruitment and study delivery process mentioned above was then repeated for a total of six cycles of the study	
July 2006 – Jan 2007	Data entry done by Research Assistant	
Feb 2007 – Feb 2008	Quantitative data analysis done by Clinician-Researcher with Research Assistant. Qualitative data analysis done by Clinician-Researcher	
Feb 2008 – Aug 2009	Thesis write up done by Clinician-Researcher	

For an overview of the overall project plan, please see Appendix 8. Below is outlined the different aspects of the study design.

4.8.1 Study setting

The study was set at the first day centre opened by the registered charity Breast Cancer Haven in Fulham, London in 2000. 'Havens' are now located in London, Hereford and Leeds. The charity aims to open further Havens around the country that are easily accessible to anyone affected by breast cancer as well as family and friends. Breast Cancer Haven provides welcoming and tranquil day centres offering free support, information and complementary therapies to anyone affected by breast cancer before, during or after medical treatment. Counselling and support groups are also available to family and friends. Breast Cancer Haven receives no government money and is supported by the hard work of its own fundraisers. Havens are specifically designed healing spaces using colour and light and Breast Cancer Haven won the 2008 Healing Space Award for large projects by the British Holistic Medical Association.

Breast Cancer Haven works closely with hospital based breast cancer clinicians and nursing staff. Most Visitors to Breast Cancer Haven are self-referred having been told about the centre from breast care nurses or family/friends. The only criterion to enable someone to use the services of Breast Cancer Haven is that they have been diagnosed with breast cancer. In addition, family and friends of those with breast cancer may receive counselling and join support groups. If undergoing treatment for breast cancer, Haven therapies are offered in an integrated manner following the Breast Cancer Haven model of integrated healthcare (see Appendix 2). This means that consideration is given to the way that Haven therapies can support the individual during ongoing medical treatment. Written consent is obtained from those using the services so that correspondence between hospitals, GPs and Haven clinical staff is exchanged to ensure that there is knowledge of clinical condition, medical treatment and Haven therapies offered between all parties.

Haven teams are nurse-led and comprise specialist nurses, nurse therapists, counsellors and complementary therapists. They work within a professional framework for clinical practice including regular peer-group clinical supervision, individual performance review, continuing professional development including annual clinical update and an annual programme review. Breast Cancer Haven has a Clinical and Scientific Advisory Board comprised of leading professionals in the field of breast cancer, complementary medicine and research which supports the development of the ongoing clinical and research programmes. The Breast Cancer Haven programme provided at the time of this study can be found in Appendices 9 and 10.

A large group room and the adjoining space were used for the weekly MBSR classes. For the day of mindfulness, a Saturday in week six of the programme where participants spent six hours practising mindfulness, including eating their lunch mindfully, a larger space was

needed for concurrent groups to join and the reception and library on the ground floor of Breast Cancer Haven was ideal for this as the centre was not being used on a Saturday.

4.8.2 Samples, sampling and recruitment

A convenience sampling strategy was used to recruit participants into this study. It is recognised that women attending a Haven are a self-selected population, mostly from AB socio-economic groups, and are not necessarily typical of all women with breast cancer in the UK and that this means that the results are only generalisable to a substratum of the breast cancer population, and not to the population at large, such as those who did not seek support and complementary therapies. A sample of women who had completed their main Haven programme was sought for the study so that this would reduce the number of confounding factors. Every woman with breast cancer who attended the Haven programme who meets the selection criteria (see Table 4.2) was entered into the recruitment process.

Eligibility Criteria

Women diagnosed with stages 0 to III breast cancer were chosen for the study. Stage 0, although sometimes referred to as a very early or pre-breast cancer, is usually treated with surgery and radiotherapy, thus this group were included in the study. An overview of the stages is described in Table 2.1. These women were chosen as they usually go through a varying regime of treatment that usually includes surgery, chemotherapy before and/or after surgery and/or radiotherapy. Unfortunately, even after such treatments, there is no guarantee that the cancer will not return either locally or as distant metastatic spread later in life. The introduction of hormone drugs such as Tamoxifen® has significantly improved chances of five and 10 year survival up in women with early stage breast cancer whose disease is oestrogen receptor positive (Early Breast Cancer Trialists Collaborative Group 1998) and Arimidex® is more efficacious in oestrogen-receptive post menopausal women (Nabholtz et al 2003). When setting up the study, there was had been news about the potential benefits of the drug Herceptin® which could benefit some of the 20 to 25% of women whose breast cancer test positive for the protein HER-2 (Hortobagyi 2005). In spite of their high costs and subsequent patchy availability via the NHS, these medical advances hope to increase the survival of this population. It is important to evaluate self-management programmes that may contribute to overall health and wellbeing of these women who are living with the threat of recurrence of this disease and may regard it as a long-term condition.

Women with Stage IV breast cancer, who had distant metastatic spread, where breast cancer has spread to distant organs such as lung, liver, bone or brain, were excluded from this study on the grounds that their health may be or become too poor for them to

participate fully in the study and this may have become a source of unnecessary additional stress to them. This is not to say that women with advanced disease do not have issues affecting mood state, quality of life and wellbeing and the knowledge that they may be dying may bring a new range of issues for which they need support. Nor is it to say that MBSR cannot be adapted to work with this group, but for those coming towards the end of life with breast cancer, it could be argued that doing an RCT of an MBSR intervention may not be the most appropriate form of research and that a more inclusive qualitative design would be more appropriate.

4.8.2.1 Inclusion and exclusion criteria

Study inclusion or exclusion criteria are important to establish precision of the sample, enabling replication in a future study, as well as making sure potential participation would be safe and appropriate for any potential participants.

Inclusion and exclusion criteria for the study are outlined in Table 4.2 below.

Table 4.2. Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
Female	Male
Diagnosis of stages 0 to III breast cancer	Diagnosis of stage IV breast cancer
Age 18 to 80 years	Non-English speaking
Ability to complete a questionnaire	Substance misuse
Aware of their cancer diagnosis	Suicidal thoughts
Within 2 months to 2 years following the completion of surgery, chemotherapy and/or radiotherapy	Unable to give informed consent due to current psychosis or apparent serious intellectual impairment

Rationale for inclusion and exclusion criteria

1. Females only

As nearly 46,000 people are diagnosed with breast cancer annually in the UK and only 1% of these are men (Cancer Research UK 2008a), men were excluded from the study as they would not have been a representative group and an average of one per year attends the Haven.

2. Stages of breast cancer

Women with breast cancer without distant metastatic spread (stages 0–III) were chosen as they can suffer a great deal of emotional distress with the diagnosis and treatment of breast cancer (Derogatis et al 1983); they may also live with many fears, including those of cancer recurrence and death. Women already diagnosed with metastatic disease

(stage IV) were excluded from the study as possible deterioration in their physical condition may have prevented them from full participation in the intervention. In a previous study (Shapiro et al 2000), recurrence of breast cancer led to dropout. It would also have been difficult for the clinician-researcher to manage any complex clinical issues which might arise in this group who may be more ill as she was teaching large groups without assistance.

3. Age

It was thought appropriate to include adults as young as 18 as Breast Cancer Haven in London has seen Visitors in their early 20s. An upper age limit of 80 years old was chosen as to ensure that results would be comparable to those of other studies. Shapiro et al (2000) had participants with ages ranging from 38 to 77 years.

4. Non-English speaking and ability to fill in a questionnaire

Participants needed to be able to understand the nature of the research and sign an informed consent as well as complete the measurement tools. Non-English speaking women were also excluded as the programme was run in English only with no facility for translation.

5. Substance misuse, suicidal or psychotic, or intellectually impairment

Mindfulness interventions have been found to be beneficial for people in between psychiatric episodes (Teasdale et al 2000) and can help reduce the recurrence of depression. In teaching mindfulness, it is recognised that trying to bringing more attention and awareness to already severely ill psychiatric patients or people in a drug-induced altered state may exacerbate existing mental states rather than improve them. Women suffering from substance misuse, who were suicidal or psychotic were therefore excluded for their own safety. Teasdale et al (2000) required participants to be in recovery or remission from depression and off anti-depressant medication in their study. Women who were intellectually impaired were also excluded as the understanding of and participation in the MSBR programme would have been beyond their capabilities.

6. Recurrence of breast cancer

Enrolled participants were able to continue in the study if they developed a recurrence of cancer as it was perceived as unethical to exclude them from a potential source of support. If these participants became unwell and wished to continue, then the clinician-researcher instructing the MSBR programme would be able to guide them and encourage them to participate in a manner that was appropriate for that individual.

7. Timing of study

The recruitment period of between two months to two years following the completion of hospital treatment of surgery, chemotherapy and/or radiotherapy was made to allow people some time to recover a little from hospital treatment before embarking on the research programme as well as providing a limit at two years post hospital treatment gave a pragmatic limit that would allow inclusion of majority of people with needs as a consequence of diagnosis and hospital treatment for breast cancer and would allow comparisons with other studies. Shapiro et al (2000) also chose two years post hospital treatment as an upper limit following breast cancer treatment. There is support in the literature that this period is one when many physical and emotional symptoms and side effects from breast cancer as well as quality of life are at their worst (Wheelan et al 2000, Hassey Dow et al 1996, Shag et al 1993).

4.8.2.2 Sample size and power calculation

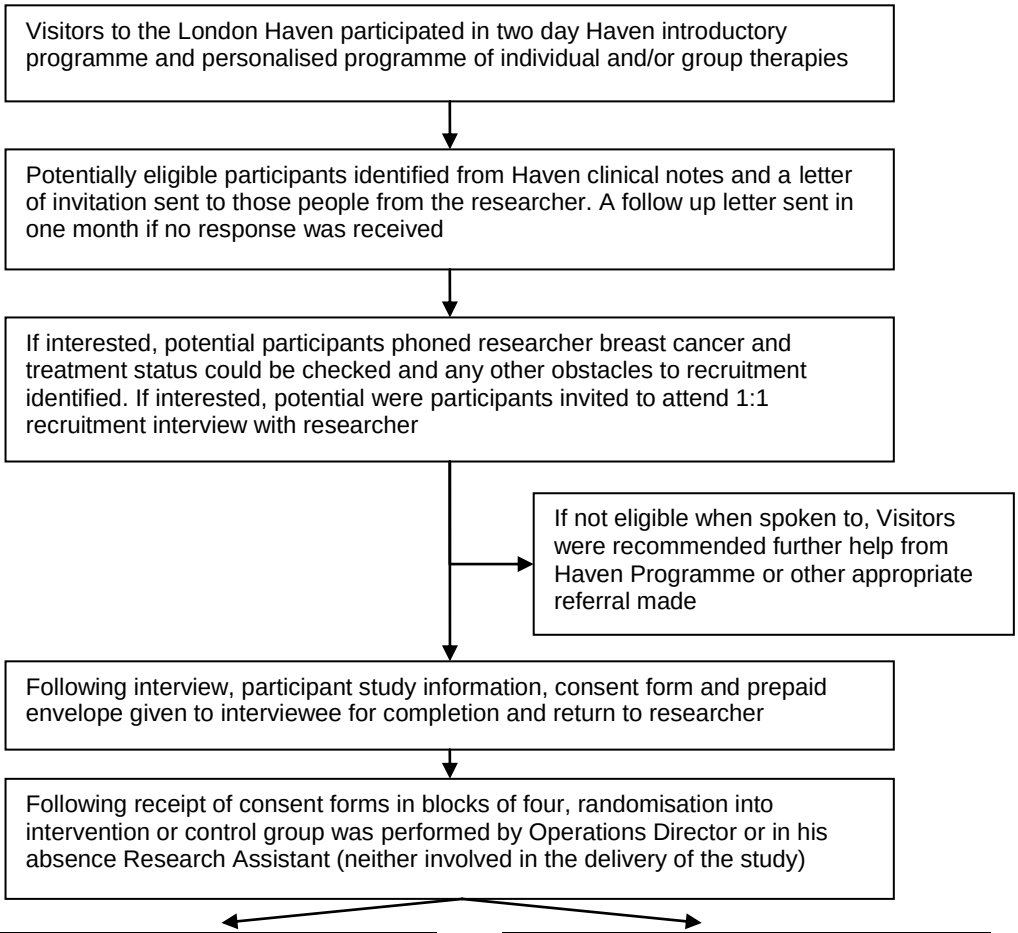
The sample size for this study was determined by a power calculation, which is important for any experimental study. Power calculations give the probability of gaining statistical significance and for detecting effects of different sizes (Lipsey 1990). Advice was sought from Dr Ruth Pickering, Statistician in the School of Medicine in 2004. Following guidance from the CONSORT statement, the sample should be large enough to have a high probability (power) of detecting as statistically significant and clinically important difference of a given size if such a difference exists (Altman et al 2001b).

Following the closely related study of Speca et al (2000), the sample size calculation for the present study was based on a difference in primary outcome (Profile of Mood States score) of 13 points with standard deviation of 30. Using a statistical power calculation programme nQuery (version published in 2004), results indicated that recruiting 85 participants per arm provided 80% power for a two-sided t-test using the 5% level of significance. To allow for drop out and other non-attendance we therefore planned to recruit 120 subjects per arm. The total number of participants sought for recruitment into the study was 240.

4.8.2.3 Participants' pathway through the study

An outline of the pathway of participants, communication and data flow through the study can be found in Figure 4.1 below. The term 'Visitor' is used at Breast Cancer Haven instead of 'patient'.

Figure 4.1 Flow diagram indicating the pathway of research participants in MBSR study



Week	Intervention Group	Control Group
-2 -0	Completion of Measurement Tools: POMS, FACT-B and FACT-ES and WHO-5 at T1	Completion of Measurement Tools: POMS, FACT-B and FACT-ES and WHO-5 at T1
1-8	Participation in MBSR eight week programme, two hours per week and one 6hour day in week 6. Suggested home practice of 45 minutes per day guided by CDs, 6 -7 days per week, during programme	Treatment as usual (TAU)– could attend other Haven groups as these were not based on mindfulness
8 -10	Completion of Measurement Tools: POMS, FACT-B and FACT-ES and WHO-5 at T 2 and completion of short-form proforma	Completion of Measurement Tools: POMS, FACT-B and FACT-ES and WHO-5 at T 2
12 -14	Completion of Measurement Tools POMS, FACT-B and FACT-ES and WHO-5 at T3	Completion of Measurement Tools POMS, FACT-B and FACT-ES and WHO-5 at T3
	Study completed	Wait-list control group: participation in MBSR eight week programme, two hours per week and one 6hour day in week 6. Suggested home practice of 45 minutes per day guided by CDs, 6-7 days per week, during programme and completion of short-form proforma (this data was not included in study).

Eligible women were identified for the study from their Breast Cancer Haven Visitor notes and they were written a letter of invitation by the researcher to join the study (see Appendix 11). This was accompanied by a leaflet explaining in more detail about the study (see Appendix 12). After a month, if no response had been received, a second letter was sent. On replying by phone to the researcher, women were then questioned briefly to establish 1) when hospital treatment for breast cancer (surgery, chemotherapy and radiotherapy) had finished, 2) current breast cancer status. If eligible at this point, they were invited to come in for a one-to-one interview with the clinician-researcher for up to one hour to further assess eligibility and discuss the study in more detail. If, during the telephone conversation, women were identified as having developed distant metastases and were therefore not eligible for the study, they were informed of this and invited to obtain additional support from the regular Haven Programme.

An individual, (up to) one-hour long recruitment interview was given to all participants prior to them receiving the information sheet or signing the consent form. Individual interviews prior to MBSR have been carried out in another similar study (Speca et al 2000). It was recognised that for the clinician-researcher to spend this length of time with all potential study participants may be a therapeutic encounter and needs to be considered to be part of the therapeutic intervention of the study received prior to randomisation. This is a pragmatic departure from the objective rigour of the RCT. This interview was carried out as it was paramount was to ensure the safety and appropriateness of the intervention for any potential participant. This is recognised as key by those who lead the MBSR intervention at the University of Massachusetts (Santorelli 2004b). Appendix 13 outlines the recruitment interview format that was followed for potential participants. At the end of the interview they were given the study information sheet (see Appendix 6) and consent form (see Appendix 7) with a reply paid envelope to read and sign and return as appropriate. Participants were given a minimum of 24 hours to consider the impact of being involved in the research on themselves, their family and their lives. Once the completed consent form was received, participants entered into the randomisation process outlined below.

4.9 Randomisation, controls and blinding

4.9.1 Randomisation, controls and blinding

Random allocation was used for the allocation to treatment groups. This means that each participant had a known probability of receiving each treatment before it was assigned, but the actual process was determined by the chance process and could not be predicted (Altman et al 2001b). Restricted randomisation in the form of a randomised block design was used to ensure close balance of numbers between intervention and control groups (Roberts and Torgerson 1998) at any time during the study. This was particularly

important to ensure that the size of the MBSR intervention groups were consistently manageable across the study. Blocks of four were used to allocate Intervention group (1) and Control group (0). A computer programme for this randomisation was designed by Dr Spencer Polley from the London School of Hygiene and Tropical Medicine, that randomly gave a combination of two x 1 and two x 0 at each click of the mouse (1100, 1010, 1001, 0110, 0011, 0101). This process could be repeated as many times as needed for the required sample size. This meant that the randomisation process needed to be done in groups of four, so the researcher would have to wait until she had received a group of four consent forms before allocation. To reduce any possible bias, this allocation to groups was performed by the Simon Lanyon, Operations Director at Breast Cancer Haven or, in his absence, the Research Assistant, neither of whom were involved with the clinical delivery of the study.

4.9.2 Controls

In this group, participants did not receive any prescribed intervention during the period of the study, but were essentially a 'treatment as usual' group, continuing with their lives as usual whilst waiting for their opportunity to join the intervention. They were offered the measurement tools at weeks -2 to 0, 8 to 10 and 12 to 14 whilst the intervention group was having their programme and completing tools at the same time. After the study period, controls were offered the MBSR programme, joining with intervention group participants from later MBSR cycles.

4.9.3 Blinding

It was not possible to blind either the intervention or control group to their allocation, but at interview, it was explained that they would be allocated to receive the MBSR intervention either sooner or later, where later would necessarily involve a three month wait. The term 'control group' was deliberately not used with interviewees, in case their perception of being allocated to that group had an effect on their participation in the study. Interviewees were asked for two possible times when they would be potentially available to do the study, for example Spring or Summer OR Spring or Autumn. In this way, when they were randomised, then if they were allocated to the second time, for example, Summer or Autumn, they would be in the control group and they would be sent a letter giving dates for that cycle. If any participants found they could not do the study at the allotted times, then their allocation at randomisation was maintained but they could join a later cycle. To reduce bias in an RCT, ideally there should be concealment of the allocated intervention at the time of enrolment (Altman et al 2001b). Due to the nature of offering the MBSR intervention this was not possible. The clinician-researcher was not blind to allocation, however all MBSR class participants received the same intervention despite their allocation.

4.9.4 Liaison with medical staff

Following randomisation, a letter was sent to the hospital medical consultants and General Practitioners of each participant informing them that their patient was participating in the MBSR study, see Appendix 14 for details.

4.10 Research Instruments and timing of their administration

It was important to choose rigorous and validated measurement tools to meet the research objectives and gain answers to the research questions posed. The rationale for choosing the measurement tools and a description of the primary and secondary outcome measures are given below. The main measurement tools were administered at three time points, T1, -2 to 0 weeks (week 0 being the week of the first group study entrance) prior to the commencement of the MBSR programme, this provided baseline measurements, 8 to 10 weeks later, to allow for a between group comparison after the intervention group had finished the MBSR intervention and at 12 to 14 weeks to give a short follow up period. This was done for pragmatic reasons as a longer follow-up period could not be given due the wait-list control design which meant that controls needed to start the intervention after this final measurement had been done. In addition, due to the time constraint of the PhD course, the clinician-researcher was aware that a limitation of the study would be a short follow-up period.

4.10.1 Rationale for the choice of measurement tools for the study

In this study, therapeutic effectiveness was measured in terms of mood, disease-related quality of life including endocrine symptoms and wellbeing. In choosing measurement tools to answer the research questions, the aim was to obtain data enabling a greater understanding of common issues that affect women treated for breast cancer including psychological and general wellbeing, breast cancer related physical, social, emotional and functional aspects of quality of life and menopausal symptoms.

A summary of the measurement tools can be found in Table 4.3 and a full copy of the measurement tools in Appendices 15 and 16.

Table 4.3. Measurement tools for this study

Primary or secondary outcome measure	Measurement Tool	Validated
Primary outcome measure	Mood disturbance using the Profile of Mood States (POMS) (65-item)	Yes
Secondary outcome measures	Functional Assessment of Cancer Therapy-Breast (FACT-B) 37 item (Version 4) and Breast Trial Outcome Index (FACT-B TOI)	Yes
	Functional Assessment of Cancer Therapy-Endocrine (FACT-ES) 19 item subscale and Endocrine Trial Outcome Index (FACT-ES TOI)	Yes
	World Health Organisation 5 item wellbeing questionnaire (WHO-5)	Yes, but not with breast cancer
	Non-validated introductory questions relating to stress from illness and stress from other recent life events included with measurement tools	No
	A short proforma with open questions for qualitative feedback was given to each participant on the completion of the MBSR programme	No

4.10.2 Primary outcome measure

The Profile of Mood States (POMS)

The Profile of Mood States (POMS) was chosen as the primary outcome measure as it can evaluate both overall mood state and also capture different aspects of mood from its subscales which measure anxiety, depression, anger, vigour, fatigue and confusion. It was useful to identify which specific aspects of mood were affected. POMS had been used in mindfulness studies of cancer outpatients undergoing MBSR (Speca et al 2000) and with breast cancer (Shapiro et al 2003). Using this tool also provided data from the Speca et al (2000) study to inform the power calculation for this study as described earlier.

POMS Tension-Anxiety subscale

Tension and anxiety as measured by the POMS Tension-Anxiety subscale describes heightened levels of musculoskeletal tension, reports of somatic tension which may not be

overtly observable (tense, on edge) as well as psychomotor manifestations (shaky, restless) and vague, diffuse anxiety states (anxious, uneasy).

POMS depression-dejection subscale

Depression and dejection were measured by the POMS Depression-Dejection subscale which represents a mood of depression accompanied by a sense of personal inadequacy. It includes items enquiring about feelings of personal unworthiness (unworthy), futility regarding the struggle to adjust (hopeless, desperate), a sense of emotional isolation from others (blues, lonely, helpless, miserable), sadness (sad, unhappy) and guilt (guilt, sorry for things done).

POMS anger-hostility subscale

Levels of anger and hostility were measured using the POMS Anger-Hostility subscale which represents a mood of anger and antipathy towards others. The items anger, fury, ready to fight describe feelings of intense, overt anger, whilst milder hostility are represented (grouchy, annoyed), the more sullen and suspicious components of hostility are represented by deceived, bitter. The items peeved, bad tempered and rebellious simply broaden the domain of anger.

POMS Vigour-Activity subscale

Vigour and activity were measured by the Vigour-Activity subscale of the POMS which represents a mood of vigorousness, ebullience and high energy. It is negatively related to the other POMS factors.

POMS Fatigue-Inertia subscale

Fatigue and inertia, when measured by the POMS Fatigue-Inertia subscale represents a mood of weariness, inertia and low energy levels. It includes items such as worn-out, fatigued, exhausted, sluggish and weary.

POMS Confusion-Bewilderment subscale

Confusion and bewilderment were characterised by bewilderment and muddle headedness by the POMS Confusion-Bewilderment subscale. There is doubt as to whether this factor represents a trait of cognitive inefficiency, a mood state or both (McNair and Heuchert 2005).

4.10.3 Secondary outcome measures

Three validated tools were chosen for secondary outcome measures and two non-validated Likert-scales. The validated tools were Functional Assessment of Cancer Therapy –Breast (FACT-B), Functional Assessment of Cancer Therapy –Endocrine

Symptom subscale (FACT-ES), their trial outcome indices and the World Health Organisation five item wellbeing questionnaire (WHO-5). The non validated Likert-scale scored questions related to perceived stress and a short proforma to evaluate participants' experience of MBSR. The Likert-scale scored questions were previously used for the Bangor study (Soulsby 2003, personal communication) and the short-form proforma was specifically developed by the clinician-researcher to capture data at the end of the MBSR intervention period to capture qualitative data in the form of from the MBSR course.

Functional Assessment of Cancer Therapy –Breast (FACT-B) and –Endocrine Symptoms (FACT-ES)

The choice of tool for quality of life was a tool developed in the USA, Functional Assessment of Cancer Therapy –Breast (FACT-B) and Functional Assessment of Cancer Therapy –Endocrine Symptom subscale). FACT-B and FACT-ES were chosen in preference to the closest European equivalent, European Organisation for the Research and Treatment of Cancer EORTC Quality of Life Questionnaire (EORTC QLQ-C30), as the FACT –B is a specific breast cancer related quality of life tool and the FACT-ES added the extra dimension of evaluating menopausal symptoms which are suffered by a large percentage of women due to treatment for breast cancer or the age at which breast cancer may occur. FACT-B had been used in another breast cancer and MBSR study (Shapiro et al 2003) and is one of the few quality of life scales available that is validated specifically for this population. It has subscales of physical, social/family, emotional, functional wellbeing, as well as disease-specific additional concerns. In choosing tools previously used in related studies with women with breast cancer, it was hoped that some comparisons were possible between the results from different studies. The Functional Assessment of Cancer Therapy – Endocrine Symptom subscale (FACT-ES) was chosen to evaluate whether MBSR can help with the distressing symptoms of hot flushes, night sweats and other endocrine symptoms induced by chemotherapy or hormonal treatments for breast cancer to add new knowledge ways that might help with these distressing long-term symptoms.

The trial outcome indices (TOI) used relate to the FACT-B and the FACT-ES. The TOI combine physical and functional wellbeing scales plus the specific subscale for breast or endocrine symptoms as appropriate.

World Health Organisation 5-item Wellbeing questionnaire (WHO-5)

The World Health Organisation 5-item wellbeing questionnaire (WHO-5) evaluates general wellbeing and was chosen as it simply evaluates overall wellbeing. In addition it had been used in cancer populations who have undergone Mindfulness Based Cognitive Therapy (MBCT) in Bangor (Soulsby 2003, personal communication) so that comparisons could be made with this data if possible. Since this study was developed, van Gestel et al

(2007) published a study using WHO-5 in breast cancer, commenting that he thought this to be the first use of the tool in this population.

Other scales commonly used to evaluate psychological wellbeing are those which measure the presence or absence of psychiatric disorders such as anxiety and depression, not directly measuring positive states of wellbeing as identified in the WHO-5. Using this scale gave participants the opportunity to respond to a positively angled questionnaire deliberately placed as the last of the outcome measures given to participants.

Using this particular battery of tools allowed for a more substantial validation of the study allowing for some triangulation which provided an opportunity to capture any overlap between these measures. They also provided a way of obtaining a breadth of data on psychological and physiological states, particularly on the measures associated with mood and wellbeing.

Evaluating Stress

As this research evaluated the effects of a stress reduction programme, it seemed pertinent to explore the nature of stress with participants. Two additional questions were added to the front of the questionnaires (see Appendix 15) with Likert-scales of 0 to 10 relating to perceptions of stress from breast cancer and stress from other recent life events where 0 is not stressful at all and 10 is extremely stressful. These additional non-validated introductory questions were added by the researcher to gain some insight into participants' perceptions of stress relating to breast cancer and stress from other recent life events that might influence scores on measurement tools. These had also been used in the Bangor mindfulness study (Soulsby 2003, personal communication) and it was hoped that after analysis, comparisons could be made between the two sets of data.

Feedback from MBSR group attendees

The qualitative data from the study was collected via a short proforma with one closed but otherwise open questions that were given to all participants at the end of their 8-week course (see Appendix 16). This enabled the researcher to gain additional feedback on the experience of mindfulness and participation in the MSBR course from the intervention group. Questions 1.1 and 1.2 to explore the participants own experience of mindfulness were added following the advice of the internal examiner at the Transfer Viva held at the University of Southampton in December 2005, to gain further insight into the participants experience of mindfulness. As two of the six cycles of MBSR programmes had already been completed at this point, not all participants completed those additional questions.

4.11 Validation of measurement tools of POMS, FACT-B and FACT-ES subscale and WHO-5

The three major tools POMS, FACT-B and FACT-ES and WHO-5 used in this study were all validated. Validation ensures that the tools measures what they are supposed to. There are different ways of measuring this:

1. Face validity (ensures that the scale measures the underlying concept of interest)
2. Content validity (ensuring all relevant concepts of the attribute)
3. Criterion validity (the extent to which the measure correlates to the 'gold standard')
4. Predictive ability (demonstrates the psychometric properties of the measure and is commonly used in quality of life measures)
5. Construct validity (enables hypotheses to be generated and the scale tested against a measure central to the hypothesis) (Bowling 2001).

Below are details of the validation process of each tool used this study.

4.11.1 Profile of Mood States (POMS 65-item)

The long version of the POMS is a 65 item self-administered, Likert-scale measure of affective states (McNair et al 1971) was used in this study. The instrument provides a Total Mood Disturbance Scale and six subscales. POMS has an acceptable test-retest reliability (ranging from 0.65 for Vigour to 0.74 for depression) (McNair et al 1971), it has high levels of concurrent validity with related scales, and is sensitive to emotional changes within patient groups (Gotay and Stern 1995). Their scores on POMS were consistent with mood scores reported by other authors for patients with cancer (Cassileth et al 1985). POMS has been used in at least 57 breast cancer studies, as reported by McNair and Heuchert (2005). POMS has previously been used in other recent MBSR studies with cancer populations including breast cancer (Speca et al 2000, Shapiro et al 2003).

Total scores for POMS can range from -32 to +200. Higher scores indicate greater mood disturbance. Mean scores for breast patients (N=118) are reported as 20, with a standard deviation of 32.4 (Cassileth et al 1985).

4.11.2 Functional Assessment of Cancer Therapy-Breast (FACT-B)

The Functional Assessment of Cancer Therapy – Breast (FACT-B) was chosen to evaluate the overall functioning of women affected by breast cancer. The FACT-B is a 37–item self-report instrument designed to measure multi-dimensional quality of life in patients with breast cancer. The FACT-B consists of the FACT-General (FACT-G) 27-items, plus the 10-item breast cancer subscale (BCS), which complements the general scale with items specific to quality of life in breast cancer. It covers areas of physical, social/family, emotional and functional wellbeing.

The validation of the Functional Assessment of Cancer Therapy-Breast (FACT-B) was published by Brady et al (1997), then a 44-item self-report instrument designed to measure multidimensional quality of life in patients with breast cancer. The FACT-B consists of the FACT-General (FACT-G) plus the Breast Cancer Subscale (BCS), which complements the general scale with items specific to quality of life in breast cancer. The FACT-B was developed with an emphasis on patients' values and brevity and is available in nine languages. The alpha coefficient, indicating internal consistency, for the FACT-B total score was high (α =0.90), with subscale alpha coefficients ranging from 0.63 to 0.86. Evidence supported test-retest reliability, as well as convergent, divergent, and known groups validity. The authors concluded that the FACT-B is appropriate for use in oncology clinical trials, as well as in clinical practice. It demonstrates ease of administration, brevity, reliability, validity, and sensitivity to change. The current 37-item FACT B (Version 4) was used in this study (Functional Assessment of Chronic Illness Therapy 2005).

4.11.3 Functional Assessment of Cancer Therapy Endocrine Symptom subscale (FACT-ES)

The FACT-ES consists of the FACT-General (FACT-G) plus the Endocrine Subscale (ES), This scale was chosen as it was recognised that women who have undergone chemotherapy or who are undergoing hormonal therapy which block oestrogen (for example Tamoxifen® or Arimidex®) frequently suffer from distressing menopausal symptoms (Courzi et al 1995).

A version of the FACT-ES including the BSC subscale (FACT-G plus BSC plus ES) was tested on 268 women with breast cancer receiving endocrine treatments. Alpha coefficients for all subscales demonstrated good internal consistency, ranging from 0.65 to 0.87. Test – retest reliability of the ES indicated good stability ($r= 0.93$, $p<0.001$). The authors concluded that FACT-ES has acceptable validity and reliability and is sensitive to clinically significant change. The alpha coefficient for ES alone was 0.79 (high) and for FACT ES 0.92 (very high) (Fallowfield et al 1999).

According to FACIT staff (Functional Assessment of Chronic Illness Therapy 2008, personal communication), the FACT tools can be put together in combination as done by Fallowfield et al (1999), but this was not the way the main analysis was performed in the current study as the clinician-researcher was hoping to be able to get a distinction between breast related symptoms and endocrine related symptoms.

4.11.4 World Health Organisation five-item wellbeing questionnaire (WHO-5)

The World Health Organisation five-item wellbeing questionnaire (WHO-5) is a short screening instrument for the assessment of wellbeing in the general population. The five items are 1) I feel cheerful and in good spirits; 2) I feel calm and relaxed; 3) I feel active and vigorous; 4) I feel fresh and rested; 5) My daily life is filled with things that interest me.

The items are rated on a six-point Likert-scale from 0 (=not present) to 5 (=constantly present). The formation of the WHO-5 (World Health Organisation 1998) has been based on the results of Guelfi's European study (Guelfi et al 1997) comparing the WHO 22-item version with the 22 item versions with 22-item psychological General wellbeing inventory. WHO-5 scores range from 0 to 25 and can be converted to 0 to 100% where 0 means the lowest possible wellbeing and 100% means the highest possible wellbeing. WHO-5 has been used in an unpublished study of cancer patients undergoing MBCT (Soulsby 2003, personal communication) and in a research published after the current study was designed, breast cancer quality of life study (van Gestel et al 2007).

In a study examining validity of two recent versions of the WHO-5 in an elderly population (Bonsignore et al 2001), both with five items but with the 1995 version having one negative prompt compared to the 1998 version with all positive prompts, the internal validity of the wellbeing questionnaire was evaluated by calculating Loevinger's (version 1=0.38, version 2=0.47) and Mokken's (>0.3) homogeneity coefficients in nearly all items. External validity for the detection of depression was evaluated by Receiver Operating Characteristic (ROC) analysis showing that both versions adequately detected depression. This scale has been previously used (Soulsby 2003, van Gestel et al 2007) but not validated for use in a breast cancer population.

4.12 Rigour and validity of methods

Using an experimental design is regarded to be the optimum quantitative method of obtaining information about the effect of a treatment or intervention (Richardson 2000). The power and strength of experimental research is related to control.

The pilot group (see section 4.13) enabled the clinician-researcher to test out the intervention. Threats to validity in the delivery of the MBSR programme were issues of the consistency and standardisation of the intervention. Running the pilot group helped to minimise variations in the programme by allowing for a 'trial run' under close clinical supervision, closer than would be possible during the trial itself. The maturation effect is another possible threat to validity, the concern that the teaching of MBSR may improve and that the results of groups taught later might be better than earlier ones.

Selection bias from using a convenience sampling strategy with visitors who came to Breast Cancer Haven meant that a higher socio-economic group of participants in the study as these are group of patients who are also female that are the highest users of complementary therapy and supportive services (Molassiotis et al 2005, Downer et al 1994, Cassileth and Vickers 2005). It could be argued that even with different methods of selection, participants may have come from the same socio-economic groups. Even so,

this means that results will only be generalisable to a substratum of the breast cancer population; those who actively seek complementary therapies.

The presence of inclusion and exclusion criteria assures as homogeneous sample as possible, the use of a comparison group helped to see the true effect of the intervention through the randomisation process. As this study also has a pragmatic element, blinding for the participants has not been possible through randomisation process but all MBSR participants were treated the same despite group allocation. To minimise any effects of the participant 'wishing to please' the clinician-researcher, the research assistant handled the questionnaires and queries relating to them. The validity of the measurement tools is important to add rigour to the study, more details of this can be found in section 4.11 above. Standardised statistical tests were used to analyse the data collected as outlined in section 4.18. Reporting of the study is in accordance with the Consort statement (Altman et al 2001b) that suggests a model of reporting which enables complete transparency from authors (Moher et al 2001) and thus allows critical appraisal of the quality of the trial (Altman et al 2001b).

4.13 Pilot Study

This section includes the justification for conducting a pilot study and describes the testing of process that running of the pilot study enabled.

4.13.1 Justification of the MBSR pilot for the study

A pilot study was run to test out a number of areas before the main study:

- recruitment
- data collection
- evaluating the response of participants to completing the measurement tools
- understanding the practicalities and gaining experience in conducting the MBSR intervention
- receiving clinical supervision to ensure a more consistent standard of the intervention over the data collection period
- copying and labelling and use of the four 45-minute CDs recorded by the clinician-researcher to guide the home practice
- collation of materials for the practice manual and home practice sheets (see Appendix 17) that accompanies the MBSR programme.

4.13.2 Participants of the eight-week pilot MBSR programme

An 8-week pilot MBSR programme was given to 12 women, aged 30 to 50 years of whom 10 were Haven therapy and administration staff. The other two had both been treated for

breast cancer several years previously, one was a Haven volunteer and a former Haven Visitor, but not eligible for the study, and the other was friend of a staff member.

4.13.3 Rehearsing the recruitment process

Rehearsing the process of recruitment with potential study participants for the study interview, ensuring that the information given is clear and enables potential participants to fully understand what the study is about. Talking to potential participants for the pilot study enabled the clinician-researcher to refine the issues to be addressed during the pre-study interview (see Appendix 13), so that relevant information was obtained from each interviewee and the relevant information given appropriately. Telephone conversations held with those who were not spoken to in person. The formal participant information was read by all potential participants for clarity and understanding. In particular, the two women who had had breast cancer in the past, were spoken to for feedback on the information given, they did not have any difficulty with the information on the sheet. In the pilot group 11 of the 12 pilot participants were known to the clinician-researcher or to each other which may have engendered a high level of trust in the group.

4.13.4 Testing out procedures and tools

Checking the acceptability of measurement tools and process in which they are given and collected was important. The pre-study questionnaires were posted or handed to pilot group participants if they were Haven staff and, due to the short time frame, they were asked to bring the completed questionnaires with them to the first class. The delivery of measurement tools post intervention with the pilot group ensured that these were sent out and returned as intended. Pilot participants were given reply paid envelopes to return the questionnaires at the allotted times. The need to chase up the return of questionnaires was one that became clear from working with the pilot group.

Pilot participants were asked to read all the questions even though they were not all relevant to them and give feedback as appropriate to any sensitivities or difficulties they encountered. All pilot participants found the questions acceptable and a number commented that thinking about their state of health and wellbeing in this way had given them cause for self-reflection. There were no negative responses to filling in the questionnaires, finding the questions either too personal or too difficult. The handling of participants' information and data also enabled the process for data collection and data storage to be established.

4.13.5 Testing out the MBSR intervention, practising and refining teaching skills.

Details of the MBSR intervention are discussed later in this chapter. The clinician-researcher who was also the MBSR programme leader, had a major concern about the

delivery of a new programme unrehearsed to study participants. The running of the pilot programme helped to minimize this effect.

4.13.6 Clinical supervision

Receiving clinical supervision during the pilot cycle helped to improve and standardise the MBSR programme delivery. During the pilot period, the clinician-researcher received clinical supervision by phone from Florence Meleo Meyer, a senior MBSR instructor at the University of Massachusetts Medical Centre (who was one of the trainers who led the teacher development intensive previously attended by the researcher in 2004). A total of six one-hour phone supervision sessions of were held before, during and after the 8-week pilot programme. Following the pilot programme, it was agreed with both academic and clinical supervisors that there would be one hour of clinical supervision received at the end of each 8-week MBSR programme for the duration of the study so as not to influence each group whilst the MBSR programme was in progress. This supervision process enabled the safe clinical delivery of the MBSR programme to participants throughout the study period.

4.13.7 Refining the course practice manual

The MSBR course has home practice record sheets (see Appendix 17) an accompanying practice manual (see Appendix 18*)*, but the latter was not ready in time for the pilot group. Instead the pilot group got the relevant pages from the manual week by week. This piecemeal approach did allow for the development, refinements and corrections to be made to the manual and practice sheets in time for the main study. The course practice manual provided additional teaching points and information to facilitate reflective elements of the home practice. This development of this manual followed guidance of the Clinical Supervisor, Florence Meleo Meyer, one of two senior MBSR teacher trainers at the University of Massachusetts.

4.13.8 Testing MBSR course materials

These included the four x 45 minute CDs (see Appendix 19) which were made by the clinician-researcher based on those offered in the original University of Massachusetts study to guide the formal home practice. It was important that these were in the voice of the instructor allowing continuity from the classroom to the home practice environment. In addition, the testing of the booklet mentioned above and home practice instructions and record sheets was enabled (see Appendix 17). Home practice sheets were printed on different coloured sheets each week for easy identification. Testing these materials with this group allowed for any needed refinement of the materials for the main study.

4.13.9 Running the MBSR course in the evenings

Running the MBSR course in the evenings at the Haven helped to identify any practical resources needed, and solve logistical matters of how much space was needed, where equipment could be stored, operating the heating after hours, ensuring the administrative/reception support was in place, getting a bell to be installed if participants arrived late, clarify parking arrangements, and ensuring the building was secure after hours.

4.13.10 Attendance of the pilot group

The average number of two-hour sessions attended by pilot participants was 6.8 out of a possible eight. Nine out of 12 participants attended the six-hour day of mindfulness. Reasons for non-attendance were illness and prior commitments on the day. No participants dropped out because they did not like the course or did not find it helpful, one participant left due to the pressures of work.

4.13.11 Data entry and data analysis of pilot study

In the pilot group, questionnaires were completed by nine participants pre-intervention and five participants post intervention. As there was no plan to enter and analyse the data from this group, no 12 to 14 week follow up questionnaires were sent to this group, partly because of time pressures but in hindsight it would have been a truer completion of the pilot process. A system for sending out reminders for questionnaires was put in place for the main study.

Data entry and data analysis were not performed with the pilot group as the group was not representative of the study population. It was not the intention of this pilot group data to inform the feasibility of the main study through analysing the results although the researcher is aware that this is often the reason for conducting such a pilot study. In hindsight, this would have been a valuable exercise to rigorously check the data sheets as due to a typographical error, one of the items on one of the secondary outcome measures, (in the FACT emotional wellbeing subscale) had been omitted and this was not noticed until after the early groups of the study had commenced when it was then rectified. In data analysis of the main study, this piece of missing data was handled according to the instructions from the FACT manual (see 4.18.2 for more details of this procedure).

4.13.12 Feedback from pilot group participants participating

An informal feedback form from the pilot group was returned by four participants, three rated the overall experience of the course as 8/10 and one rated it 9/10. All but one commented on the benefits of being in a group and being able to practice meditation

together. One commented on the benefit of the whole mindfulness day. One participant found it difficult to find a set time to practice each day and another thought the home practice of 45 minutes unrealistic. Another participant commented that more awareness should be given to any physical limitations in participants with the practice of the mindful stretches. All these comments were addressed in the recruitment for the main study ensuring there was a better understanding of these issues by potential participants. One of the pilot group participants who had been treated for breast cancer said '*Thank you for taking/leading me on this journey of self-discovery in mindfulness. I have really grown in this life experience and recognise that I have a long way to go…I'm sure your non-pilot groups will greatly benefit'*. The other participant who had had breast cancer was concerned that the term 'mindful body scan' might conjure up negative associations for participants of hospital scans as it did for her. As the term mindful body scan had been historically used in all patient groups in the teaching of MBSR, the clinician-researcher decided not to change the name. If any distress around this term arose again from any other participants, the clinician-researcher planned to change the name from 'mindful body scan' to a 'body awareness exercise'. This issue was not raised by any other participant in the main study so no further action was taken.
All this information was helpful for the researcher in preparation for the main study, to enable her to address any of the same or similar issues should they arise.

4.14 Changes made to the study as a result of the pilot project

As a result of the pilot project, the main study design and overall MBSR programme content remained the same. The main changes were to the teaching approach which occurred as a result of the weekly phone clinical supervision. This enabled a higher and more consistent quality of teaching throughout the eight-week programme. The need to send reminders regarding questionnaires that had not been completed on time was another area that was highlighted via the pilot study and a mechanism was put in place for this. The qualities of copies of the MBSR CDs was occasionally problematic and the ability to for it to work on different CD players. Participants were asked to contact clinician-researcher or research assistant immediately if they needed a replacement.

4.15 The MBSR Intervention

MBSR teaches participants to become more mindful through the learning of a series of practices which can help cultivate mindfulness through bringing attention and awareness to each moment. This is done by cultivating a fuller awareness of oneself in the present moment, noticing how things are, aware of the experience of breathing, bodily sensations, thoughts, feelings and sounds as they arise. This then enables participants to notice their responses to stressful situations in life and to play an active part in choosing how to respond, rather than solely being driven by automatic habituated reactions. This 'stepping

back' from a situation or finding a new perspective on it can facilitate positive behavioural choices (Teasdale et al 2000).

The formal mindfulness practice techniques used to do this include

1. mindful body scan – taking attention and awareness to different parts of the body (usually done lying down)
2. mindful stretches – a series of lying down stretches and a series of standing stretches (similar to simple slow yoga stretches)
3. mindful sitting meditation

In addition there was teaching about mindfulness in everyday life, including eating and walking, as well as teaching and discussion to better understand the experience of mindfulness practice and as the course progresses, stress and communication. The mindful exercises were allocated for home practice each week. A detailed summary of the MBSR programme, is given in Appendices 3 and 4.

The MBSR intervention in this study was run over a period of eight weeks offering the 2.0 hours sessions per week with a choice of two times (Tuesday evenings 6pm to 8pm or Wednesday mornings 10.30am to 12.30pm). The first and last classes had an additional 15 minutes added to them for introduction to and debriefing from the course). Programmes around the world have varied class times and hours to suit individual populations and needs. The optimal length of time for classes has not been tested. See Table 4.4 for comparisons of other relevant programmes to this one.

Table 4.4. Comparisons of classroom time in MBSR Programmes at University of Massachusetts (UMass) and with other cancer studies

	UMass	Speca et al (2000)	Shapiro et al (2003)	Current study	Rationale for this study
Average class sizes	40	Approximately 15	Not stated (31 in total)	Average of 15	Hours chosen allowed time to offer necessary contents of programme, facilitate discussion as well as allow for travel to and from central London for many who were back at work
Number of weeks	8	7	6	8	
1st and last weekly sessions (in hours)	3	1.5	2	2.25	
Other weekly sessions (in hours)	2.5	1.5	2	2	
Day of mindfulness	7	None	6	6	
Total hours class time per course	28	10.5	18	22.5	
Length of home practice CDs	45 minutes	Not stated but 30 minutes according to Speca (2009)	Not stated but 30 minutes implicated	45 minutes	

A classroom time of two hours was chosen for this population as it allowed enough time to fit the weekly programme in and was not too long for participants who may still be fatigued from breast cancer treatment to come long distances in and out of London. This same rationale was used to shorten the day of mindfulness (silent retreat) to six rather than seven hours in week six of the programme, although some programmes miss this day out altogether (Speca et al 2000) or provide a half-day. So it can be seen that the time spent delivering the MBSR programme is not exact.

If unable to attend either the evening or morning group, participants were able to swap the other group so that they do not miss a session. Home practice of 45 minutes per day, six to seven days per week of formal mindfulness practice guided by CDs was suggested and in addition, some informal mindfulness techniques. MBSR courses around the world also vary with home practice time. Home practice record sheets are detailed in Appendix 17.

The researcher endeavoured to benchmark the MBSR intervention to standard practice as described in the literature.

Intervention group sizes were limited to a maximum of approximately 20 participants, as this was the maximum limit for the room size. In addition, larger groups may require a co-facilitator, input than was not available for this study. The cycles of eight-week MBSR programmes being run in 2005 to 2006 for participants were seven in total (see Appendix 20). The autumn cycle for 2006 enabled any controls still outstanding to do the MBSR programme. All cycles were designed to avoid major holiday periods.

4.16 Data collection

Participants completed the measurement tools (see Appendix 15) at weeks -2 to 0, 8 to10 and 12 to14. At -2 to 0 weeks, evaluation was done pre-MBSR intervention for the intervention group and the control group were asked to complete these at the same time. The intervention group completed the weeks 8 to10 and weeks 12 to 14 questionnaires post intervention and the control group completed this at the same time before being offered the MBSR intervention. Table 4.5 indicates the data collection points for this study.

Table 4.5. Data collection schedule: Dates that questionnaires were sent to participants

Cycle	Questionnaire 1	Questionnaire 2	Questionnaire 3
Spring 2005	17. 4 .05	8.6.05	24.6.05
Summer 2005	20.06.05	24.8.05	16.9.05
Autumn 2005	9.9.05	16.11.05	9.12.05
Winter 2006	4.1.06	8.3.06	31. 3. 06
Spring 2006	31.3.06	14.6.06	5.7.06
Summer 2006	30.6 06	6.9.06	29.9.06
Autumn 2006	No questionnaires (control group programme did MBSR only)		

The data collection was facilitated by a research assistant who was independent from the clinician-researcher offering the intervention. The research assistant posted questionnaires out to participants at the relevant time points. The research assistant facilitated the completion of the questionnaires by participants, if needed, by speaking to them by phone (-2 to 0, 8 to10 and 12 to14 weeks). The research assistant also contacted participants by phone if questionnaires were not received on time.

Most participants found the questionnaires straight-forward and only six participants asked for help from the research assistant for the following reasons:

1. Three participants did not understand the Americanised terms on the POMS including ‘full of pep’, ‘bushed’ and ‘peeved’. Not all participants had English as their first language.
2. Clarification on timescale concerning stressful life events and time scale regarding items on the FACT was needed. Some participants were concerned that how they were feeling ‘over the last seven days’ was not typical of how they were feeling generally. The research assistant encouraged them to follow the instructions on the questionnaire.
3. One participant found the questionnaires too distressing to complete and therefore had to be excluded from the study. She was then offered further support from the Haven Programme.

As the time between the collection of the third questionnaire and the beginning of the next cycle was tight, the research assistant reminded those in the control group who were entering the next MBSR programme to complete and return the final questionnaire prior to its commencement.

4.17 Process of quantitative data entry

4.17.1 Coding of data and handling missing data

All data was entered in numerical form using 9, 99, 999 as missing values as recommended by Altman (1991). See Appendices 21 and 22 for details.

4.17.2 Data entry

To facilitate the accuracy of data entry, a specifically designed Access data base was set up by the research assistant to mimic the pages of the forms given out to participants. Raw questionnaire data was then entered by the research assistant. The clinician-researcher joined the research assistant to enter the first cycle of data for the study to ensure that all the codes were correctly entered. At the start of this process, checks were done with the clinician-researcher for data entered on the first three questionnaires. This data base was then saved into Excel and could be opened into the statistical package SPSS Version 14.1 for data analysis. Each participant then had a row of data that was identified by study number. For accuracy, random checks were performed by the clinician-researcher together with the research assistant on every 10^{th} row of the data using the questionnaire data sheets to check the entries in SPSS. For questionnaire data there was found to be nearly 100% accuracy with less than 10 empty cells in SPSS which were corrected from the raw data.

Master copies of the databases containing data from baseline measures and questionnaires responses were saved in SPSS. These databases were left untouched to ensure a backup in case of errors in analysis. These data bases were then merged together for analysis. Checks were performed at each stage by the researcher and research assistant together.

4.17.3 Cleaning the data

Data needed to be in a format that could be analysed accurately. One of the main reasons for missing data was that questionnaires were posted back to the research assistant, so there was no way of checking for missing data at the time of their completion. It was found that on four occasions that a whole page of the questionnaire was missed by participants, but most missing data was from missing single items on the questionnaire. Fortunately, due to the way that this was missing data was handled in the analysis, it did not significantly impact the results of the study. There were three participants who had more than 20% of the overall data missing in questionnaire one (completed at baseline) and these participants were necessarily excluded as their data was too sparse to analyse. In the intervention group, excluded participants included those who had begun the MBSR programme before completing the baseline questionnaire and in the control group where participants' week eight or 12 questionnaires arrived too late where participants had

already commenced the MBSR programme. This data was removed so that answers would not be influenced from having commenced the MBSR programme. One study participant, ineligible by age (over 80 years of age), was also excluded as she did not meet entry criteria. It is noted that, when performing ITT analysis, there is controversy on this matter, with some authors suggesting inclusion of such cases regardless of the fact that it contravenes exclusion criteria (Hollis and Campbell 1999).

The clinician-researcher and research assistant together checked all data manually for data that need to be removed for ITT analysis, this was done when there were less than 50% of subscale data present in any of the questionnaires at 8 to 10 weeks or 10 to 12 weeks and these gaps treated as missing data.

4.18 Quantitative data analysis

All data analysis was carried out according to a pre-established analysis plan using the statistical package SPSS version 14. This section describes the methods used in data analysis including the personnel involved in the analysis, the cleaning of the data, handling of missing data, descriptive statistical tests used, the data used in the various analyses, handling of output data, methods of linear regression used and those of qualitative data analysis.

4.18.1 Personnel involved in quantitative data analysis

The clinician-researcher at Breast Cancer Haven performed all the quantitative data analysis with the support of the research assistant. This complex process was done with the research assistant for quality control purposes. At no time was the research assistant left to perform this work alone. Dr Peter Nicholls, statistician from the University of Southampton, supervised this process. This involved regular meetings, emails and phone contact throughout the period of analysis with the clinician-researcher, and on occasions, joined by the research assistant.

4.18.2 Handling of missing data for the purpose of analysis

As intention to treat (ITT) analysis was used, it was important that missing data was managed in a way that kept to this principle. In the ITT analysis, where data is missing, it is important that any data added accurately reflects the most likely value of the missing item. Missing data for each of the questionnaires was handled according to instructions in the relevant manuals. The POMS technical update states that a prorated item score should be calculated, also known as standard mean imputation, as the mean of the completed items defining the same factor (McNair and Heuchert 2005). For the proration in this study, mean scores for each of the subscale scores were calculated from the completed items of that subscale and this was substituted if any missing item where over

50% of any subscale was completed. The FACT manual also instructed the use of proration for handling missing data where more than 50% of individual item subscales was completed. It also states that 80% of the entire FACT questionnaire must be completed. When there was insufficient data to perform proration, the scores from baseline were brought forward. For the 5-item WHO-5 missing data was handled in the same way as a subscale of the FACT where three or more items out of five completed in order to compute an overall score.

The clinician-researcher and research assistant together ran checks on three different methods of missing value replacement:
1. Proration (standard mean imputation)
2. Previous value brought forward
3. Proration where applicable, then previous value brought forward when not

They found that using the 'previous value brought forward' method gave identical results to the 'proration method' on independent sample t-tests with probability levels differing by <0.001 between methods. Researchers thus followed the proration method advised in the manuals for the handling of missing data, only bringing baseline scores forward when proration could not be performed as described above.

4.18.3 Statistical analysis

In order to analyse the data in a way that would adequately address the study hypotheses, there were a number of steps undertaken to perform the various analyses summarised in Table 4.6. Data was analysed using the statistical computer programme Statistical Package for Social Sciences known as SPSS Version 14.1.

The statistical analysis was performed on an intention-to-treat basis (ITT) which has two main purposes: 1) It maintains treatment groups that are similar apart from random variation 2) It allows for non-compliance and deviations from policy by clinicians (Hollis and Campbell 1999). See section 4.18.2 for more details.

Step 1: The primary analysis performed to answer the main research questions and to address hypotheses one to four. The characteristics of the intervention and control groups were described at baseline. Summary statistics in the form of means and standard deviations were calculated for the primary and secondary outcomes, POMS, FACT-B and FACT-ES and WHO-5, at each time point, baseline, T1 (0 weeks), T2 (8 weeks) and follow up, T3 (12 weeks). In addition, the mean differences between groups were presented with 95% confidence intervals which showed the probability that these results could have occurred by chance.

Step 2. The secondary analysis sought to identify alternative explanations for the results other than that of the MBSR intervention. A series of regression analyses were used to identify baseline assessments which together with MBSR, were predictive of each primary and secondary outcome. This included variables such as age, stage of breast cancer, previous medical treatment and time between the finish of medical treatment and the commencement of the study. Mean differences between groups were presented with 95% confidence intervals. The best predictive model was identified using first univariate, then multivariate and finally stepwise analyses.

The independent variables were grouped in the following way:

1. age and socioeconomic status
2. breast cancer staging at all medical treatment variables
3. attendance of Breast Cancer Haven before and during study
4. time of randomisation to T1 (weeks -2 to 0)
5. stress of illness, stress of other life events

For each POMS, FACT and WHO-5 outcome at each time point a separate analysis was completed for each independent variable. Each of these analyses also included baseline measure for the outcome measure of the intervention group. They therefore identified variables with a significant effect adjusting from baseline and for group. Statistically significant variables from the univariate analysis were then included in a multivariate analysis which again included baseline assessment and group. Variables found to be statistically significant retain some predictive value after adjusting for other predictors. To complete the regression analysis, forward stepwise regression was then performed by taking the variables that were significant from the univariate and multivariate analysis and mixing them into appropriate sized groups. Forward stepwise regression is an automated procedure available in SPSS which selects and adds variables one at a time to the regression model. At each step the variable added is the strongest remaining predictor of outcome not already included in the model. The process stops when all statistically significant variables have been included. Overall the process identifies an optimal model in which all the variables contribute to the predictive value. Please see Section 4.18.5 for further details.

Step 3. A similar procedure was followed to identify intervention-specific variables predictive of outcome in the intervention group.

Table 4.6. Research questions, data used and statistical tests use to analyse data

Question needing answering	**Data used to answer questions**	**Type of data and analysis**	**Tests to use**	**Regression Analysis**
What are the effects of MBSR for women with stages 0 to III breast cancer on mood, disease related quality of life, including endocrine symptoms, and wellbeing?	POMS, FACT-B and FACT-ES and WHO-5 data at weeks 0, 8 and 12 between intervention and control groups	Nominal Between group	Mean, SD using independent sample t-tests at weeks 0, 8 and 12 with confidence intervals and significance levels	Univariate, multiple, and stepwise regression - outcome measures compared at 8 and 12 weeks using baseline measures as a covariate
What effect does participating in MBSR have on the perception of stressors relating to breast cancer?	Likert scale scores of perception of stress in relation to breast cancer at weeks 0, 8, 12.	Nominal Between group	Compare mean and SD using independent sample t-tests at weeks 0, 8 and 12 with confidence intervals and significance levels	Univariate, multiple, and stepwise regression with Likert scale scores at weeks 8, 12 using baseline measures as a covariate
What effect does participating in MBSR have on the perception of stressors relating to other life events?	Likert scale scores of perception of stress in relation to other life events at weeks 0, 8, 12	Nominal Between groups	Compare mean and SD using independent sample t-tests at weeks 0, 8 and 12 with confidence intervals and significance levels	Univariate, multiple, and stepwise regression with Likert scale scores at weeks 8, 12 using baseline measures as a covariate
Is there a dose-related effect from attending more MBSR classes?	0 to 24.5 hours of possible attendance for MBSR programme from intervention group attendance sheets	Nominal Within group	Compare pre and post mean, SD with intervention group data	Univariate, multiple, and stepwise regression with hours of class attendance as co-variate
Is there a dose-related effect from doing MBSR home practice during the 8-week programme?	Add up number of hours of formal home practice from intervention group home practice sheets	Nominal Within group	Compare pre and post mean, SD with intervention group data	Univariate, multiple, and stepwise regression with hours of home practice as co-variant

4.18.4 Handling of output from analysis

Analysis was checked from the SPSS output and any errors that were highlighted in the output were corrected in the syntax and the tests rerun. Paper copies of the output were stored in marked lever arch files so that the results could be transcribed into tables which form the results section of the thesis. This transcription was done by the clinician-researcher with the help of the research assistant to minimise errors and allow checks.

4.18.5 Linear regression

Regression analysis was used to identify variables predictive of each of the primary and secondary outcomes. These included univariate followed by multiple regression analyses. Forward stepwise regression was then used to identify the subset of statistically significant variables that together predict outcome (Altman 1991). SPSS syntax was written to automate this process. Outcomes were assessed at 8 to10 and 12 to14 weeks, in each case using baseline (weeks -2 to 0) measures as a covariate.

4.18.5.1 Univariate and multiple regression

Univariate and multiple regression analyses were performed with all scales and subscales at T2 (8 to 10 weeks) and T3 (12 to14 weeks) adjusted for baseline with the following the dependent variables:

1. POMS Total Mood Disturbance (Primary Outcome Measures)
2. POMS subscales: Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigour-Activity, Fatigue-Inertia, Confusion-Bewilderment
3. FACT-B Total Score, FACT-B Trial Outcome Index total score, FACT-ES Total Score, FACT-ES Trial Outcome Index total score
4. WHO-5 Wellbeing questionnaire

4.18.5.2 Stepwise regression

For each dependent variable the results found to be significant from the multiple regression analysis was put into the forward stepwise regression. To remain within the rule of thumb of 10:1 in the ratio of cases to variables (Halinski and Feldt 1970), three different mixes of independent variables were created. This process identified a few additional variables reaching statistical significance that were then added to the stepwise analysis.

4.19 Qualitative data analysis

Qualitative data collected through the study period needed analysis. There were three pragmatic reasons for analysing the qualitative data in addition to the qualitative (Rossman and Wilson 1985):

1. To enable confirmation and corroboration or results via triangulation
2. to elaborate or develop analysis, providing richness and detail
3. to offer new interpretations and fresh insight

Where appropriate, the qualitative data was used to add weight to the data gathered in the quantitative data. The quantitative data gave information about mood, specifically anxiety, depression, anger, vigour and confusion; quality of life specifically in the areas of physical, social/family, emotional and functional areas, breast related symptoms, endocrine symptoms and general wellbeing. Themes found in the qualitative data were used to support these findings. This allowed for a further level of analysis, providing detail and additional insights into the experience of participants in these areas specifically.

The qualitative data in this study, whilst not extensive, was considered fit for purpose in the provision of additional information to further understand participants' experience of the nature of mindfulness and doing an MBSR course. This information could not have been generated from the analysis of the quantitative data. To gather the qualitative data, a short proforma with open questions was given to those who completed the MBSR programme. For the purposes of data analysis for this thesis, only results from the intervention groups' short proforma were analysed as this data was collected within the time frame of the study, whereas that from the control group was after the study period had been completed.

A method of content analysis and constant comparison was used to analyse the qualitative data. Detail of the qualitative analysis and rationale can be found in Table 4.7. A set of analytic steps outlined by Miles and Huberman (1994) were followed. In this study, patterns and themes were noted, clustering took place where data was put into categories. A method of constant comparison was used to highlight the similarities and differences in the data. To make sure the comparisons were the right ones and make sure they made sense, the results of comparisons were then compared with existing knowledge to note any differences. The counting of items in categories followed to identify consistency of findings and their saliency. Through noting patterns, clustering, subsuming particulars into the general, discrete bits of information came together to build a chain of evidence (Miles and Huberman 1994). If present, any key negative cases were noted too.

Table 4.7. Detail of qualitative analysis and rationale

Steps taken in qualitative analysis	**Rationale**
Familiarisation and immersion in the data	To obtain the overview of presenting data
The noting of patterns and themes	To clarify units of data, patterns and themes were noted, but coding was not performed as there was insufficient data to warrant this.
Clustering and categorising of data	Starting to make sense of the data into grouping text containing common content and ideas.
Constant comparison to refine categories and ensure that original meaning is kept and information is captured accurately	Identifying data that fits into categories and that which does not, therefore fitting it into other categories. Presenting the negative cases contradicting data presented. This provides numerical information regarding the reliability of the data (Miles and Huberman 1994).
Counting of contents of categories	This can give weight to the evidence knowing how many participants made the same or similar comments in a category
Development of overall themes	These themes present the overall information found in the qualitative data

Relevant qualitative data results were then interspersed with quantitative data results to make sense of the data overall. Additional qualitative data results which were important, but did not fit serve as a further verification of the quantitative data, such as participants' experience of mindfulness, was discussed in its own themes.

4.20 Summary of methods

Methods for this study have been selected to answer the research questions as rigorously as possible. The study evaluated the effects of MBSR on mood quality of life including endocrine symptoms and wellbeing in women treated for stages 0 to III breast cancer who had attended Breast Cancer Haven in London. Philosophical underpinning, methods of designing and conducting the study, collecting and analysing the data have been specifically described and justified. This was a mixed methods study with a focus on a quantitative approach but with a pragmatic component. Qualitative data was also collected to gain additional data that could not be obtained from the quantitative questionnaires. Quantitative data was analysed using

both descriptive statistics and linear regression. Content analysis was used to analyse qualitative data.

Chapter 5. Results

5.1 Introduction

This chapter presents the results of the study. Accrual, attrition and the profile of the sample will first be described. This is followed by results from the questionnaires given to participants including descriptive and predictive statistics. Qualitative findings relevant to particular quantitative results will be presented together. Further quantitative results from the intervention group who participated in the MBSR intervention will be presented which gives details of the uptake of the mindfulness-based stress reduction programme (MBSR). Additional qualitative findings from the intervention group, important to understanding participants' experience of mindfulness and MBSR will also be presented, although not all themes were saturated. Intention-to-treat (ITT) analysis was applied to the analysis of all data except for the demographic data. All participants who underwent randomisation were analysed according to the groups to which they were originally allocated.

5.2 Study accrual

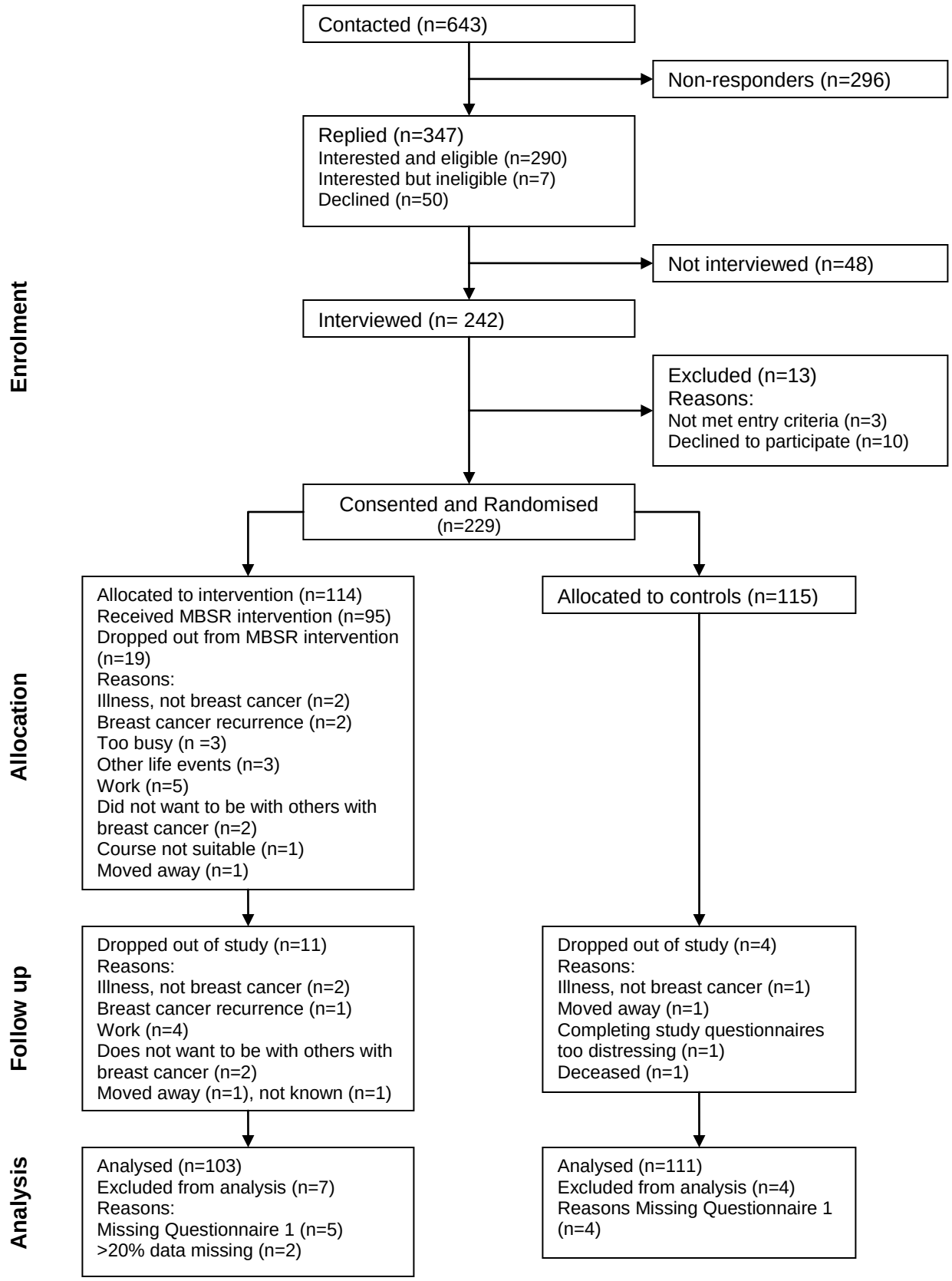
Recruitment took place between January 2005 and June 2006 and Figure 5.1 shows the precise numbers in the flow of participants through the study. Six hundred and forty-three women were identified from Haven Visitor notes as being potentially eligible for the study and were then contacted by letter with an accompanying leaflet explaining the study (See Appendices 11 and 12). There was a response rate of 347 (54%) to this initial contact. Of those who responded, 50 (14%) declined whilst 242 (70%) went on to be interviewed. Of those who responded but declined, work commitments and not being able to manage the class times were the main reasons given for not participating despite interest expressed in having an opportunity to learn ways to reduce stress. Of the seven Visitors who were ineligible, three Visitors had developed stage IV breast cancer, one was too old and two had too poor a command of English. Those with stage IV breast cancer were invited to take up further support from the Haven programme. Of those who were interviewed, travel, work and unsuitable timings of the MBSR programme were the main reasons for not participating.

The total number of participants recruited and randomised was 229, the number allocated to the intervention group was 114 and 115 were allocated to the control group. Of these, there were 103 completed data sets in the intervention group and 111 in the control group. A total of nineteen of the 114 participants in the intervention group could not complete the eight-week programme for a variety of reasons including the development of an illness other than breast cancer, breast cancer recurrence, work, not wanting to be with others with breast

cancer, being too busy, due to other life events, or had moved away. However, many of them agreed to complete questionnaires even if they did not complete the MBSR programme, which accounts for the differences in the figures above.

Dropouts from the study overall were 11 in the intervention group and four in the control group. Reasons for dropping out included other illness, breast cancer recurrence, work, not wanting to be with others with breast cancer, had moved away, travel/weather difficulties, completing study questionnaires was too distressing, or deceased after recruitment but before commencement of the study. Where appropriate these participants were offered additional support from the Haven Programme.

Figure 5.1. Flow of participants through the study



5.3 Questionnaire response rates

The numbers of participants who returned questionnaires is outlined in Table 5.1. Questionnaire response rates were high overall with 86.8% return in the intervention group and 94.5% in the control group. It is possible that those in the control group were more motivated to complete the questionnaires as they were awaiting the commencement of the MBSR intervention. Participants who did not return the baseline questionnaire were excluded from the study. Details of reasons for missing data can be found in Table 5.2. Work was given as the most common reason for not being able to return questionnaires.

Table 5.1. Questionnaire Response Rates

	Intervention Group (N=114) Returned (%)	Control Group (N=115) Returned (%)
T1	109 (95.6)	111 (96.5)
T2	97 (85.1)	109 (94.8)
T3	91 (79.8)	106 (92.2)
Overall (average)	297 (86.8)	326 (94.5)

T1= -2 to 0 weeks, T2= 8 to 10 weeks, T3= 12-14 weeks

Table 5.2. Reasons for missing questionnaire data

Reason	Intervention Group	Control Group
T1 (N =9)	(n=5)	(n=4)
Work	2	0
Does not want to be with others with breast cancer	2	0
Moved away	1	1
Deceased	0	1
Completing study questionnaires too distressing	0	1
Too busy	0	1
T2 (N=23)	(n=17)	(n=6)
Work	5	0
Does not want to be with others with breast cancer	2	0
Breast cancer recurrence	1	0
Illness, not breast cancer	0	1
Moved away	1	1
Deceased	0	1
Completing study questionnaires too distressing	0	1
Lost contact	1	0
Not known	1	1
Decided not to take part	0	1
T3 (N=32)	(n=23)	(n=9)
Work	5	2
Does not want to be with others with breast cancer	2	0
Breast cancer recurrence	2	0
Illness, not breast cancer	3	1
Moved away	1	1
Deceased	0	1
Completing study questionnaires too distressing	0	1
Lost contact	2	0
Not known	6	1
Decided not to take part	0	1
Too busy	1	1
Further surgery	1	0

T1= -2 to 0 weeks, T2= 8 to 10 weeks, T3= 12 to 14 weeks

5.4 Profile of the sample

In Tables 5.3 to 5.9, personal demographic and treatment details at baseline are presented. Following guidelines from the revised CONSORT statement which warns of the inappropriateness of significance tests on baseline differences, no such testing was performed on these measures (Altman et al 2001b).

5.4.1 Age and socioeconomic status

Details of the age and socioeconomic status of participants can be found in Table 5.3. The mean age (standard deviation (SD)) of the intervention group was 48.96 (9.26) and the control group was 50.09 (9.14). This is younger than the average age of people affected by breast cancer in the UK as 80% of breast cancers are diagnosed in women over the age of 50 years (Office of National Statistics 2007) but is typical of the average age of women with breast cancer coming to Breast Cancer Haven. Regarding employment and social class of participants, most participants fell into social class AB, 73.7% in the intervention group and 78.3% in the control group. Virtually all studies conducted internationally report that, where detailed, people with cancer who seek complementary therapies are better educated, of higher socio-economic status, and more likely to be female and also younger than those who do not (Molassiotis et al 2005, Downer et al 1994, Cassileth and Vickers 2005). It is a limitation of the current study that due to an oversight, socioeconomic data was not collected at baseline so was collected retrospectively from Haven Visitor notes. Standard tables for age related social grade and postcode from the 2001 census were used to help provide this information for those where data was missing numbers (n=22 for intervention group and n=19 for control group). In this case, participants were assigned the most prevalent social grade for the area in which they lived.

Table 5.3. Age and social grade

	Intervention Group (N=114)	Control Group (N=115)
Mean age in years (SD)	48.96 (9.26)	50.09 (9.14)
Social grade in frequency (%)		
AB: Higher and intermediate managerial/ administrative/ professional	84 (73.7)	90 (78.3)
C1: Supervisory clerical junior managerial/ administrative/ professional	20 (17.5)	16 (13.9)
C2: Skilled manual workers	2 (1.8)	2 (1.7)
D: Semiskilled and unskilled manual workers	6 (5.3)	5 (4.3)
E: On state benefit, unemployed, lowest grade workers	2 (1.6)	2 (1.7)
Total *N*	114	115

Stages of breast cancer

Most participants in the study had stage I or II breast cancer as shown in Table 5.4. In the intervention group, 29.8% or participants had stage I compared to 39.1% of controls. Stage II breast cancer accounted for 41.2% of the intervention group and 40.9% of controls.

Participants in the intervention group had a slightly higher proportion of stage III breast cancers with 19.3% compared to 14.8% of controls. Only 5.3% of the intervention group and 7% of controls had suffered a local recurrence of breast cancer. Due to the widespread use of mammography, the detection of earlier stage breast cancers e.g. stage 0, ductal carcinoma in situ (DCIS) has risen (Cancer Research UK 2008b).

Table 5.4. Stage of breast cancer diagnosis at recruitment

	Intervention Group (N=114)	Control Group (N=115)
Stage of breast cancer frequency (%)		
Stage 0	11 (9.6)	6 (5.2)
Stage I	34 (29.8)	45 (39.1)
Stage II	47 (41.2)	47 (40.9)
Stage III	22 (19.3)	17 (14.8)
Breast cancer recurrence frequency (%)		
Yes	6 (5.3)	8 (7.0)
No	108 (94.7)	107 (93.0)

5.4.2 Surgery for breast cancer prior to study

All but one participant in the study had undergone surgery for breast cancer (see Table 5.5), and in the nearly 40% of participants had undergone mastectomy compared to 60% who had breast conserving surgery. The single participant who did not have surgery made an informed choice not to have this treatment. Over 7% of the intervention group and 17% of the control group had needed a second operation following the initial wide local excision or partial mastectomy. Approximately 25% of all participants had undergone breast reconstruction and a few had undergone this more than once.

Table 5.5. Surgical treatment for breast cancer prior to study

	Intervention Group (N=114)	Control Group (N=115)
Surgery		
Yes (%)	113 (99.1)	115 (100)
No (%)	1 (0.9)	0
Wide local excision/partial mastectomy mean number of operations (SD)	0.75 (0.6)	0.93 (0.7)
none	38 (33.3)	28 (23.4)
once	67 (58.8)	67 (58.3)
twice	8 (7.0)	20 (17.4)
three times or more	1 (0.9)	0 (0)
Mastectomy		
mean number of operations (SD)	0.54 (0.6)	0.45 (0.6)
none	57 (50.0)	68 (59.1)
once	52 (45.6)	40 (34.4)
Twice	5 (4.4)	5 (4.4)
Breast Reconstruction (frequency)		
mean number of operations (SD)	0.36 (0.70)	0.30 (0.6)
none	83 (72.8)	87 (75.6)
once	24 (21.1)	22 (19.1)
twice	5 (4.4)	5 (4.4)
three times	1 (0.9)	1 (0.9)
four times	1 (0.9)	0 (0)

5.4.3 Chemotherapy and radiotherapy for breast cancer prior to study

Details of the chemotherapy and radiotherapy received by participants are found in Table 5.6. Just over half the participants had chemotherapy, 58.8% in the intervention group and 52.2% in the control group. Neoadjuvant chemotherapy (given prior to surgery) was received by 17.5% of the intervention group and 7% of controls. The mean number (SD) of neoadjuvant chemotherapy cycles received in the intervention group was 1.07 (2.44) compared to 0.39 (1.43) in controls. Adjuvant chemotherapy was received by 47.4% of intervention group participants compared to 48.7% of controls. The mean (SD) number of cycles was similar for both groups. The majority of participants had radiotherapy, 80.7% of the intervention group and 73% of controls.

Table 5.6. Chemotherapy and radiotherapy for breast cancer prior to study

	Intervention Group (N=114)	Control Group (N=115)
Chemotherapy		
Yes	67 (58.8)	60 (52.2)
No	47 (41.2)	55 (47.8)
Neoadjuvant chemotherapy		
Yes (%)	20 (17.5)	8 (7.0)
No (%)	94 (82.5)	107 (93.0)
Number of neoadjuvant cycles		
mean (SD)	1.07 (2.4)	0.39 (1.4)
range	0 to10	0 to 8
Adjuvant chemotherapy frequency (%)		
Yes	54 (47.4)	56 (48.7)
No	60 (52.6)	59 (51.3)
Number of adjuvant cycles		
mean (SD)	3.03 (3.5)	3.01 (3.3)
range	0 to12	0 to 8
Radiotherapy		
Yes	92 (80.7)	84 (73.0)
No	22 (19.3)	31 (27.0)

5.4.4 Ongoing drug treatment for breast cancer

Details of the ongoing drug treatments for breast cancer taken by participants are presented in Table 5.7. Nearly half of the participants were taking ongoing endocrine medication which lowered levels of oestrogen. The most common of these was Tamoxifen taken by 31.6% of the intervention group and 33.9% of controls and with a much smaller numbers taking Anastrozole (Arimidex®) in each group, 13.2% and 11.3% respectively. These figures were representative of the wider population of women with breast cancer treated hormonally within the first two years following hospital treatment at the time of the study.

5.4.5 Herceptin

Herceptin, the monoclonal antibody for women with HER2 positive breast cancer was being taken by less than 4% of participants. There are 15 to 25% of breast cancer patients who test positively for the protein HER2 who may benefit from taking Herceptin, but at the time of this study, 2005 to 2006, administration of Herceptin had only just begun and was not being given for women with early stage breast cancer (Cancer Research UK 2007).

Table 5.7. Endocrine treatment and Herceptin for breast cancer during the study period

	Intervention Group (N=114)	Control Group (N=115)
Endocrine treatment		
Yes (%)	56 (49.1)	54 (47.0)
No (%)	56 (49.1)	59 (51.3)
Total *N*	112	113
Missing	2	2
Type of endocrine treatment frequency (%)		
Anastrozole (Arimidex®)	15 (13.2)	13 (11.3)
Goserelin (Zoladex®)	0	2 (1.7)
Letrozole (Femara®)	3 (2.6)	0
Tamoxifen®	36 (31.6)	39 (33.9)
Toremifene (Fareston®)		
Type not stated	1 (0.9)	0
Not applicable	57 (50.0)	59 (51.3)
Second type of endocrine treatment		
Anastrozole (Arimidex®)	0	1 (0.9)
Goserelin (Zoladex®)	5 (4.4)	2 (1.7)
Megestrol acetate (Megace®)	0	0
Tamoxifen®	0	0
Not applicable	107 (93.9)	110 (95.7)
Herceptin		
Yes (%)	4 (3.5)	3 (2.6)
No (%)	108 (94.7)	111 (96.5)
Missing	2 (1.8)	1 (0.9)

5.4.6 Attendance of the Haven Programme

The number of hours that participants attended the Haven Programme before and during the study period has been outlined in Table 5.8. The mean (SD) number of hours of those attending the Haven Programme prior to entering the study and completing questionnaire one was just over 30 hours in both groups. During the period of the main body of the study, those in the intervention group who were already attending the centre weekly to do the MBSR programme, attended an additional mean (SD) of 0.97 (1.48) hours of Haven therapy time compared to 0.68 (1.4) hours for controls during the same period. This amounts to a total of 58 minutes in the intervention group and 40 minutes in the control group between T1 (week 0) and T2 (week 8). Coming to the Haven for MBSR each week may have alerted intervention group participants to other events happening at the Haven that they could also attend which may be why this figure is greater.

Table 5.8. Haven Programme attended hours: means (SD)

	Intervention Group (N=114)	Control Group (N=115)
Pre questionnaire 1	30.09 (17.0)	31.48 (13.9)
Between questionnaire 1 and questionnaire 2	0.97 (2.3)	0.68 (1.4)
Between questionnaire 2 and questionnaire 3	0.59 (1.5)	0.32 (1.3)

The mean period of time following the completion of surgery, chemotherapy and radiotherapy and randomisation for the study was just over nine months for both groups. The time between randomisation and commencement of the study as denoted by participants receiving questionnaire one was under two months for both intervention and control groups. See Table 5.9 for these results.

Table 5.9. The period of time before and after randomisation: means (SD)

	Intervention Group (N=114)	Control Group (N=115)
Time between breast cancer treatment finish and date of randomization in months	9.27 (5.6)	9.50 (5.9)
Time between randomization and date of Questionnaire 1 in months	1.79 (1.3)	1.86 (1.3)

As can be seen from the tables above, the intervention and control groups were comparable at baseline with minor differences.

5.4.7 Summary

To summarise, the intervention and control groups were comparable at baseline with respect to age, socioeconomic status, stage of breast cancer, medical treatment, participation in the Haven programme and time between finishing medical treatment and entering the study. Any differences were of no practical significance.

5.5 Results of the effectiveness of the intervention

The quantitative and qualitative results for each hypothesis will now be presented. Whilst not specifically collected for the purpose of triangulation, qualitative data which was found to support the quantitative findings are presented alongside those findings below. Where the qualitative data is presented, any key negative cases will be mentioned in the relevant parts of the results, but the number of these is small.

Research hypothesis 1: Mood state

Hypothesis 1 is shown in Textbox 5.1. Mood state is the main outcome for the study.

Textbox 5.1: Hypothesis 1

> As a consequence of being exposed to MBSR, there will be an improvement in mood state of women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.
>
> Mood state will be measured using Profile of Mood States (POMS):
>
> POMS: Total Mood Disturbance
>
> POMS Subscales: Tension-Anxiety
> Depression-Dejection
> Anger-Hostility
> Vigour-Activity
> Fatigue-Inertia
> Confusion-Bewilderment

5.5.1 The main outcome for the study

Mood state

Mood state was evaluated to see whether MBSR had any effect on this. Independent sample t-tests were used to compare means. Mood state was measured by using the Profile of Mood States (POMS), the primary outcome measure, which when used its entirety provides a measure for Total Mood Disturbance (TMD) as well as the information from its subscales for Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigour-Activity, Fatigue-Inertia and Confusion-Bewilderment. Using SPSS, scores were plotted and a graphical representation was created to check and validate that results were normally distributed. Results for all these measures at T1, T2 and T3 are presented below in Table 5.10 and Chart 5.1. There were no

significant differences between the mean scores of the intervention and control groups at baseline, T1. Lower scores indicate better mood state in all POMS scales and subscales.

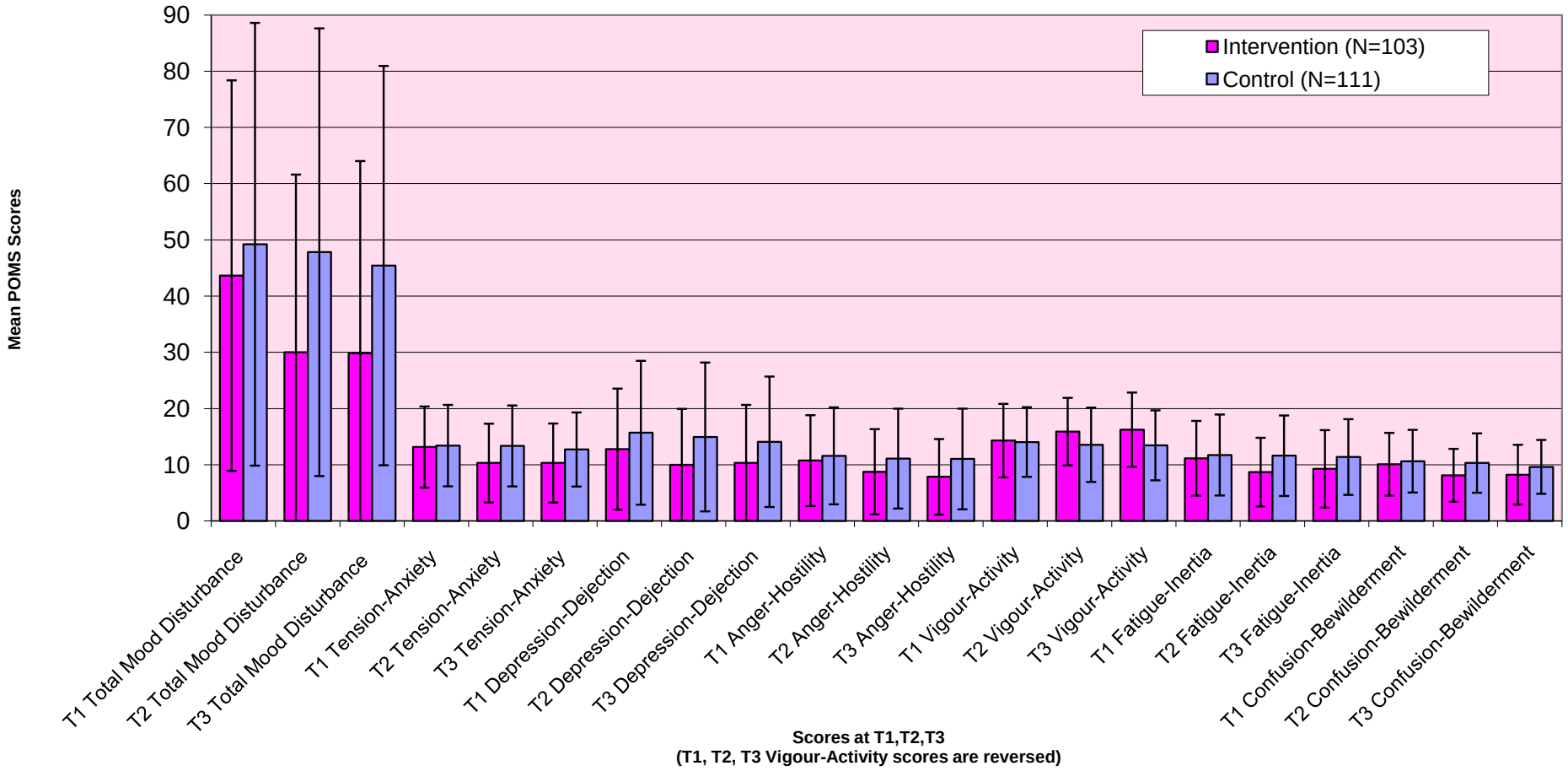
Table 5.10. Mean and standard deviation (SD) scores for Profile of Mood States (POMS) and subscales plus statistically significance of differences between groups assessed by independent sample t-tests

Outcome measure mean (SD)	Intervention (N=103)	Control (N=111)	Mean difference and p value	CI (95%) for difference
T1 Total Mood Disturbance	43.65 (34.73)	49.23 (39.37) *N*=110	-5.58	
T2 Total Mood Disturbance	30.02 (31.60)	47.81 (39.81)	-17.79***	-27.44, -8.14
T3 Total Mood Disturbance	29.83 (34.19)	45.43 (35.51)	-15.60***	-25.01, -6.20
T1 Tension-Anxiety	13.16 (7.21)	13.42 (7.24)	-0.26	
T2 Tension-Anxiety	10.32 (7.0)	13.36 (7.20)	-3.04**	-4.95, -1.18
T3 Tension-Anxiety	10.33 (7.02)	12.73 (6.59)	-2.40**	-4.24, -5.66
T1 Depression-Dejection	12.79 (10.76)	15.70 (12.79)	-2.91	
T2 Depression-Dejection	10.0 (9.95)	14.96 (13.23)	-4.96**	-8.11, -1.83
T3 Depression-Dejection	10.34 (10.32)	14.10 (11.60)	-3.76**	-6.72, -0.80
T1 Anger-Hostility	10.75 (8.08)	11.60 (8.62)	-0.85	
T2 Anger-Hostility	8.78 (7.57)	11.11 (8.88)	-2.33*	-4.57, -0.10
T3 Anger-Hostility	7.87 (6.72)	11.04 (8.95)	-3.17**	-5.29, -1.04
T1 Vigour-Activity	-14.31 (6.53)	-14.06 (6.19)	0.25	
T2 Vigour-Activity	-15.91 (6.0)	-13.57 (6.61)	-2.34**	-4.05, -0.64
T3 Vigour-Activity	-16.23 (6.63)	-13.47 (6.22)	-2.76**	-4.50, -1.03
T1 Fatigue-Inertia	11.17 (6.64)	11.75 (7.20)	-0.58	
T2 Fatigue-Inertia	8.71 (6.10)	11.62 (7.16)	-2.91**	-4.71, -1.11
T3 Fatigue-Inertia	9.27 (6.90)	11.39 (6.73)	-2.12*	-3.95, -0.28
T1 Confusion-Bewilderment	10.11 (5.58)	10.65 (5.57) *N*=110	-0.54	
T2 Confusion-Bewilderment	8.13 (4.71)	10.32 (5.28)	-2.19**	-3.54, -0.87
T3 Confusion-Bewilderment	8.24 (5.32)	9.64 (4.79)	-1.4*	-2.76, -0.40

*p<0.05, **p<0.01, *** p<0.001

T1 = weeks -2 to 0, T2 = weeks 8 to 10, T3 = weeks 12 to 14

Chart 5.1. Profile of Mood States (POMS) and subscales mean scores and standard deviations



5.5.1.1 Overall mood state

Overall mood state was measured using the POMS Total Mood Disturbance (TMD). The possible range of scores for this measure is from -32 to +200. The ranges of scores for POMS TMD are presented in Table 5.11, these are similar for both groups.

Table 5.11. The range of POMS Total Mood Disturbance scores for intervention and control group

	Intervention group score range	Control group score range
T1	-22 to 145	-20 to 139
T2	-22 to 160	-18 to 160
T3	-20 to 182	-20 to 182

T1= weeks -2 to 0, T2= weeks 8 to 10, T3 = weeks 12 to 14

From Table 5.10, at baseline, T1 (weeks -2 to 0), means scores (SD) were 43.65 (34.73) for the intervention group and 49.23 (39.37) for controls. There were no significant differences between the two groups.

There were statistically significant improvements in mood state as measured by POMS Total Mood Disturbance (TMD) in the intervention group at T2 (weeks 8 to 10), post intervention, and these persisted at T3 (weeks 10 to 12), follow-up, compared to controls showing that participating in MBSR had a significant effect on improving overall mood state. Mean scores and standard deviations (SD) measured at T2, significant improvements were found in the intervention group 30.02 (31.60) compared to controls 47.81 (39.81) ($p<0.001$), at T3, 29.83 (34.19) for the intervention group and 45.43 (35.51) for controls, ($p<0.001$).

5.5.1.2 POMS Tension-Anxiety subscale

The results (see Table 5.10) showed significantly less tension-anxiety in the intervention group compared to controls at both T2 ($p<0.01$), and persisting at T3 ($p<0.01$), post MBSR intervention, showing that both tension and anxiety were reduced following participation in MBSR and that this effect continued for four weeks afterwards.

There was evidence from the qualitative data supporting these results:

> *'it has given me a number of tools to deal with stress and tension and also helped me trust my inner voice more. As a result I am much more "with me" and feel a bit more confident'*

> *'anxiety level dropped slowly'*

'being aware of anxious thoughts and being able to let go of them'

'I feel more capable (mentally) to deal with fears and anxieties'

'More aware now of anxious thoughts and their effects on the body. Aware of when I am reacting to thoughts in a stressed or anxious manner'

5.5.1.3 POMS Depression-Dejection subscale

Results were found to be significantly better in the intervention group compared to controls at T2 post MBSR, ($p<0.01$), and at T3, follow-up, ($p<0.01$), showing that depression and dejection were reduced following participation in MBSR and that this lasted for a further four weeks.

Quotes from the qualitative data that support these finding included:

'It (being mindful) has given me a very finely and acutely tuned awareness of how behavioural patterns are affecting my moods and causing me to feel low/depressed. I no longer feel pressured to make drastic changes to my life that will not actually change the core/root cause.'

'I can face what may be a nasty future with more confidence that I will be able to cope'

'It has given me hope that I will be able to have a normal life and enjoy the ordinary things as well as becoming a bit more adventurous'

One participant did not find MBSR helped with feelings of desperation:

'I enjoyed the course but it didn't help with the things I hoped it would, i.e. insomnia, fatigue, despair'

This participant had spoken to the clinician-researcher in the middle of the eight-week MBSR programme about feeling low and it was agreed that she could continue to come to the classes for the social support but not do the home practice as she was struggling with that. She was also under the care of her GP.

5.5.1.4 POMS Anger-Hostility subscale

Results for anger-hostility were found to be significantly better in the intervention group compared to controls at T2, ($p<0.05$) post MBSR intervention, and persisting at T3, follow-up,

($p<0.01$), showing that the self perception of anger and hostility were reduced following participation in MBSR and that was sustained in four week follow up period.

Comments from participants support these results and show how mindfulness helped with anger:

> *'If I am getting angry or annoyed about something, I try and concentrate on my breathing for a while and it usually calms me down.'*

> *'not getting angry so quickly, letting go of things I cannot change'*

One participant found that she noticed frustration as a result of doing mindfulness practice:

> *'felt frustrated and beat myself up for not reaching the 'plane' others seemed to'*

5.5.1.5 POMS Vigour-Activity subscale

There was a significant improvement in levels of vigour and activity following the intervention group's participation in MSBR compared to controls measured using the POMS Vigour-Activity subscale. This was found at T2, ($p<0.01$), and persisting at T3, ($p<0.01$).

Quotes from the qualitative data that shows the positive impact of practising mindfulness supports this:

> *'Self-esteem restored, humour restored, more energy, new zest for life'*

> *'far more energy than before the course began, a greater sense of wellbeing – although achieving more by not rushing about'*

5.5.1.6 Fatigue-Inertia

Fatigue and inertia improved significantly in the intervention group at T2, immediately post MBSR, ($p<0.01$) and again at T3, follow-up, ($p<0.05$) compared to controls.

Findings in the qualitative data supported this:

> *'I have found the practices at times energising and at times relaxing, but always beneficial. My sleeping has benefited and the exercises are helping to loosen my body'*

5.5.1.7 POMS Confusion-Bewilderment subscale

The intervention group showed significant improvements in confusion and bewilderment at T2, following MBSR, ($p<0.01$) and persisting at follow up compared to controls, ($p<0.05$).

There was evidence of reductions in confusion and bewilderment from the qualitative data:

> *'The most positive effect has been the ability to stand back and view situations / thoughts / events in their true context and being more generally aware, my life has a greater quality, is more enhanced'*

5.5.1.8 Links between results for overall mood state and qualitative data

This improvement in general mood state experienced from participation in MBSR and practising mindfulness was supported by some of the qualitative data. One of the key themes that emerged was **'**being calmer, centred, at peace, connected and more confident'**.** There were 30/92 (32.6%) participants who commented on this. This supports the quantitative findings improvements in overall mood state as well as the subscales. Participants perceived themselves to be calmer and were also perceived by others to be so. These improvements were perceived to be both in mind and body.

> *'people are commenting about how I seem calmer even though they don't know I have been on the course…'*

> *'a means of producing calmness, serenity from stress and panic attacks'*

Being more centred was also mentioned by participants

> *'I feel more centred, watch less TV and drink less'*

Achieving some peace in both mind and body was expressed from the practice of mindfulness

> *'I feel both physical and mental peace. I am now a lot calmer in everyday life'*

> *'Achieving peace in my mind to deal with life'*

> *'The most positive thing I have got is feeling more inner calm and at peace with myself'*

'I feel more at peace and at home with myself and my body than I have in a very long time.'

'Regular meditation brings peace and energy'

An increased sense of confidence enabled participants to be more empowered and to act in their lives in ways that they may not have done previously.

The opportunity to change

'I am much more confident and self-assured than I was in the beginning. With this confidence I have the courage of my convictions to change certain aspects of my life which I wouldn't have done before – in my job, I'm very much aware of what is good for me (mentally and physically) and will actively change things'

It is not possible to know the link between the causes of mood disturbance from the qualitative data presented here, but improvements in anxiety, depression, anger, vigour, fatigue, confusion could all have contributed to these experiences reported above.

5.5.2 Clinical significance for POMS

Following communication with the office that administers the POMS tool, (Brown 2008, personal communication), there are no established methods of calculating levels of clinical significance for POMS so this calculation could not be undertaken in this study.

Research hypothesis 2: Quality of life including endocrine symptoms

Hypothesis 2 is shown in Textbox 5.2

Textbox 5.2: Research Hypothesis 2

As a consequence of being exposed to MBSR, there will be an improvement in quality of life, including endocrine symptoms, for women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks

Quality of Life

Breast specific quality of life

FACT-B

Subscales: Physical wellbeing
Social and family wellbeing
Emotional wellbeing
Functional wellbeing
Breast-specific subscale

FACT-B TOI

Subscales: Physical wellbeing
Functional wellbeing
Breast-specific subscale

Endocrine specific quality of life

FACT-ES

Subscales: Physical wellbeing
Social and family wellbeing
Emotional wellbeing
Functional wellbeing
Endocrine-specific subscale

FACT-ES TOI

Subscales: Physical wellbeing
Functional wellbeing
Endocrine-specific subscale

Secondary outcomes

5.5.3 Quality of life

Functional Assessment of Cancer Therapy –Breast and –Endocrine

To see how quality of life was impacted by participation in MBSR, participants completed quality of life measures relating to breast cancer. The measures included the breast specific quality of life scale, Functional Assessment of Cancer Therapy –Breast (FACT-B). Additional quality of life measures including the measurement of endocrine symptoms were included as nearly 50% of participants were taking hormonally-related medications or may have been experiencing menopausal symptoms induced by chemotherapy. Functional Assessment of Cancer Therapy –Endocrine (FACT-ES) scale was used to measure endocrine symptoms. Results for this quality of life data can be found in Table 5.12 and Chart 5.2. Higher numbers indicate better scores on all FACT scales.

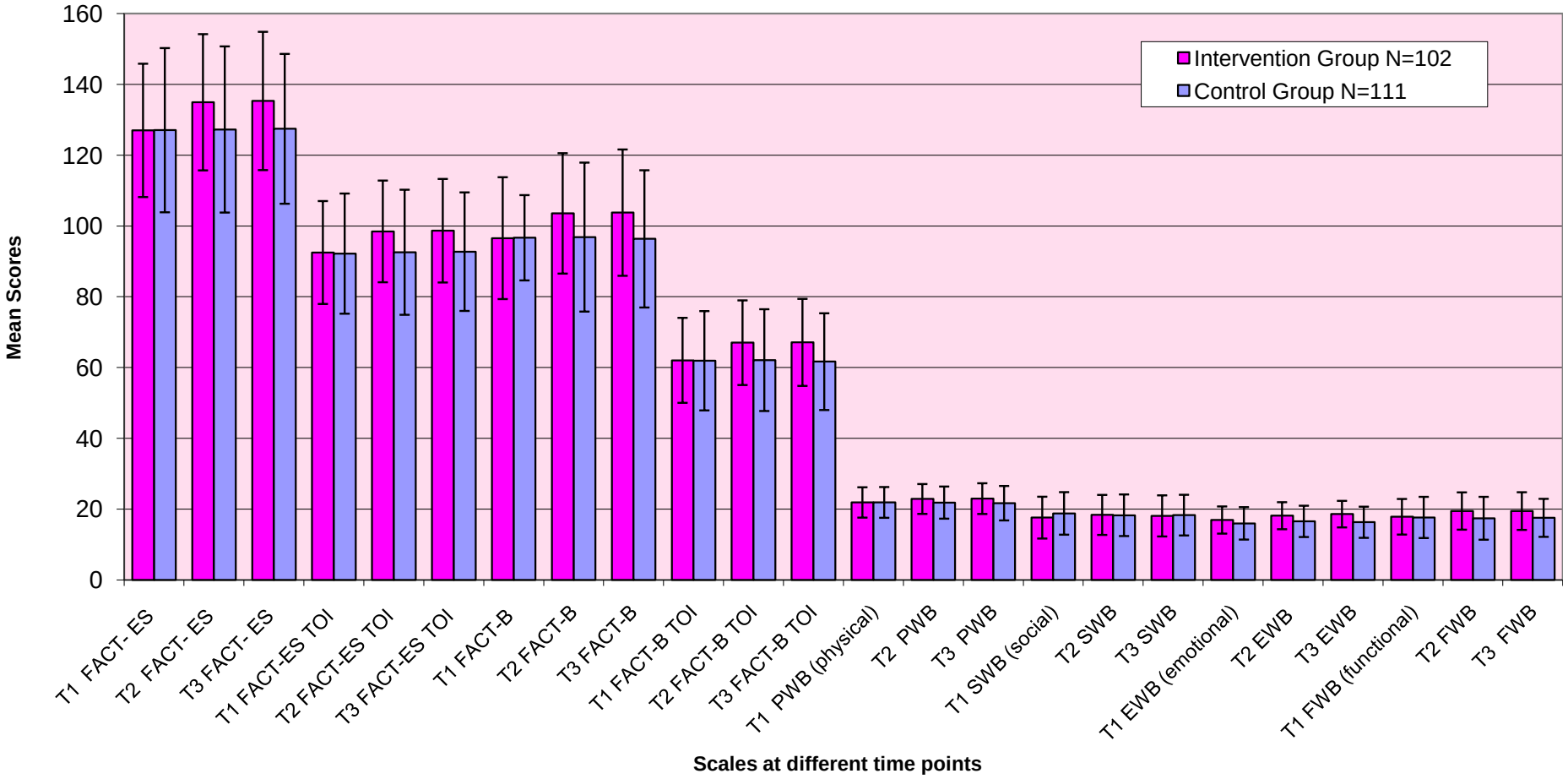
Table 5.12. Mean and standard deviation scores for FACT-B and FACT-ES and subscales plus statistical significance of differences between groups assessed by independent sample t-tests.

FACT scores mean (SD)	Intervention Group (N=102)	Control Group (N=111)	Mean difference and p value	CI (95%) for difference
FACT-Endocrine Symptoms (FACT-ES)				
T1 FACT- ES	127.02 (18.84)	127.08 (23.20)	0.06	
T2 FACT- ES	134.97 (19.25)	127.28 (23.48) N=108	7.69**	1.83, 13.55
T3 FACT- ES	135.34 (19.54)	127.46 (21.17) N=110	7.88**	2.33, 13.44
FACT-Endocrine Symptoms (FACT-ES) Trial Outcome Index (TOI)				
T1 FACT-ES TOI	92.51 (14.54)	92.20 (16.98)	0.31	
T2 FACT-ES TOI	98.47 (14.37)	92.58 (17.67) N=110	5.89**	1.52, 10.28
T3 FACT-ES TOI	98.67 (14.63)	92.75 (16.75) N=107	5.92**	1.65, 10.19
FACT Breast Specific (FACT-B)				
T1 FACT-B	96.57 (17.22)	96.68 (12.05)	-0.11	
T2 FACT-B	103.56 (17.01) N=101	96.87 (21.05) N=107	6.69*	1.33, 12.05
T3 FACT-B	103.78 (17.85) N=101	96.36 (19.39) N=107	7.42**	2.32, 12.52
FACT Breast Specific (FACT-B) Trial Outcome Index (TOI)				
T1 FACT-B TOI	62.04 (12.01)	61.92 (14.03)	0.12	
T2 FACT-B TOI	67.02 (11.96) N=101	62.10 (14.38) N=109	4.92**	1.31, 8.54
T3 FACT-B TOI	67.11 (12.30) N=101	61.67 (13.67) N=109	5.44**	1.89, 8.98
FACT physical wellbeing subscale (PWB)				
T1 PWB (physical)	21.88 (4.29)	21.89 (4.35)	-0.01	
T2 PWB	22.86 (4.22)	21.84 (4.54)	1.02	-0.16, 2.21
T3 PWB	22.96 (4.34)	21.67 (4.87)	1.29*	0.05, 2.54
FACT social wellbeing subscale (SWB)				
T1 SWB (social)	17.59 (5.91)	18.78 (6.01)	-1.19	-2.81, 0.43
T2 SWB	18.36 (5.65)	18.26 (5.88) N=109	0.1	-1.46, 1.67
T3 SWB	18.08 (5.81)	18.30 (5.75) N=109	-0.22	-1.78, 1.35
FACT emotional wellbeing subscale (EWB)				
T1 EWB (emotional)	16.91 (3.84)	15.97 (4.58)	0.94.	
T2 EWB	18.13 (3.82)	16.53 (4.42) N=110	1.6**	0.48, 2.73
T3 EWB	18.58 (3.75)	16.28 (4.40) N=110	2.3***	1.19, 3.41
FACT functional wellbeing subscale (FWB)				
T1 FWB (functional)	17.83 (5.03)	17.65 (5.82)	0.18	
T2 FWB	19.46 (5.27)	17.41 (6.06) N=110	2.05**	0.50, 3.59
T3 FWB	19.45 (5.32)	17.53 (5.37) N=110	1.92**	0.47, 3.37

p<0.05, **p<0.01, *** p<0.001

T1 = weeks -2 to 0, T2 = weeks 8 to 10, T3 = weeks 12 to 14

Chart 5.2. FACT-B and FACT-ES and subscales mean scores and standard deviations



5.5.3.1Breast-specific quality of life

Breast specific quality of life as measured by FACT-B gives an overall measure of quality of life including subscale measurements relating to physical, social, emotional, functional wellbeing and symptoms specifically related to breast cancer. Results from FACT-B showed statistically significant improvements in mean scores and SD for the intervention group at T2, ($p<0.05$), and persisting at T3, ($p<0.01$), compared to controls, showing a reduction of symptoms specifically related to breast cancer following MBSR.

5.5.3.2 Physical and functional wellbeing specific to breast cancer

Breast cancer specific symptoms, including physical and functional wellbeing of participants were measured by the FACT-B Trial Outcome Index (TOI), the sum of physical and functional wellbeing and the breast specific subscale. At T2, mean scores for FACT-B TOI improved statistically significantly, ($p< 0.01$) persisting at T3, ($p<0.01$).

5.5.3.3 Endocrine symptoms

The impact of doing MBSR and practising mindfulness on endocrine symptoms including menopausal symptoms can be seen from the FACT-ES. These scores look at the combination of physical, social, emotional, functional and endocrine-specific symptoms. Statistically significant improvements were found in mean scores of the intervention group compared to controls at T2, ($p < 0.01$), persisting at T3 ($p < 0.01$).

This indicates that participation in MBSR reduced endocrine symptoms and is supported by the qualitative data:

> *'Sometimes I can relieve pain or hot flushes and change my mood by taking awareness to bits of my body'*

> *'Hot flush reaction – using calming methods to help avoid stress so I don't get so many hot flushes resulting'*

5.5.3.4 Physical and functional wellbeing specific to endocrine symptoms

Endocrine system specific symptoms, physical and functional wellbeing of participants were measured by the FACT-ES Trial Outcome Index (TOI), the sum of physical and functional wellbeing and the endocrine specific subscale. At T2, mean scores for FACT-ES TOI improved statistically significantly, ($p<0.01$) persisting at T3, ($p< 0.01$) showing a reduction on the physical, functional aspects of endocrine related symptoms.

5.5.3.5 The wellbeing of participants

The specific elements of the wellbeing of participants was measured using the four main subscales from the FACT tool evaluating physical, social and family, emotional an functional wellbeing. There were improvements seen specifically in emotional and functional aspects of wellbeing following participation in MBSR. Details of these findings can be found below.

5.5.3.6 Physical wellbeing

Physical wellbeing was measured by the physical wellbeing (PWB) subscale on the FACT. Participation in MBSR did not show statistically significant improvements in physical wellbeing of the intervention group compared to controls at T2, this was only found at T3, ($p < 0.05$). Whilst there were no statistically significant differences between groups post intervention on this subscale alone, comments by participants in the qualitative data found that a number experienced physical and mental symptoms which were helped by mindfulness including hot flushes, pain and insomnia. Mindfulness was found to help cope with, face and accept pain and these comments can also be linked to improvements in the significant improvements on the vigour subscale of the POMS:

> '*Mindful breathing has helped enormously to cure my insomnia'*

> *'It far exceeded my expectations. I have noticed changes on both a physical and mental level. The physical changes (improved posture, body tone and energy) were a big surprise. I will take a lot from this course'.*

One participant who suffered from continuous pain from peripheral neuropathy following chemotherapy said:

> *'I at first wondered if the program was for me. After the first session, I was in tears, but Caroline convinced me to continue with the body scan and I did. It has helped greatly with my pain. The other practices have helped with my daily stress and remaining calm.'*

Mindfulness meditation and mindful stretches were found to give energy, gain flexibility, relax the mind:

> *'Regular mediation brings peace and energy'*

> *'… and the exercises are helping to loosen my body'*

'Lying down is restful and stretching makes me feel free and strong'

Four of the participants found difficulty with the stretching exercises due to their lack of flexibility:

'The stretching exercises were difficult for me'

'Some of the exercises (were difficult) due to osteoarthrtitis'

It seems that some physical benefits have been noted by participants, but these were only reflected in the quantitative data at follow-up.

5.5.3.7 Social and family wellbeing

Social and family wellbeing was measured by the FACT social/family wellbeing subscale (SWB). There were no statistically significant differences between groups for social/family wellbeing at any of the time points, indicating that MBSR did not make a difference to levels of social wellbeing.

Comments from the qualitative data found evidence of a difference in these areas for some participants. There were 16/92 (17.4%) participants who identified better and more effective communication and family and social relationships to be a consequence of practising mindfulness:

'I have noticed I am much more 'present' with my children'

'In moments of tension in relationships, mindfulness has slowed my reactions and given me an opportunity to view things in a more considered way'

'I have found it easier to deal with the crises involving family life'

Creating time and space for practising mindfulness also provided tools for participants to manage family or other social situations better:

'It has enabled me to create some space and time for myself away from my children (pre-school and inevitably demanding) and I feel I cope better with them as a result and they in turn respond better to me.'

'It has opened up a sense of space both physical and in time for me. And I feel I've got more space because the practice has given me a way of taking time for myself without pushing others in my life away. And the non-judgemental 'permission' concept has made space from the critical part of my mind which has often overwhelmed me in the past'

5.5.3.8 Emotional Wellbeing

Participation in MBSR did make a statistically significant difference to emotional wellbeing measured by the FACT emotional wellbeing subscale (EWB) compared to controls at T2, ($p<0.01$), and persisting at T3 ($p<0.001$), suggesting a sustained emotional benefit following the completion of MBSR during the follow up period.

One of the themes of the qualitative data 'coping with stress, anxiety and panic' supported this improvement in emotional wellbeing indicating that mindfulness led to a greater sense of being in control as well having more emotional control:

'being mindful when I feel things are getting out of control'

'a greater feeling of wellbeing, more relaxed, and better able to control negative feelings'

5.5.3.9 Functional Wellbeing

The ability of participants to function well in life including work and enjoyment of life was statistically significantly improved by participation in MBSR as assessed by the FACT functional wellbeing (FWB) subscale compared to controls T2, ($p< 0.01$), and persisting at T3 ($p<0.01$).

These improvements in function in life were supported by comments from participants from the qualitative data who identified improved coping with stress, reduced anxiety in work and everyday life. Through mindfulness, participants reported an increased awareness of stress and its impact and were experiencing less stress with day to day events and activities. They also found mindfulness useful to cope with stress and anxiety in the work place and in other aspects of daily living as shown by quotes and comments below:

'Dealing with the stress of work and trying to avoid constant planning ahead'

Many found that they were more aware of work related stress and were coping with it better:

'Coping with work stress - awareness of it and ability to deal with it'.

Improved regulation of workload was also noticed as a result of mindfulness:

'pacing myself better'

'coming to the realisation you can only do so much'

'focussing on the task or time of the moment – not juggling tasks at work '

There were also challenges recognised in applying mindfulness to the workplace:

'applying it (mindfulness) in situations where perhaps needed most, like work!'

The challenge of applying mindfulness in everyday situations was observed:

'I'm back at work now and my job is getting more complicated just as I am trying to stay "chilled out". I've decided to see this as an opportunity for mindfulness rather than an obstacle to it'

Being more mindful in daily activities was an important element of reducing the stress of daily living. Many participants expressed increased mindfulness around food and eating:

'eating and drinking mindfully has made me eat less and eat better'

'cooking mindfully seems to make a better meal'

Commuting or travelling was helped by being more mindful:

'Coping with stressful situations - being calm and accepting difficult travel experiences…'

'less tense when I am driving'

'noticing lots more during my day - on my journey to work; while I'm on the tube'

'The mindfulness has become a way of life'

As can be seen from these examples, mindfulness can be useful with coping with the potentially stressful events around commuting, work and day to day activities.

5.5.4 Clinically significant changes in quality of life

Clinical significance of results from the FACT scales was measured by the Minimally Important Difference (MID) scores. These are the smallest score difference on health related quality of life questionnaire that is clinically significant and therefore likely to be meaningful to both patients and clinicians (Yost and Eton 2005). Clinically significant differences between intervention and control groups were achieved for FACT-B, FACT-B TOI but not for the breast specific subscale alone at T2 and T3 (see Table 5.13).

Table 5.13. Minimally Important Differences scores (MIDs) for FACT-B, FACT-B TOI and breast cancer subscale compared between intervention and controls at T1, T2, T3.

Scales	MIDs score	Reference: Clinically significant range for MIDs
T2 FACT-B	7*	7-8
T3 FACT-B	8*	
T2 FACT-B TOI	5*	5-6
T3 FACT-B TOI	5*	
T2 Breast subscale	0	2-3
T3 Breast subscale	0	

* denotes significant values

T1= weeks -2 to 0, T2= weeks 8 to 10, T3 = weeks 12 to 14

5.5.5 Overall wellbeing

The overall wellbeing of participants measured using the WHO- 5 item Wellbeing Questionnaire.

Research hypothesis 3: Overall wellbeing

Hypothesis 3 is shown in Textbox 5.3

Textbox 5.3: Research Hypothesis 3

> As a consequence of being exposed to MBSR, there will be an improvement in overall wellbeing of women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks
>
> Overall wellbeing is measured by:
>
> WHO 5-item wellbeing questionnaire

5.5.5.1 WHO-5 item wellbeing questionnaire

Results for overall wellbeing as measured by the WHO-5 wellbeing questionnaire can be found in Table 5.14 and chart 5.3. Higher numbers indicate better scores on the WHO-5 scale.

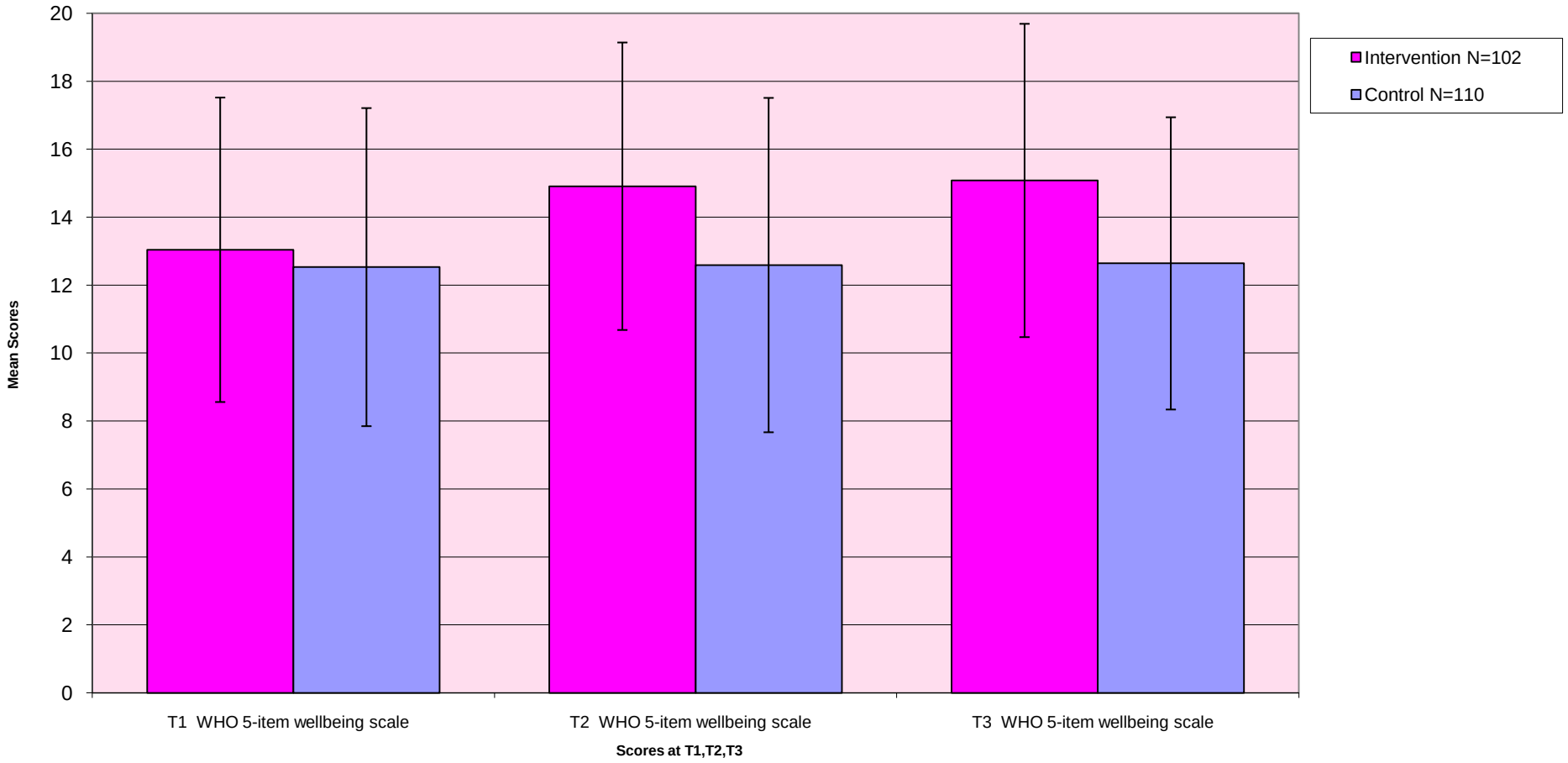
Table 5.14. Mean and standard deviation and equivalent percentage scores for WHO 5-item Wellbeing questionnaire (WHO-5)

WHO 5-item wellbeing questionnaire mean (SD) % score	Intervention (N=102)	Control (N=110)	Mean difference and p value	CI (95%) for difference
T1 WHO-5	13.04 (4.48) 52.2%	12.53 (4.68) 50.1%	0.09	
T2 WHO-5	14.91 (4.23) 59.6%	12.59 (4.92) 50.4%	2.32***	1.06, 3.56
T3 WHO-5	15.08 (4.61) 60.3%	12.64 (4.30) 50.6%	2.44***	1.23, 3.64

p<0.05, **p<0.01, *** p<0.001

T1 = weeks -2 to 0, T2 = weeks 8 to 10, T3 = weeks 12 to 14

Chart 5.3 WHO-5 Wellbeing questionnaire mean scores and standard deviations



The intervention group showed statistically significant improvements in the mean wellbeing scores following MBSR at T2, ($p<0.001$), and persisting at T3, ($p<0.001$), compared to controls. It is worth noting that mean scores for all time points in both groups were twelve or above (possible range of scores is from 0 to 25).

The qualitative data enabled elaboration on this improvement in overall wellbeing with participants finding greater connection with self and a chance to get to know oneself again was another outcome of practising mindfulness:

'helps me connect to myself in a profound way'

'that I was given this opportunity to rediscover myself'

Hope for the future was also found from practising mindfulness:

'It's given me hope that I can do something to keep stress at bay in the future'

'It has given me hope that I will be able to have a normal life and enjoy ordinary things as well as becoming a bit more adventurous'

'In a way, mindfulness changes, has the power to change everything!'

Participants mention feeling more contented and happier with life, also being happier with silence, being with themselves:

'Living a better life and easier to live with. Happier!'

Participants found that being more aware led to a greater appreciation of life's beauty and its quality:

'simply noticing beauty in everyday life is a treasure'

'…and being more generally aware of my life has greater quality – is more enhanced'

This notion of increased clarity in the perception of life and of a greater quality of life can be related to enhancements in quality of life and wellbeing.

Mindfulness can be helpful with inner connection allowing more contentment and happiness. Being more aware enhanced the quality of life generally.

5.5.6 Clinically significant changes in overall wellbeing

In order to measure clinically significant changes of WHO 5-item wellbeing scale, a standardised percentage score is made by multiplying raw scores by four. A standardised score of zero represents the worst possible outcome, whereas a score of 100 represents the best possible quality of life. A change of 10% in scores represents a clinically significant change in wellbeing (Ware 1995) (see Table 5.15). As can be seen, differences between intervention and control groups were approaching clinical significance at T2, 9.2% and T3, 9.7% respectively compared to baseline differences of T1, 1.1%. It therefore seems that participating in MBSR and practising mindfulness almost reached a clinically significant change in wellbeing.

Table 5.15. Clinical significance indicated by change in percentage of scores between intervention and control group for WHO 5-item wellbeing questionnaire (WHO-5)

WHO-5 mean (SD) % score	Intervention (N=102)	Control (N=110)	Level of clinical significance in % (changes of ≥10% are significant)
T1 WHO-5	52.2%	50.1%	1.1%
T2 WHO-5	59.6%	50.4%	9.2%
T3 WHO-5	60.3%	50.6%	9.7%

T1= weeks -2 to 0, T2= weeks 8 to 10, T3 = weeks 12 to 14

Research Hypothesis 4: Stress

Hypothesis 4 is shown in Textbox 5.4

Textbox 5.4: Hypothesis 4

> As a consequence of being exposed to MBSR, there will be a reduction in the perception of stressors for women with stages 0 to III breast cancer relating to 1) breast cancer 2) other life events in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks
>
> Likert scales (0 to 10) to measure stressors were used to answer the following questions:
>
> 1) How difficult or stressful is your illness for you at the moment?
> 2) Apart from your illness, have you had any recent events in your life which has affected you strongly or been particularly stressful?

5.5.7 Perceptions of Stress

As this study has evaluated a stress reduction programme, measuring participants' perceptions of stress at each time point throughout the study was relevant. This was measured using a simple Likert scale (0 to 10) where 0 was not stressful at all and 10 was extremely stressful. Participants were asked to score 1) how difficult or stressful their breast cancer was for them at the moment, 2) Apart from their breast cancer, had they had any recent event in their lives which had affected them strongly or been particularly stressful. Table 5.16 and 5.17 gives results to these questions at each time point. Stress relating to breast cancer was significantly reduced by participation in MBSR at T2 ($p<0.01$) and T3 ($p<0.001$), but there were no significant differences between groups for perceptions of stress for other recent life events as a result of doing MBSR at either time point.

Table 5.16. Mean and standard deviation (SD) scores of perceptions of difficulty or stress caused by breast cancer plus statistical significance between groups assessed by independent sample t-tests

	Intervention Group Means (SD)	Control Group Means (SD)	Mean difference and p value	CI 95% for difference
T1	4.20 (2.03) (N=105)	4.11 (2.24) (N=110)	0.09	-0.48, 0.67
T2	3.28 (2.20) (N=92)	3.98 (2.24) (N=104)	-0.7**	-1.32, -0.07
T3	2.63 (1.94) (N=86)	3.64 (2.24) (N=94)	-1.01***	-1.63, -0.40

*p<0.05, **p<0.01, *** p<0.001

T1 = weeks -2 to 0, T2 = weeks 8 to 10, T3 = weeks 12 to 14

Table 5.17. Mean and standard deviation (SD) scores of perceptions of stress caused by recent life events apart from breast cancer plus statistical significance between groups assessed by independent sample t-tests

	Intervention Group Means (SD)	Control Group Means (SD)	p value	CI 95% for difference
T1	6.69(3.05) (N=102)	6.48 (3.09) (N=106)	Not significant	-0.63, 1.05
T2	5.63 (3.26) (N=88)	5.33(3.20) (N=100)	Not significant	-0.64, 1.23
T3	4.85 (3.42) (N=86)	5.59 (3.08) (N=94)	Not significant	-1.69, 0.22

T1= weeks -2 to 0, T2= weeks 8 to 10, T3 = weeks 12 to 14

In the qualitative data 27/92 (29.3%) of participants commented that they were coping better with stress, anxiety and panic.

'giving me a technique to cope with stress and anxiety'

'I now feel that I have a way of understanding and dealing with stress which is available to me every moment of my life'

'better coping mechanism in the face of stress, able to detach myself from the (stressful) situation and come back to my centre whenever I am thrown off it as I now know where my centre is'

'Stress reduction – I feel calmer, grounded, less 'wound up' in daily life'

From the qualitative data, participants found some of the techniques learned on the course useful for helping to reduce levels of stress. Returning to the awareness of breathing was one used in moments of stress and commented on by 8/92 (8.7%) participants:

'using breath to regain calm at difficult moments'

'in fleeting moments noticing that I pay attention to my breath so whatever the situation – it diffuses'

5.6 Predictors of outcomes

To test whether any of the variables were predictors of outcome, univariate, multivariate and stepwise regression was performed using SPSS. All regression analysis on each

independent variable was adjusted for baseline, T1 scores. The independent variables for the multiple regression can be found in Appendix 23. The results of regression analysis appear in Appendices 24 to 55. As so many tests were performed in this analysis, it is acknowledged that 5 times out of 100 those results significant at 5% level may have occurred by chance. For that reason, focus will be given to predictors significant at the 1% or 0.1% level according to the Bonferroni Method (Bland and Altman 1995).

5.6.1 Significant predictors of outcome measures

Summary tables of the significant predictors of outcomes at T2 and T3 resulting from stepwise regression is found in Tables 5.18 and 5.19 respectively. The scores at baseline were predictive of all outcomes at T2 and T3 and being in either the intervention or control group was largely predictive as well. The results presented below are the only results to reach statistical significance.

Table 5.18. Summary table of predictors for outcome measures at Time 2 from stepwise regression

	Outcome Measures															
	POMS							FACT								WHO-5
Variable	TMD	TA	DD	AH	VA	FI	CB	FACT - ES	FACT-ES TOI	FACT-B	FACT-B TOI	PWB	SWB	EWB	FWB	WHO-5
T1 baseline measure	1%	0.1%	0.1%	0.1%	1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Intervention or control group	0.1%	0.1%	0.1%	5%	1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	1%	5%	1%	0.1%	0.1%
Age at randomisation															1%	
Breast cancer staging											5%					0.1%
Breast cancer local recurrence															5%	
Mastectomy	1%		5%	0.1%			0.1%			5%	1%				1%	5%
Number of neoadjuvant chemo cycles			5%			1%								1%		1%
Difficulty or stress of illness										1%	1%		5%	1%	5%	
Stressful life events														1%		

T2= weeks 8 to 10.

Table 5.19. Summary table of predictors for outcome measures at Time 3 from stepwise regression

	Outcome measures															
	POMS							**FACT**								**WHO**
Variable	TMD	TA	DD	AH	VA	FI	CB	FACT ES	FACT-ES TOI	FACT-B	FACT-B TOI	PWB	SWB	EWB	FWB	WHO-5
T1 baseline measure	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Intervention or control group	0.1%	1%	1%	0.1%	0.1%	1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%		0.1%	0.1%	0.1%
Age at randomisation									5%		1%					
WLE/ Partial mastectomy								5%	5%					5%		
Mastectomy	1%	5%		0.1%		5%	0.1%	1%	0.1%	5%	5%			1%		
Neoadjuvant chemotherapy																5%
Number of neoadjuvant chemo cycles			5%			5%								5%		1%
Treatment finish to randomisation (months)				1%												
Time from randomisation to Q1 (months)				1%											5%	
Difficulty or stress of illness								0.1%	0.1%		0.1%	1%	5%			

T3 = weeks 12 to 14

5.6.1.2 Predictors of Mood Disturbance

Worsened levels of overall mood disturbance at T2 as measured by POMS TMD was predicted by poorer baseline scores at T1 (p<0.01) and having undergone mastectomy (p<0.01), whereas participating in MBSR improved mood (p<0.001) (see Appendix 24). At T3, worsened mood disturbance at T1 (p<0.001) and mastectomy (p<0.01) predicted poorer scores, in contrast, participating in MBSR predicted improvements (p<0.001) (see Appendix 25).

5.6.1.3 Predictors of Tension-Anxiety

Reduced levels of tension and anxiety at T1 as measured by POMS Tension-Anxiety (TA) subscale (p<0.001) and participating in MBSR (p<0.001) were predictors of reduced tension-anxiety at T2 (see Appendix 26). Reduced levels of tension and anxiety at T1 (p<0.01) and participation in MBSR (p<0.01) predicted reduced levels of tension and anxiety at T3 (see Appendix 27).

5.6.1.4 Predictors of Depression-Dejection

Less depression and dejection as measured by POMS Depression-Dejection subscale at T1 (p<0.001) and participation in MBSR (p<0.001) were predictors of improved scores at T2 (see Appendix 28). At T3, improved Depression-Dejection subscale scores at baseline (p<0.001) and participating in MBSR (p<0.01) predicted improved scores (see Appendix 29).

5.6.1.5 Predictors of Anger-Hostility

A lower level of anger and hostility, as measured by POMS Anger-Hostility (AH) subscale at T1 (p<0.001), was a predictor of improved POMS Anger-Hostility scores at T2 , whilst having undergone mastectomy (p<0.001) predicted worse scores (see Appendix 30). At T3, a lower level of anger and hostility (p<0.001) at T1, having participated in MBSR (p<0.001), decreased time from the finish of hospital treatment for breast cancer and the time of randomisation (p<0.01), and decreased time from randomisation to receiving questionnaires at T1 (p<0.01) predicted improved POMS Anger-Hostility scores (see Appendix 31) suggesting that starting MBSR sooner after the finish of treatment helped with the management of these symptoms in the follow-up period. Having undergone mastectomy predicted worse scores at T3 (p<0.001).

5.6.1.6 Predictors of Vigour-Activity

Predictors of improved vigour and activity at T2, as measured by POMS Vigour-Activity were T1, improved baseline scores (p<0.01) and having participated in the MBSR (p<0.01) (see Appendix 32). At T3, improved baseline scores for vigour-activity (p<0.001)

and participating in the MBSR ($p<0.001$) were predictive of improvements in vigour-activity (see Appendix 33).

5.6.1.7 Predictors of Fatigue-Inertia

Improvements in levels of fatigue and inertia at T2 as measured by POMS Fatigue-Inertia subscale were predicted by better scores at T1 ($p<0.001$) and participating in MBSR ($p<0.001$) (see Appendix 34), whilst the number of neoadjuvant chemotherapy cycles predicted worsened scores ($p<0.01$). At T3, less fatigue and inertia at T1 ($p<0.001$) and participating in MBSR ($p<0.01$) were predictors of improved POMS Fatigue-Inertia (see Appendix 35).

5.6.1.8 Predictors of Confusion-Bewilderment

Less confusion and bewilderment experienced at T1, as measured by POMS Confusion-Bewilderment subscale ($p<0.001$) and participating in MBSR ($p<0.001$) were predictors of improved POMS Confusion-Bewilderment scores at T2 (see Appendix 36) whilst having undergone mastectomy predicted worse scores ($p<0.001$). The same predictors of outcomes with the same levels of significance were predictive of outcomes at T3 (see Appendix 37).

5.6.2 Predictors of quality of life

5.6.2.1 Predictors of Endocrine symptoms

Fewer endocrine symptoms at T2 were predicted by improved scores on FACT-ES at T1 ($p<0.001$), and having participated in MBSR ($p<0.001$) (see Appendix 38). At T3, the same predictors of outcomes and levels of prediction were present and in addition, having undergone a mastectomy ($p<0.01$) and suffering increased difficulty or stress of illness ($p<0.001$), were predictive of poorer scores (see Appendix 39).

5.6.2.2 Predictors of physical/functional wellbeing in relation to endocrine symptoms

Improved physical and functional wellbeing in relation to endocrine symptoms as measured by FACT-ES TOI at T2 was predicted by better scores at T1 ($p<0.001$) and participating in MBSR ($p<0.001$) (see Appendix 40). The same predictors of outcomes and levels of prediction were present at T3, and in addition, having undergone mastectomy ($p<0.001$) and experiencing increased difficulty or stress of illness ($p<0.001$) predicted poorer scores (see Appendix 41).

5.6.2.3 Predictors of breast related quality of life

Improved breast-related quality of life as measured by FACT-B at T2, was predicted by improved scores at T1 ($p<0.001$) and participation in MBSR ($p<0.001$), whilst having experienced increased difficulty or stress of illness predicted worse outcomes ($p<0.01$)

(see Appendix 42). Improved scores at T1 ($p<0.001$) and MBSR ($p<0.001$) predicted better breast-related quality of life at T3 (see Appendix 43).

5.6.2.4 Predictors of physical and functional wellbeing relating to breast cancer

Improved physical and functional wellbeing relating to breast cancer at T2 as measured by scores on FACT-B TOI, was predicted by improved scores at T1 ($p<0.001$) and participation in MBSR ($p<0.001$), whilst having undergone mastectomy ($p<0.01$) and the difficulty or stress of breast cancer ($p<0.01$) predicted worse scores (see Appendix 44). At T3, baseline scores at T1 ($p<0.001$), and participation in MBSR ($p<0.001$), were predictors of improvement, whilst increased age at randomisation ($p<0.01$) and increased difficulty or stress of illness ($p<0.001$) predicted worse outcomes (see Appendix 45).

5.6.2.5 Predictors of physical wellbeing

Predictors of improved physical wellbeing (FACT PWB) at T2 were measured by improved scores on FACT PWB at T1 ($p<0.001$) and participation in MBSR ($p<0.01$) (see Appendix 46). At T3, predictors of improved scores were better scores of FACT PWB at T1 ($p<0.001$) and participation in MBSR ($p<0.001$), whilst increased difficulty or stress of illness predicted worse outcomes ($p<0.01$) (see Appendix 47).

5.6.2.6 Predictors of social/family wellbeing

Improved social and family wellbeing (FACT SWB) at T2 was predicted by better scores on FACT SWB subscale at T1 ($p<0.001$) (see Appendix 48), the same predictor applied at T3 ($p<0.001$) (see Appendix 49).

5.6.2.7 Predictors of emotional wellbeing

Predictors of better emotional wellbeing (FACT EWB) at T2 were improved scores on FACT EWB at T1 ($p<0.001$) and participation in MBSR ($p<0.01$), whilst an increase in stressful life events ($p<0.01$), an increased number of neoadjuvant chemotherapy cycles ($p<0.01$), and experiencing more difficulty or stress of illness ($p<0.01$) worsened scores (see Appendix 50). At T3, better scores on FACT EWB at T1 ($p<0.001$) and participation in MBSR ($p<0.001$) predicted improved emotional wellbeing whilst having undergone mastectomy predicted worse scores ($p<0.01$) (see Appendix 51).

5.6.2.8 Predictors of functional wellbeing

Predictors of improved functional wellbeing (FACT FWB) at T2 were improved scores on FACT FWB at T1 ($p<0.001$) and participation in MBSR ($p<0.001$) whilst increased age at randomisation ($p<0.01$) and having undergone mastectomy ($p<0.001$) worsened scores (see Appendix 52). At T3, improved baseline scores at T1 ($p<0.001$) and participation in MBSR predicted improved scores on FACT FWB ($p<0.001$) (see Appendix 53).

5.6.3 Predictors of overall wellbeing

Improvements in overall wellbeing at T2 were predicted by better scores on WHO-5 wellbeing questionnaire at T1 ($p<0.001$) and MBSR ($p<0.001$) (see Appendix 54), whilst higher levels of breast cancer staging ($p<0.001$) and an increased number of neoadjuvant chemotherapy cycles ($p<0.01$) predicted worsened scores. At T3, better wellbeing scores at T1 ($p<0.001$) and MBSR ($p<0.001$) predicted improved scores, whilst an increased number of neoadjuvant chemotherapy cycles ($p<0.01$) predicted worsened scores (see Appendix 55).

Research Hypothesis 5: Dose related effects of mindfulness

Dose related effects of mindfulness relate to the amount of classroom attendance and hours of home practice undertaken by participants during the MBSR programme.

Hypothesis 5 is shown in Textbox 5.4

Textbox 5.4: Hypothesis 5

Dose-related effects of mindfulness Increased MBSR classroom attendance and mindfulness home practice hours will predict improvement in mood state, quality of life and wellbeing for women with stages 0 to III breast cancer in the intervention group, the effects being measured after eight weeks and again after 12 weeks Data from class attendance sheets home practice sheets

5.6.4 Participation in MBSR and mindful home practice

To see how the degree of participation in MBSR and the amount of home practice done by participants affected outcomes, data from the intervention group, who undertook MBSR during the course of the study, was analysed and the results found in Table 5.20 and 5.21 are summarised below.

5.6.4.1 Mindful home practice and classroom practice

The amount of formal mindfulness practice, i.e. mindful body scan, mindful stretches or mindful sitting meditation done at home was recorded by participants each week. The mean (SD) number of hours of formal home practice of mindfulness was 19.58 (11.49) over eight weeks. This is an average of 21 minutes per day spent at home doing formal mindfulness practice such as body scan, stretches and meditation. This shows that participants did indeed change their behaviour and comply with home practice as requested. When mean classroom mindfulness practice time is added to this, (an average of 12 minutes per day over the eight weeks measured), 33 minutes per day of practice was done in this study, fractionally more than the 32 minutes per day in the 7-week study of cancer outpatients by Speca et al (2000), which was calculated in the same way (Speca and Carlson 2008, personal communication).

5.6.4.2 Attendance of MBSR classes

Attendance of MBSR classes was high with a mean (SD) number of classroom hours attended 17.45 (6.55) hours over the course which averaged to 2.18 hours per week. This

included attendance of the six-hour day of mindfulness held on a Saturday. Each weekly session was two hours except for the first and last which were 2.25 hours. The mean (SD) number of weekly sessions attended (excluding the Saturday) was 6.26 (2.12) of a possible eight. So attendance over the programme was high suggesting that participants were motivated and willing to attend.

5.6.5 Predictors of outcomes from participating in MBSR

To identify the influence on outcomes of the level of attendance of the MBSR course and the mindfulness practice done by participants at home, a regression analysis was performed on data from the intervention group only. Stepwise regression identified several factors as being predictors of outcome at T2 and T3 (see Tables 5.20 and 5.21 respectively).

Table 5.20. Results from the intervention group at T2 to show which variables were predictive of results following attendance of the MBSR intervention.
Levels of significance from stepwise regression for these predictors have been included.

Predictor	Outcome variable	Mean (N=105)	Standard deviation	Level of significance from regression
Study dropout	POMS TA	1.94	0.23	p<0.01
Formal home practice (hours)	POMS AH	19.58	11.49	p<0.01
-	WHO-5			p<0.01

Table 5.21. Results from the intervention group at T3 to show which variables were predictive of results following attendance of the MBSR intervention.

Levels of significance at 1% and 0.1% from stepwise regression for these predictors have been included.

Predictor	Outcome variable	Mean (N=105)	Standard deviation	Level of significance from regression
Formal home practice (hours)	POMS TMD	19.58	11.49	p<0.01
-	POMS VA			p<0.01
-	POMS CB			p<0.001
-	FACT-ES			p<0.01
-	FACT-ES TOI			p<0.01
-	WHO-5 wellbeing			p<0.001
Number of weekly sessions attended	FACT-B	6.26	2.12	p<0.01
-	FACT-B TOI			p<0.01
MBSR group attended	POMS AH			p<0.01

5.6.5.1 Participants dropping out from the study as a predictor of outcome

Dropping out from the study predicted poorer scores at T2 on the POMS tension-anxiety subscale (p<0.01). This indicates that those who dropped out of the study showed higher levels of anxiety. Speca et al (2000) also found that participants with higher levels of anxiety (p<0.05), dropped out from their study.

5.6.5.2 Formal hours of home practice as a predictor of outcome

Increased hours of formal mindfulness home practice predicted improved scores at T2 for POMS anger-hostility (p<0.01) and WHO-5 (p<0.01). This shows that increased hours of home practice reduced anger and hostility. At T3, increased hours of formal home practice predicted significantly improved results in the following POMS subscales: vigour-activity (p<0.01), confusion-bewilderment (p<0.001) and on FACT scales FACT-ES (p<0.01), FACT-ES TOI (p<0.01), as well as the WHO-5 item wellbeing scale (p<0.001). This indicates that increased vigour and activity, and less confusion and bewilderment were predicted from increased hours of mindfulness practice. In addition to this, menopausal symptoms lessened, quality of life, physical and overall wellbeing improved at T3 as a result of doing more formal mindfulness home practice.

One comment which was typical of others from the qualitative data to support this information:

'Feeling more energised as a result of stretching exercises and meditation'

5.6.5.3 MBSR class attendance as a predictor of outcome

As MBSR is an activity taught in weekly groups, it was important to see if there were any effects from the level of attendance on results. An increase in the total number of hours of classroom time attended by participants did not predict any statistical benefits however from the qualitative data, the social support gained from practising mindfulness in the weekly group was found to be helpful and there was a desire expressed to have ongoing groups after the programme finished:

'The course has been very useful and the group supportive. Bringing the group together again gives a focus - useful discipline to practise'

'I find being in a group is motivating. I will miss these sessions. I hope however to join the meditation class'

'Great to be supported through a difficult time and this has truly been a gift that I will always have and I think not only support me, but my family and friends because I will be in a better place'

'Grateful to my fellow participants for their generosity'

5.6.5.4 The number of weekly sessions attended as a predictor of outcome

An increased number of weekly sessions attended predicted improved quality of life as measured by FACT-B ($p<0.01$) and FACT-B TOI ($p<0.01$) at T3.

5.6.5.5 Attending the day of mindfulness as a predictor of outcome

Attending the six hour day of mindfulness held on a Saturday did not predict any statistically significant changes on outcome measures but some participants mentioned particular benefits from doing the day of mindfulness and others noted the challenges of that longer period of practice:

Benefits:

'appreciating a longer period of time to practise and seeing its value'

'the day event (Saturday) showed me that with the right circumstances all forms of mindfulness practice could work for me'

Challenges:

> *'Found the whole day of practice very challenging to keep focused for the whole day. Felt stressed when I got home but managed to calm down easily putting mindfulness into practice'*

5.6.5.6 MBSR group attended

MBSR was provided over a two year period by the clinician-researcher. She was interested to see whether those attending MSBR groups in the second year had a more positive experience than those in the first year that she might attribute to improvements in her skills as an MBSR teacher. The only predictor that might have suggested such an improvement was found in improvements in POMS TA ($p<0.01$) at T3.

5.6.5.7 Summary

Results from multiple regression analysis from the intervention group showed that being more anxious predicted drop out from the study. Increased hours of home practice, class attendance and the number of weekly sessions attended affected a number of other outcomes positively.

5.7 Understanding of the effects of participating in MBSR and mindfulness practice

To better understand experience of MBSR and mindfulness by participants, qualitative data was collected from those who completed the MBSR programme. Mindfulness was taught as a practical tool, so time in class was not spent discussing the conceptualisation of mindfulness and the data reflects this. Qualitative results from the intervention group are presented here as this data was collected within the time frame of the study where as that from the control group was not. Amongst the data there were very few negative cases, but these have been mentioned in the relevant context.

5.7.1 Response rates for qualitative data feedback form

There were 92 feedback forms completed from a possible 95 intervention group participants who completed the MBSR programme. The three participants who did not complete the form were three who left the course for the following reason: one due to work, the second was too busy and the third left as she did not find the course suitable and did not engage with its concepts or content.

5.7.2 Becoming more mindful

An additional question was added to the feedback form following the transfer viva undertaken in December 2005. Participants were given the option to reply 'yes' or 'no', to the question 'Do you believe you have experienced a greater degree of mindfulness as a

result of participating in the stress reduction programme?'. Participants recruited in 2006 were invited to complete this additional question, so 39/92 (42.4%) participants from the intervention group completed this additional question and all replied 'yes', that they had become more mindful as a result of participation in MBSR. There were no negative cases in the intervention group measured.

Most of the data collected illustrated the outcomes and consequences from attending the MBSR course and the cultivation of mindfulness practice.

5.7.3 Themes emerging from mindfulness data

The following major themes emerged from the qualitative data:

1. Being more aware*
2. Accepting things as they are, being less judgemental of myself and others*
3. Being calmer, centred, at peace, connected and more confident
4. Making time and creating space for myself*
5. Coping with stress, anxiety, panic
6. Improved communication and personal relationships
7. Coping with physical and mental symptoms including pain
8. The value and challenges of mindfulness practice*

**These themes will be discussed in this section. Data relating to other themes was presented previously within the relevant quantitative results.*

The additional themes presented here show how participants experienced mindfulness and understood its nature. The following data also gives further information as to the process and consequences of cultivating mindfulness from participation in the MBSR course and practising mindfulness.

5.7.3.1 Being more aware

In the cultivation of mindfulness, bringing attention and awareness to present moment experiences is central to this process. Once it is recognised that the attention is no longer present, the practitioner can bring the mind back. This is the process used to develop mindfulness. Enhanced mind and body awareness can result, bringing discernment to life choices.

As a result of attending the MBSR programme and doing mindfulness practice, 27(29.3%) participants expressed the notion of being more aware of the present moment as the most positive effect. Being more aware related to both participants experience of themselves, in terms of awareness of the body and mind, as well as more awareness of life around them. A part of this was the ability to choose where the attention goes:

'just being more aware all the time'

'being aware of what I am doing and how I am doing things'

Through enhanced awareness, participants found a desire and ability to change situations that were seen as negative. In addition to this, participants described the ability to see things as they are, rather than via the filters through which we normally perceive:

'allowing for time to be was invaluable'

'I am mindful of how my thoughts can take up an awful lot of negative energy. It is as if I can stand back and now see the whole picture'

'The most positive effect has been the ability to stand back and view situations, thoughts and events in their true context'

'an awareness of how I was living my life and the desire to change it'

5.7.3.2 Accepting things as they are, being less judgemental of myself and others
In the cultivation of mindfulness or present moment awareness, the development of non-judgemental or non-discriminatory awareness enables a direct contact with reality without the filters of judgement clouding situations to such a great extent. Accepting things as they are is one way of describing this form or awareness. Judgements are naturally made all the time, however, in the cultivation of mindfulness, they are seen for what they, as 'thoughts' are rather than as being fixed as in being the truth, right or wrong .

Non-judgemental awareness allows a degree of simplicity in the view of life, where occurrences are allowed to be as they are, including thoughts, emotions, the body, other people and situations. This is in contrast to the constant battle or drive that exists in everyday life where much time and energy are wasted wanting situations and people to be different from how they are. This is not to be confused with enabling appropriate change in life, but more of a way of living with a greater degree of ease and reducing stress.

Through becoming more mindful, 18/92 (19.6%) participants said that they became more aware of how judgemental they were of themselves and others, and began to be less judgemental; that is, learning to accept things as they are. Here are examples of how practising mindfulness helped with this area:

'less judgemental and awareness of how judgemental I used to be'

There was also more acceptance of self and others which led them to feel more at home with themselves. Acceptance of one's body, oneself and others:

'more accepting of my body with all its faults'

'accepting things as they are, not trying to change it or be a control freak and change things'

'accepting people's behaviour and not trying to change it or be drawn in'.

5.7.3.3 Making time and creating space for myself

Finding ways to participate in self-management is central to finding ways to promote health and wellbeing. In the cultivation of mindfulness, formal mindfulness practice necessitates participants to reflect on creating time and space for their own health and development can be made. In the study, formal home practice of 45 minutes per day was suggested. For many participants who perceive their lives to be already busy, this was a challenge.

In the qualitative data, making time and space for myself was important to 15/92 (16.3%) participants commenting directly about this. It was interesting to note that attendance of MBSR and the practice of mindfulness at home gave participants permission to give themselves more time and space:

'giving myself permission to make time and space for myself, I feel like I've got more time because I'm not always looking forward or back'

The need to slow down was also included in this time for self:

'Made me more aware of the necessity to slow down, to take time out'

It was observed that by practising and living mindfully there was more time for other things in life:

'When given the CD and told they lasted 45 minutes - thinking when can I fit this in, but as you practise, to make time was not a challenge – Not only have I found the time to do the practice and have also found the time to swim each day which I haven't done in years.'

Making or finding time to do mindfulness practice was one of the biggest challenges for participants with 45 participants (48.9%) directly commenting on this, although it was acknowledged by some that this might be overcome by a change in thinking or perspective:

'I found it very difficult to do the practical. Sometimes this was just about making time in my head'

'the most challenging thing was to allow myself the time'

'getting down to practising even when the benefits have been experienced'

'having discipline to do the practice even when I know I feel infinitely more lively afterwards'

5.7.3.4 Value and challenges of mindfulness practice

The process of cultivating mindfulness through formal practice raises various issues for most people. These include motivation, intention, concentration, fatigue, wandering mind, stiffness in the body, preferences (wanting to do something else or not wanting to practise) and so on. All of these are commonly experienced in the practice of mindfulness and so are not unique to these participants. They are inherently part of the process of developing mindfulness through noticing what arises in the present moment.

From the qualitative data, the value of the mindfulness practices, the opportunity to do the practices and benefit from them in a way not previously experienced was evident. Also recognised was the inherent challenges that these mindfulness practices presented. Having a scheduled programme of mindfulness helped motivate participants to practise, gave them the opportunity to experience meditation on a deeper level, to appreciate the value of meditation in life, and to practise without interruption.

In addition to making or finding time to practise, other challenges included eight out of 92 (8.7%) participants who found staying awake during the body scan one of the most challenging aspects of mindfulness practice. Some participants, 20/92 (21.7%), found the meditation practice very difficult either due to the difficulties of sitting for a period of time or because they noticed the mind wandering a lot which was a challenge for them:

'Sitting meditation was something that I really struggled with – and sometimes still do – a combination of "monkey mind" and physical discomfort'

'In practising the mindful body scan which was usually done lying down, staying awake was the biggest challenge'

'the body scan continues to be a challenge – to remain present and awake whilst so relaxed'

'Not falling asleep during the body scan!'

Only one participant commented that she struggled to engage with mindfulness practice in the following way:

'I hated the first two to three sessions and felt very anti, but did appreciate it from then and I feel like it has made me a calmer person'

There was also gratitude expressed for having the CDs to practise with as ongoing resources both during and after the course:

'The CDs provide my backup to rebalance myself whenever I want – almost like an insurance policy for getting overstressed'

'The resources that we can keep will make it easier to at least try and keep up with the practice at home and in our daily lives'

5.8 Summary of qualitative results

The qualitative results show the diverse nature of impact that practising mindfulness can have. The results of the main themes which emerged and the corresponding number of participants who commented are found in Table 5.22 and a more detailed summary of all the themes is given. Although this data is qualitative, the frequency of commentary indicates salience for the themes identified.

Table 5.22. A summary of the main themes from qualitative analysis

Main themes	(N = 92) (%)
Being calmer, centred, at peace, connected and more confident	30 (32.6%)
The value and challenges of mindfulness practice	28 (30.4%)
Being more aware	27 (29.3%)
Coping with stress, anxiety and panic	27 (29.3%)
Accepting things as they are, being less judgemental of myself and others	18 (19.6%)
Improved communication and personal relationships	16 (17.4%)
Making time and creating space for myself	15 (16.3%)

5.9 Theme summaries

Given the nature of qualitative data collection using a short proforma, there is no certainty of the level of saturation of data in each theme. The qualitative data, in spite of its limitations, was consistent with the observations of the clinician-researcher from the comments of participants when teaching MBSR over the two year period of data collection in the study which can be used as a form of triangulation. Frequency or proportions can be an indication of saliency according to Silverman (2006) and themes identified in this study were attributed to between 16.3% and 32.6% of respondents, suggesting a degree of saliency had been achieved.

5.9.5.1 Being calmer, centred, at peace, connected and more confident

Participants were able to connect better with themselves and get in touch with the central, calm and peaceful place within, releasing the attention from the distractions of the busy outer life.

5.9.5.2 The value and challenges of mindfulness practice

The introduction of new experiences such as the formal practice of mindfulness into the lives of participants brought attention to behaviours and physical states of which they were not aware. These included noticing the way the mind wanders and the challenge of keeping the mind present, physical discomfort in the body, tiredness that became apparent when participants found themselves falling asleep during the bodyscan.
There was gratitude expressed as to the value of having the ongoing use of the CDs after the programme as an aid to continue practising after the MBSR programme had finished.

5.9.5.3 Being more aware

As a result of being more aware, participants gained a new perspective on life by being able to stand back and view life with more objectivity or distance. This gave more clarity to viewing life and being able to see the whole picture with thoughts and events in their true context.

5.9.5.4 Coping with stress, anxiety and panic

Participants found that coming back to the present, being mindful, was very useful when they or situations felt out of control. Coming back to the awareness of breathing was taught on the course as a way of bringing attention back to the present moment and participants commented on this as a way of regaining calm and control in a situation. It was noted that coming back to the present through awareness of breathing eased the perceived difficulty in any given situation.

5.9.5.5 Accepting things they are, being less judgemental of myself and others

Through accepting life and themselves, including their bodies, participants found that there was more peace and less struggle in their lives. Participants noticed that they were less judgemental of themselves and others.

5.9.5.6 Improved communication and personal relationships

Mindfulness enhanced the quality of attention given to relationships and this in turn enabled participants to be aware of habitual reactions resulting in the ability to respond in a more appropriate and healthy way. It was observed that creating time and space for mindfulness practice enabled a better quality in communication on both sides of relationships both with adults and children.

5.9.5.7 Making time and creating space for myself

Many participants found that making time for themselves was a challenge. Some found that making time for themselves also seemed to make time for other things. Bringing awareness to the creation of space and time, and the need to slow down and take time out, actually created more time as one participant put it ‘making time in my head’. Participation in the course and the request for home practice raised issues of their relationship with time itself.

5.10 Overall summary of qualitative data

From the process of simply being mindful or more aware, there were skills that were developed which helped participants to achieve the following outcomes: accepting things as they are, being less judgemental, being calmer, more centred, at peace, connected and confident. Making time and creating space for self was an important part of cultivating mindfulness and helped participants cope with stress, anxiety and panic. Improved communication and personal relationships, coping with physical and mental symptoms including pain were benefits of practice but not as frequently mentioned as those above. Mindfulness is seen to have been beneficial but also a challenge for many participants to practise. The value and challenges of mindfulness practice included having ongoing skills and resources to continue this practice over time.

It is important to acknowledge that not all participants in the course embraced mindfulness and its concepts, there were a few for whom this approach was neither helpful nor something they wanted to engage in.

5.11 Adverse effects of MBSR

Reported adverse effects of doing MBSR from participants included the difficulty of finding time to practise, finding the body stiff or having discomfort and therefore feeling that some of the stretches were difficult or sitting for meditation was not easy. One participant reported that she hurt her arthritic knee doing mindful walking during the day of mindfulness in week six as she was not used to walking slowly. Participants sometimes found mindfulness practice difficult as they noticed how much the mind wanders and found this frustrating.

5.12 Summary of results chapter

Using rigorous analysis, this chapter detailed quantitative results of the effects of MBSR on the primary outcome, mood, as measured by POMS and secondary outcomes and the measures used to evaluate them relating to quality of life FACT-B, endocrine symptoms, FACT-ES, overall wellbeing (WHO-5) and stress. The main predictors of outcome at eight and twelve weeks, in addition to randomisation to the intervention or control group, were found to be having had a mastectomy, the number of neoadjuvant chemotherapy cycles and the perceived difficulty or stress of breast cancer. Qualitative data has highlighted themes resulting from the participation in MBSR and the process of it, or the effects of mindfulness as: being calmer, centred, at peace, connected and more confident; the challenges of mindfulness practice; being more aware; coping with stress, anxiety and panic.

Chapter 6. Discussion

6.1 Introduction

This study demonstrated that an eight-week MBSR programme can improve mood, quality of life including endocrine symptoms and wellbeing in women diagnosed with stages 0 to III breast cancer compared to controls. Most of the improvements lasted during the four-week follow-up period after the MBSR programme. MBSR helped breast cancer survivors through the use of this self-management approach. The chapter is structured in the following way: 1) key findings in relation to each hypothesis will be summarised and discussed, 2) consideration of possible mechanisms of action and explanations given, 3) comparisons with relevant findings from other published studies, 4) limitations of the present study and methods used to minimise and compensate for these, 5) the generalisability of findings and 6) general interpretation of the results in the context of the research evidence. Details of the results are discussed with due reference to guidelines from the Consort Statement on trial reporting (Altman et al 2001b).

It is important to note that the study was set up on the basis that mindfulness would have an effect, so for all the significant results, it needs to be assumed that this element has had an effect. In the discussion there will be an examination of other possible effects that may have contributed to the results.

6.2 Hypothesis 1: Mood state

As a consequence of being exposed to MBSR, after adjusting for baseline, mood was statistically significantly improved in the intervention group compared to controls, as measured by the Profile of Mood States (POMS), the primary outcome measure, in women with stages 0 to III breast cancer, the effects being measured after eight weeks and again after 12 weeks. There were significant improvements in total mood disturbance from MBSR at eight weeks in the intervention group with a mean (SD) of 30.02 (31.60) compared to controls 47.81(39.81) (95% CI for difference -27.44 to -18.14, $p<0.001$). This shows that cultivating mindfulness, being present, can have a positive effect on overall mood state and demonstrates an effective way for those living with breast cancer to self-manage mood. These results reinforce and extend results found by Speca et al (2000) in a group of mixed cancer outpatients (N=109) where post MBSR intervention group mean (SD) scores were 14.7 (29.8) ($p< 0.01$) compared to controls 32.9 (33.0) and those by Carlson et al (2004) who found a 13% improvement in POMS scores in breast and prostate patients post MBSR of 13.65 (32.66) (n=43), but this was not significant following a low level of mood disturbance at baseline 22.62 (33.16) (N=58). This may have been accounted for by the fact that there was no evidence that the Carlson study was adequately powered.

The current study showed that at 12 weeks, after the four-week follow-up period, positive changes in overall mood were maintained with intervention group mean (SD) of 29.83 (34.19) compared to controls 45.43 (35.51) (95% CI -25.01 to -6.20, p<0.001) showing that improvements in mood state were maintained after completing the eight-week MBSR programme. In comparison, Carlson et al (2001) performed a six-month follow-up on Speca et al's (2000) study of cancer outpatients and found that significant changes were not maintained, so questions remain for further research regarding the extent to which improvement is maintained in mood post MBSR after the one-month follow-up period demonstrated in the current study.

6.2.1 Baseline levels of total mood disturbance

Baseline levels of total mood disturbance were worse than those found in other MBSR and cancer studies using POMS discussed below, showing higher levels of mood disturbance in this study. Mean score (standard deviation) at baseline were 43.65 (34.73) in the intervention group and 49.23 (39.37) in controls. The reason for mood disturbance being high at baseline is unclear but may be accounted for by the fact that women in the current study had identified themselves as needing further help through responding to the call for participants, and had already sought help through attending Breast Cancer Haven in the past. In addition, they were experiencing the ongoing psychological impact of the disease, and side effects from completed and ongoing medical treatments. Other factors of influence may be that the recruitment period of the study, between two months and two years post hospital treatment, is following a time when the majority of the intensive physical medical treatment has finished making space for emotional needs to surface, in addition to the pressures of returning to normal life (Hassey-Dow et al 1996). Compared to findings by Speca et al (2000) where baseline scores in cancer outpatients in the intervention group were 37.1 (32.7) and 34.9 (35.0) for controls, Carlson et al (2004) found baseline mean (SD) POMS scores to be 22.62 (33.16) in a smaller study (N=58) of mostly breast and some prostate cancer patients. The current study showed increased mood disturbance at baseline compared to these studies and POMS norms where mean scores for breast patients (N=118) were reported as 20 (32.4) (Cassileth et al 1985).

6.2.2 Mood state subscales

In women with stages 0 to III breast cancer, all subscales on POMS that measured mood state: anxiety, depression, anger, vigour, fatigue and confusion significantly improved following MBSR compared to controls measured after eight weeks and again after 12 weeks. This is not unexpected given the level of improvement in total mood disturbance, the combined result of these subscales. More details about the individual subscale results are found below. The improvements found from MBSR reinforced and extended results

found by Speca et al (2000) who found improvements in depression, anger, and confusion when compared to controls.

6.2.2.1 Anxiety

In the current study, after eight weeks, anxiety improved significantly in the intervention group from being exposed to MBSR, with mean (SD) scores improving significantly 10.32 (7.0) compared to controls 13.66 (7.20) (95% CI -4.95 to -1.18, $p<0.01$) and this was maintained at 12 weeks in the intervention group 10.33 (7.02) compared to controls 12.73 (6.59) (95% CI -4.24 to -5.66, $p<0.01$). An explanation for this may be that mindfulness gives rise to a non-discursive, non-analytical, direct experience of the object of attention and those who are able to identify anxious thoughts as 'thoughts', rather than as 'reality', report that this alone helps to reduce their anxiety and increases their ability to encounter anxiety-producing situations more effectively (Kabat-Zinn et al 1992).

This result extends those of other studies where anxiety in cancer patients has improved post MBSR (Speca et al 2000) but they did not find significant between group differences in anxiety in general cancer outpatients post MBSR, however anxiety change scores ($t(88)= -3.73$, $p<0.01$) were significantly improved. Following up the same group, Carlson et al (2001) found an insignificant shift towards improvement from completion of MSBR to six-month follow-up. From previous MBSR studies evaluating the treatment of anxiety disorders (N=22) MBSR (Kabat-Zinn et al 1992, Miller et al 1995) using pre- and post-tests on the Symptom Checklist-90-Revised (SCL-90R) and Medical Symptom Checklist revealed significant improvements which were maintained at three-month follow-up ($p<0.001$) and these in turn were sustained at three years (n=18) ($p<0.001$), but with such small sample sizes in these studies, it is difficult to generalise from these findings.

6.2.2.2 Depression

Depression scores in the MBSR intervention group were significantly better than controls at eight weeks with intervention group mean (SD) scores 10.0 (9.95) compared to controls 14.96 (13.23) (95% CI -8.11 to -1.83, $p<0.01$) and this was maintained at twelve weeks with the intervention group scores of 10.34 (10.32) compared to controls 14.10 (11.60) (95% CI –6.72 to -0.80, $p<0.01$).The process of becoming more aware of thoughts and feelings and relating to them as 'mental events' from a decentred perspective, rather than as aspects of self or as true reflections of reality, can be applied to depressive thoughts (Teasdale et al 2000) and is a likely explanation for the benefits found in this study. These results reinforce and extend results by Speca et al (2000) who found significant between group differences in mean (SD) post MBSR in cancer outpatients 8.4 (8.9) compared to controls 13.0 (9.9) and also found change scores were in the direction of reduced depression ($t(88) = -3.20$, $p<0.01$). These extend findings of Teasdale et al (2000) who

found that Mindfulness-Based Cognitive Therapy (MBCT) significantly reduced rates of relapse/recurrence in recovered, recurrently depressed patients (n=145), 77% with three or more episodes of previous depression. Teasdale's view was that this occurred via the decentring mechanism described above.

Finding that MBSR is an effective self-management tool in improving depression and anxiety, common and also potentially long-term psychological symptoms in cancer patients (Derogatis et al 1983, van't Spijker et al 1997, Burgess et al 2005) could positively impact on the wellbeing of many people living with breast cancer especially as the figures for depression in woman with breast cancer are estimated as between 4.5 to 50% depending on sampling and assessment methods (Fann et al 2008, Massie 2004, Burgess et al 2005, Somerset et al 2004). This extends findings in pre-post measurements using Hospital Anxiety and Depression Scale, where anxiety ($p<0.05$) and using POMS, depression ($p<0.05$) significantly declined from MBCT in Welsh cancer outpatients (n=19) (Soulsby et al 2007). The positive impact of MBSR on anxiety and depression from this study challenge a review of controlled research into mindfulness meditation in a range of clinical populations including cancer (n=15) (Toneatto and Nguyen 2007) who found that MBSR did not show an effect on anxiety and depression when control groups were used. However, they acknowledged that the methodological variability and the paucity of randomised controlled trials with active control groups limits support for the efficacy of MBSR in this area.

6.2.2.3 Anger

Anger scores in the MBSR intervention group were significantly better than controls with intervention group mean (SD) scores at eight weeks 8.78 (7.57) compared to controls 11.11(8.88) (95% CI -4.57 to -0.10, $p<0.05$) and maintained at twelve weeks 7.87 (6.72) and 11.04 (8.95) (95% CI -5.29 to -1.04, $p<0.01$) respectively. A participant comment from the qualitative data explained how this worked for her

> *'If I am getting angry or annoyed about something, I try and concentrate on my breathing for a while and it usually calms me down.'*

So bringing attention back the awareness of breathing as it was happening, helped diffuse anger. Through mindfulness, the ability to be more aware of anger as it arises 'as an event' enables a choice to be made as to whether to continue being angry or to use another technique, such as bringing awareness back to the breathing, to help diffuse the emotion. This finding confirms and extends others from MBSR found in cancer outpatients by Speca et al (2000) who found significant improvements in anger after MBSR with

intervention group mean (SD) of 6.1(5.1) compared to controls 9.5 (7.6) ($p< 0.05$) and pre- and post-test change scores ($t(88) =-3.10$, $p<0.01$) after MBSR.

6.2.2.4 Vigour

Vigour scores in the intervention group were significantly better than controls with mean (SD) vigour scores at eight weeks post MBSR in intervention group of -15.91(6.0) compared to controls -13.57(6.61) ($p<0.01$, 95% CI -4.05 to -1.04) and this was maintained at 12 weeks -16.23(6.63) in the intervention group compared to controls -13.47 (6.62) ($p<0.01$, 95% CI -4.50 to -1.03). By being mindful and bringing the attention back to the present moment allows the mind and body to become more centred and at ease (Garrie Rōshi 1998), reducing mental and physical tension, which enables more vigour. Improved vigour is an important finding from MBSR as the incidence of insomnia (Berger et al 2005, Bower 2008) and fatigue are high in breast cancer survivors (Ganz and Bower 2007, Bower et al 2000, Meeske et al 2007). These results extend findings by Speca et al (2000) who found no significant between group differences in vigour in cancer outpatients. However, change scores in Speca's study showed significant improvement post MBSR ($t(88) = 2.96$, $p<0.1$). Significant pre- and post-test scores were also found in Welsh cancer outpatients from MBCT ($p<0.05$) (n=19) (Soulsby et al 2007). Similar improvements in vigour on POMS were found from emotionally expressive coping (actively processing and expressing emotions) over a three month period in stages I and II breast cancer patients survivors where 45% (n=87) were still on Tamoxifen (Stanton et al 2000).

6.2.2.5 Fatigue

Fatigue scores in the intervention group post MBSR were significantly better than controls in the intervention group with mean (SD) fatigue scores at eight weeks of 8.71(6.10) compared to controls 11.62 (7.16) (95% CI -4.71 to -1.11, $p<0.01$) and at 12 weeks 9.27 (6.90) and 11.39 (6.73) respectively (95% CI -3.95 to -0.28, $p<0.05$). Shapiro et al (2003) found that increased mindfulness practice led to increased refreshment after sleep. As insomnia is known to increase the degree of fatigue (Fiorentino and Ancoli-Israel 2006), mindfulness practice may have contributed to improvements in fatigue in the current study. Through mindfulness, participants may also have become more aware of their fatigue and taken other steps to reduce it such as reducing some levels of activity of giving themselves more time to look after themselves. These results challenge Speca et al (2000)'s findings where no significant improvements in fatigue in cancer outpatients were found and extend results found by Carlson and Garland (2005) who found significant pre- and post-fatigue changes ($p<0.01$) in cancer outpatients, 59% (n=63) of whom were breast patients at all stages. This is an important finding as 30 to 41% of breast cancer

survivors suffer from moderate to severe fatigue (Ganz and Bower 2007, Bower et al 2000, Meeske et al 2007).

6.2.2.6 Confusion

Confusion scores in the intervention group post MBSR were significantly better than controls at eight weeks with intervention group mean (SD) scores of 8.13 (4.71) compared to controls 10.32 (5.28) (95% CI -3.54 to -0.87, $p<0.01$) and this remained at 12 weeks 8.24 (5.32) and 9.64 (4.79) respectively (95% CI -2.76 to -0.40, $p<0.05$). Practising mindfulness is known to help with clarity of awareness: moment to moment clear awareness of one's changing inner or outer worlds, including thoughts, emotions, sensations, actions, or surroundings (Brown et al 2007a) which may explain why confusion improves. It may also be that as people felt less fatigued and somewhat calmer, that they found they could think more clearly. These findings reinforce and extend those of Speca et al (2000) who found significant between group differences in cancer outpatients post MBSR , mean (SD) of 3.2 (4.8) in interventions and 5.6 (5.2) in controls. Improvements in pre- to post-test change scores MBSR were significant ($t(88) = -3.20$, $p<0.01$).

6.2.2.7 Improvements in mood in the follow-up period

As discussed above, this study found that significant improvements in mood and all its subscales (anxiety, depression, anger, vigour, fatigue and confusion) were maintained for four additional weeks post MBSR to week 12 suggesting either that the benefits were sustained from the course and/or that participants continued to practise mindfulness. As the amount of practice done in the follow-up period was not measured, this remains unknown. The level of significance of the results was sustained to follow-up with total mood disturbance, anxiety, depression and vigour whilst the effects on anger became more significant with time. The level of significance for improvements in fatigue and confusion was slightly less at week 12. See previous sections for statistical detail. Compared to the six month follow up of data from Speca et al's (2000) study performed by Carlson et al (2001) (n=54), no measurement of between group differences compared to baseline were reported, only improvements between the completion of MSBR and six-month follow-up. Carlson found insignificant levels of improvement occurred on the subscales measuring vigour followed by fatigue with smaller changes on depression, anger, confusion and anxiety. Following MBSR, long-term follow up in other studies have demonstrated maintenance of initial improvements in physical and psychological symptoms among patients with chronic pain (Kabat-Zinn et al 1986), and anxiety (Miller et al 1995) as well as mixed patient populations (Reibel et al 2001). As the cultivation of mindfulness is seen as a process, a way of being, rather than an event or a skill that

necessarily becomes automatic, it would suggest that some formal or informal mindfulness practice was being continued by participants following MBSR.

6.3 Hypothesis 2: Quality of life

As a consequence of being exposed to MBSR, there was an improvement in quality of life, including endocrine symptoms, for women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks. Measured by FACT-B and FACT-ES, quality of life was significantly improved in the intervention group post MBSR and at follow-up in terms of endocrine symptoms, breast specific symptoms, emotional and functional wellbeing. Each of the FACT quality of life subscales which include physical (PWB), social/family (SWB), emotional (EWB) and functional wellbeing (FWB) followed by breast-specific and endocrine specific quality of life will be discussed in turn.

6.3.1 Physical wellbeing dimension of quality of life

Following exposure to MBSR, the physical wellbeing dimension of quality of life (PWB) was significantly improved at 12 week follow-up with mean (SD) 22.96 (4.34) for intervention group compared to controls 21.67 (4.87) (95% CI 0.05 to 2.54, $p<0.05$) but not at eight weeks, post MBSR. It may be that continued practice of the mindful exercises into the follow-up period continued to improve physical wellbeing or it may be that this result is a type 1 error and no significant improvement was found. As part of a systematic review and meta-analysis of the effects of exercise on breast cancer patients and survivors, McNeely et al (2006) found from four studies (n=208), two of which used FACT physical wellbeing scale, that breast patients found statistically significant increases in functioning and wellbeing from exercise (mixed aerobic (walking) and resistance) (95% CI 0.36 to 1.32, Standardised Mean Difference 0.84). The implications are that mindful exercise may be added to those other types of exercises known to be helpful for breast cancer.

6.3.2 Social/family wellbeing dimension of quality of life

Being exposed to MBSR made no significant between group differences at any time point on the sub-scale of social/family wellbeing dimension of quality of life as measured by social/family wellbeing (SWB) subscale. From the qualitative data, 16/92 (17.4%) MBSR participants identified better and more effective communication and improved family and social relationships to be a consequence of practising mindfulness so there appeared to be benefit to some. The format of the MBSR group is more psycho-educational than emotional expressive (Esplen et al 2000), so the impact on social wellbeing may be less. It is also possible that the SWB subscale did not measure the particular factors that changed for participants.

An imagery programme that also looked at stress (Freeman et al 2008) involving six classes of 2.5 hours over eight-weeks for recovering breast cancer patients in an uncontrolled study (n=30) similarly found significant improvements in all other FACT-B subscales except SWB post intervention. This raises the question as to whether interventions such as MBSR or imagery which cause participants to be aware more of themselves, their own thoughts and reactions, has less impact on social and family wellbeing. Social wellbeing mean (SD) at baseline was worse for intervention 17.59 (5.91) and controls 18.78 (56.01) when compared to the same norms 23.3 (4.2) (Brady et al 1997), suggesting that a higher level of baseline social wellbeing was not the reason for lack of change in this dimension of quality of life.

In contrast to the current results, a RCT involving a 12 week yoga programme with multiethnic mixed stage breast patients not on chemotherapy (mostly stages I to III) diagnosed over year ago (n=71), between group analysis showed that SWB was significantly improved (95% CI -4.18 to -0.84, $p<0.01$) after the programme (Moadel et al 2007). Whether smaller numbers in Moadel's study gave a Type 1 error or whether this was due to other factors such as programme variation or the relevance of the factors measured by the subscale, more research will be need here.

In a study examining quality of life in younger women (N=202) (mean age 41.6 years) with stages I to III breast cancer between four to 42 months post diagnosis, Avis et al (2005) found mean (SD) SWB higher 21.05 (5.44) than in the current study 17.59 (5.91) at baseline for the intervention group or at any time point for either group, but the mean age of their participants was lower than in the current study. They found that lower SWB was associated with not being in a relationship since diagnosis and relationship problems, missed days of work or usual activity after diagnosis, not being prepared for how they might feel about themselves or how cancer diagnosis may influence their relationships. SWB was the only dimension of quality of life not significantly improved by MBSR compared to controls in the current study.

The impact on sexual relationships was measured within the social wellbeing domain. Breast cancer treatments, for example, mastectomy or breast conserving surgery, ongoing hormonal treatments such as hot flushes and vaginal dryness, may have affected scores on sexuality as found in other studies (Carpenter et al 2002). In answer to the question at baseline, how satisfied are you with your sex life 41.2% (n=40) of the intervention group and 36.1% (n=35) of controls answered that they were not at all satisfied however 58.7% (n=57) of intervention group and 82.1% (n=74) of controls chose not to answer this question, leaving questions about the validity of this result.

6.3.3 Emotional wellbeing dimension of quality of life

Being exposed to MBSR significantly improved emotional wellbeing (EWB) dimension of quality of life at eight weeks, post MSBR with intervention group mean (SD) of 18.13 (3.82) compared to controls 16.65 (4.42)(95% CI 0.48 to 2.73, $p<0.01$) and more so at 12 weeks, follow-up 18.58 (3.73) compared to 16.28 (4.40) (95% CI 1.19 to 3.41, $p<0.001$). These results suggest that the impact of MBSR on emotional wellbeing is ongoing and support the findings from the POMS with improved mood. In the RCT of yoga by Moadel et al (2007) cited in 6.3.2, between group analysis showed that EWB was significantly improved ($p<0.05$, 95% CI -3.77 to -0.42) after a 12 week yoga programme. This supports the idea that the yoga, the linking or union of mind and body in each moment in the MBSR programme may have had some impact on emotional wellbeing in the current study. The fact that EWB is significantly improved offers triangulation to the POMS results where so many different aspects of mood or emotional wellbeing improved. MBSR may be a useful addition to the range of intervention strategies such as group therapy, education, structured and unstructured counselling, and cognitive behavioural therapy that offer promise for their medium- and long-term benefits for many of the psychosocial outcomes explored (Newell et al 2002).

6.3.4 Functional wellbeing dimension of quality of life

Following exposure to MBSR, functional wellbeing dimension of quality of life (FWB) was significantly improved at eight weeks with intervention group mean (SD) of 19.46 (5.27) compared to controls 17.41(6.06) (95% CI 0.50 to 3.59, $p<0.01$) and at follow-up (95% CI 0.47 to 3.37, $p<0.01$). It is not surprising to find this dimension of quality of life to be improved as mood, physical and emotional wellbeing have been found to be better, then it may follow that people would be able to function better. It is important to find a method to improve functional wellbeing as Avis et al (2005), cited in 6.3.2 found (N=202) lowered functional wellbeing to be associated with not being employed, ongoing treatment, sexual functioning problems, missing work or activities for three months, keeping to self and not using positive cognitive restructuring. Avis's FWB scores were already better than those at any time point in this study, but this could be affected by the younger age group in that study.

6.3.5 Breast-specific quality of life

Breast-specific quality of life as measured by FACT-B evaluating a combination of physical, social, emotional, functional and breast-specific symptoms found there to be significant improvements following exposure to MSBR at eight weeks in intervention group with mean (SD) of 103.56 (17.01) compared to controls (96.87 (21.05) (95% CI 1.33 to 12.05, $p<0.05$,) and at week 12, follow-up 103.78 (17.85) compared to 96.36 (19.39) (95% CI 2.32 to 12.52, $p<0.01$). Finding improvements from MBSR in those factors directly

related to breast cancer and the side effects of treatments is important as it offers a proven way to improve quality of life with breast cancer specifically. Fallowfield (1995) commented on the need to improve psychological, sexual and physical dysfunction in the face of improving 10-year breast cancer survival figures and these results suggest that MBSR may one way of achieving this.

6.3.6 FACT-B trial outcome index

The breast-specific trial outcome index (FACT-B TOI) which includes physical, functional and breast-specific symptoms, was also significantly improved following exposure to MBSR at week eight with mean (SD) in the intervention group of 98.47 (14.37) compared to controls 92.58 (17.67) (95% CI 1.33 to 8.54, $p< 0.01$,) and at maintained week 12, follow-up 98.67 (14.63) compared to controls 61.67 (13.37) (95% CI 1.89 to 8.98, $p<0.01$). Significant improvements found from MBSR in breast-specific quality of life are important findings as restricted range of movement, function and pain (Poleshuck et al 2006, Jung et al 2005, Whelan et al 2000) are known to be problematic post treatment and can last for a long time.

6.3.7. Clinical significance of breast-specific quality of life and trial outcome index

According to previous work on the magnitude of change (Cella et al 2002a, Cella et al 2002b), Fallowfield et al (2004) set a change of over five points to be clinically significant. This equated to around 60% of patients who improved at some point and about 20% who always improved whilst on either anastrazole, Tamoxifen and in combination. The current study showed clinically significant change in breast-related quality of life compared to controls.

Clinically significant improvements were found both post MBSR and at follow-up in FACT-B and FACT-B TOI that demonstrated clinically meaningful improvements (see Table 5.12) in breast related symptoms from MBSR. Comparing results to Fallowfield et al (2004) who measured changes in FACT-B TOI with (n=682) women with no intervention, she found gradual improvements in scores over two years. At 12 weeks improvements in scores in Fallowfield's sample were, for those on Tamoxifen (+2.35) and Armidex (anastrazole) (+0.85). Calculated in the same way, comparing Fallowfield's results to the intervention group exposed to MBSR, mean changes in FACT-B TOI scores rose much more sharply (+ 5.07) in three months from pre-intervention to follow up, however only 56 (49.1%) of the current study's sample were on endocrine treatments.

6.3.8 Endocrine-specific quality of life

Endocrine-specific quality of life was measured in the standard way using FACT-ES combining physical, social/family, emotional, functional and endocrine-specific quality of life. Significant improvements were found at eight weeks in the mean (SD) in the

intervention group 134.97(19.25) compared to controls 127.28 (23.48) (95% CI 1.83 to 13.55, p<0.01) and at 12 weeks 98.67(14.63) and 135.34 (19.54) respectively (95% CI 2.33 to 13.44, p<0.01) demonstrating the value of MBSR to help with endocrine symptoms including hot flushes.

Obtaining statistically significant improvements in endocrine-specific quality of life for these women, around 50% (N= 229) were on Tamoxifen or aromatase inhibitors for up to five years, is an important finding and suggests that MBSR is helping with these symptoms. This study is novel in measuring the effects of MBSR on endocrine symptoms in women affected by breast cancer so brings important new knowledge to this area which affects a large number of women over a long period of time. Being present, returning to the awareness of the body and 'facing symptoms', rather than 'turning away' can help reduce them. Resisting the present moment, fighting against ourselves causes further mental and physical tension, whereas being present, allowing things to be as they are without resistance or aversion, there is an ease brought to any mental or emotional sensation allowing it to be as it is without judgement (Santorelli 2000). This can be applied to symptoms such as hot flushes and insomnia.

Fenlon et al (2008) did not find significant changes in her group from relaxation, endocrine-specific quality of life at baseline was already quite high and her intervention involved only one single relaxation training session followed up with home practice tapes, compared to the eight-week MBSR programme with CDs for daily practice.
Poorer levels of endocrine-specific quality of life were found in this study than those at baseline in Fenlon et al's study of breast cancer survivors with hot flushes). The breast cancer survivors with hot flushes (Fenlon et al 2008) had better baseline endocrine-specific quality of life scores than the current study when measured by FACT-ES mean (SD) scores 170 (152.8 to 173.3) for relaxation (intervention) group and 168.2 (149.3 to 183) for controls. When calculated in the same manner as in Fenlon et al's study, (including breast specific subscale scores), the current study's baseline scores on FACT-ES were poorer with 149.37 (85.69 to 193) for MBSR intervention group and 149.98 (70.00 to 209.00) for controls.

Fallowfield et al (1999), in validating the FACT-ES subscale (N=306), including 136 with primary disease, found that loss of interest in sex was the most frequently reported item with 31% (n= 58) reporting 'very much' or 'quite a bit'. This was reinforced by the current study, where at baseline 39.2% (n=40) of the intervention group and 23.4% (n=26) of controls also reported 'very much' or 'quite a bit'. Measured in the same study, Fallowfield et al found weight gain suffered by 25% of women which is similar to 24.5% (n= 25) in our intervention group and 30.63% (n=34) in controls at baseline. Weight gain has long been

recognised as a side effect of adjuvant treatments for breast cancer and may pose a risk for further recurrence (Levine et al 1991) and finding ways to help reduce it are important. Mindfulness is applied to eating in the first MBSR class with an exercise spent eating three raisons mindfully, so participants can practise awareness of eating and some informally reported that they found this useful with weight gain. The area of mindfulness and eating / eating disorders, has begun to be researched (Smith et al 2006b).

The hot flush rate in the current study was much higher with 42.2%,(n=46) of intervention and 36.9%, (n=41) of controls reported hot flushes at baseline to be 'very much' or 'quite a bit' compared to Fallowfield's (N=306) results of 24%. The high incidence of hot flushes found in the Breast Cancer Haven group give another reason why the current findings of MBSR to help with these symptoms are important in this group and why they sought out additional support from the charity in the first place.

Compared to normative values from the general American population which included both men and women on FACT subscales of physical, social, emotional and functional wellbeing (Webster et al 2003), baseline scores in this breast cancer population were lower, indicating poorer quality of life. There are no UK population norms available for FACT, but as has been seen in the previous discussion, the baseline measures in the current study are lower than some other norms in the cancer population.

6.4 Hypothesis 3: Wellbeing

As a consequence of being exposed to MBSR, there was a significant improvement in overall wellbeing as measured by WHO-5 item wellbeing scale of women with stages 0 to III breast cancer after eight weeks in the intervention group with mean (SD)14.91 (4.23) compared to controls 12.59 (4.92) (95% CI1.06 to 3.56, $p<0.001$) and again after 12 weeks with intervention group scores of 15.08(4.61) compared to controls 12.64 (4.30) (95% CI 1.23 to 3.64, $p<0.001$).

The mean baseline scores (SD) for the WHO-5 wellbeing scale of 13.04 (4.48) for intervention group and 12.53 (4.68) for controls. Although these differences were not significant, control group scores remained below 13 throughout the study. The classification of patients via the Major Depression Inventory (ICD-10) is recommended if the raw WHO-5 score is below 13 or if respondents answered 0 or 1 on any of the five items (World Health Organisation Regional Office for Europe 1998), so referral for psychological review should be considered in patients where WHO-5 scores fall into this category when it is used in clinical practice. This raises issues of the management of such scores in a clinical trial and future studies may want to further screen patients with scores under 13.

Intervention group mean scores improved significantly (95% CI 1.06 to 3.56, p<0.001) from 13.04 to 14.91 post MBSR and 15.48 at follow-up (95% CI 1.23 to 3.64, p<0.001). Scores in the current study were lower at baseline compared to population norms and another Dutch study where van Gestel et al (2007) reported that in women with DCIS, 21% (n=33) WHO-5 wellbeing scale mean score was 16.3 (p=0.14) and women with invasive breast cancer, 35% (n=91), mean score 14.4 (p=0.06). For DCIS, their results were better than Dutch population norms of 15.3 for the same age group, but worse for those with invasive breast cancer. In an uncontrolled study of Mindfulness-Based Cognitive Therapy (MBCT) with oncology and haematology patients of mixed sites (*N*=25), six of whom had breast cancer, Soulsby et al (2007) reported lower baseline mean score of 11.15, calculated from her mean Standardised Percentage Score (SPS) (SD) of 44.6 (22.34). Pre-intervention, 12% of participants in Soulsby et al's study indicated poorer levels of wellbeing than in the current study.

6.4.1 Clinically significant changes in wellbeing

A 10% difference in between-group scores at each time point was deemed to be a clinically significant change (Ware 1995), following exposure to MBSR, the level of change from MBSR was 9.2% at eight weeks and at 12 weeks was 9.7% nearing but not reaching the 10% level of meaningful change. In contrast, Soulsby et al (2007) measuring pre and post MBCT found and an increase of 15.8% in mean SPS scores (SD) 60.40 (22.02). This was a clinically significant level of change, however small sample size (N=25) and lack of randomisation have to be taken into account in that study.

6.5 Hypothesis 4: Stress

As a consequence of being exposed to MBSR, there was a reduction in the perception of stressors of women with stages 0 to III breast cancer relating to 1) breast cancer and 2) other life events in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks.

The perceived difficulty or stress of breast cancer was significantly reduced at eight weeks in the intervention group following exposure to MBSR with mean (SD) of 3.28(2.20) compared to controls 3.98 (2.24) (95% CI -1.32 to -0.07, p<0.01) and at 12 weeks 2.63 (1.94) and 3.64 (2.24) respectively (CI -1.63 to -0.40, p<0.001, 95%). These improvements in stress from MBSR confirm and extend findings by Speca et al (2000) measured with Symptoms of Stress Inventory (SOSI), who found an overall reduction of 30% (n=53) of stress symptoms in cancer patients compared controls with 11.1% (n=36) with significant differences (between <0.05 and <0.01 on several subscales). This demonstrates the value of MBSR in helping with cancer stress, one which is prevalent and can last into the survivorship period (Luecken and Compas 2002, Amir and Ramati 2002).

No significant changes were found as a result of stress caused by major life events apart from breast cancer, but this is in contrast to findings from other studies. In a Finnish study, Lehto et al (2005) found that non-cancer life stresses seem to be very important in lowering the quality of life of newly diagnosed breast cancer patients (n=103). Perceived stress measurements in the current study were made with a simply constructed Likert-scale rather than using validated measures which may have affected the validity of the results and their variations from some other studies in finding patterns.

6.6 Predictors of outcomes

There were a number of factors that were statistically significant predictors of outcomes across both groups at eight weeks and at 12 weeks; these are detailed in Tables 5.18 and 5.19. The baseline measurements of all scales and subscales predicted outcomes in the expected direction, for example, that poorer baseline measurements predicted poorer outcomes as did being in the control group rather than the intervention group at both eight weeks and 12 weeks. The only exception to this was with social wellbeing measured at 12 weeks where being in the intervention group predicted no significant improvement. This is not surprising given the non-significant between group differences found at all time points for social wellbeing. These results are to be expected and provide an indication of a high level of rigour of the current study. The other main predictors of worse outcomes in this study were 1) having undergone mastectomy, 2) an increased number of neoadjuvant chemotherapy cycles received, and 3) the increased stress of the illness.

6.6.1 Mastectomy

Having undergone mastectomy predicted worsened mood scores on a number of different measures both at eight weeks and at 12 weeks. At eight weeks, it predicted worsened scores in total mood disturbance (95% CI 4.03 to 14.4, $p<0.01$), depression (95% CI 0.44 to 5.12, $p<0.05$), anger (95% CI 1.12 to 4.52, $p<0.001$), confusion (95% CI 0.72 to 2.68, $p<0.001$), breast-specific quality of life (95% CI -5.7 to -0.02, $p< 0.05$), breast-specific trial outcome index (95% CI -4.84 to -0.88, $p<0.01$), functional wellbeing (95% CI -2.35 to -0.43, $p<0.01$) and general wellbeing (95% CI -1.95 to -0.19, $p< 0.05$). At 12 weeks mastectomy predicted worse scores on total mood disturbance (95% CI 3.47 to 17.11, $p<0.01$), anxiety (95% CI 0.21 to 3.09, $p<0.05$), anger (95% CI 0.95 to 3.83, $p<0.05$), fatigue (95% CI 0.25 to 3.09, $p<0.05$), confusion (95% CI 0.72 to 2.7, $p<0.001$), endocrine-specific quality of life (95% CI -8.78 to -1.94, $p< 0.001$), endocrine-specific trial outcome index (95% CI -7.0 to -1.76, $p<0.01$), breast-specific quality of life (95% CI -5.15 to -0.15, $p<0.05$), breast-specific trial outcome index (95% CI -3.52 to -0.04, $p<0.05$), and emotional wellbeing (95% CI -2.2 to -0.48, $p<0.01$). In contrast, at 12 weeks, breast conserving surgery (wide local excision or partial mastectomy) predicted worsened endocrine-specific symptoms (95% CI -6.42 to -0.18, $p<0.05$), endocrine-specific trial

outcome index (95% CI -4.88 to -0.16, p<0.05), and emotional wellbeing (95% CI –1.72 to -0.16, p<0.05). These results suggest that mastectomy had a more negative impact on these participants than wide local excision or partial mastectomy. Other research around this issue is equivocal. Dorval et al (1998) found that in breast cancer survivors (N=124), eight years on, where 47 had undergone mastectomy and 77 had partial mastectomy, they found that in women under the age of 50, partial mastectomy was protective against psychological distress whereas for those on or over the age of 50, it was associated with higher levels of distress. As the mean age of participants in the current study was just under 50, this may partially account for mastectomy being a predictor of poorer areas of quality of life. In contrast, Ganz et al (1992) and Kiebert et al (1991) found evidence contrary to this that concluded that the impact of mastectomy versus breast conserving surgery was not significantly different on quality of life but Dorval et al (1998) found that both short and long term levels of distress may depend on age at diagnosis of breast cancer. This was not borne out by the current study. Several studies suggest that lumpectomy patients judge their body image and sexual attractiveness more positively than mastectomy patients, however when psychological adjustment of both groups of patients are compared, most studies found little or no difference in depression and anxiety levels (Rowland and Massie 1998).

In the current study, both wide local excision/partial mastectomy and mastectomy predicted poorer emotional wellbeing and worse endocrine symptoms at 12 weeks which suggests longer term physical and emotional impact from breast surgery. Levy et al (1992) also found ongoing effects of breast surgery, that having breast conserving surgery was no psychological panacea and that those who were younger, appeared to have psychological symptoms that appeared worse at three months post surgery and in the end are similar to those who elect to have mastectomies when measured at 15 months. There is a need for further research to clarify the psychological and physical impact of different kinds of surgery for breast cancer.

6.6.2 Increased number of neoadjuvant chemotherapy cycles

Having received an increased number of neoadjuvant chemotherapy cycles (pre-surgery) predicted worse outcomes at eight weeks of depression (95% CI 0.1 to 1.42, p<0.05), emotional wellbeing (95% CI -0.51 to -0.11, p<0.01), and general wellbeing (95% CI -0.60 to -0.08, p<0.01). At 12 weeks, worse scores were predicted in depression (95% CI 0.10 to 1.30, p<0.05), fatigue (95% CI 0.01 to 0.81, p<0.05), emotional wellbeing (95% CI -0.41 to -0.01, p<0.05), and general wellbeing (95% CI -1.94 to -0.30, p<0.01). In contrast, adjuvant chemotherapy (post surgery) did not predict worsened outcomes at all, however it should be noted that 7/20 in the intervention group and 4/8 in the control group who had neoadjuvant chemotherapy also had adjuvant chemotherapy, the impact of having both on

quality of life is not clear from this study. Previous research has suggested impact on physiological functioning in some people but the mechanisms for these changes are not fully understood (Hermelink et al 2007). Recommendations have been made for quality of life evaluation in trials (van der Hage 2001, Fallowfield 1995) and more research is needed to fully understand the impact of having both neoadjuvant and adjuvant chemotherapy on quality of life.

6.6.3 Increased difficulty or stress of illness

At eight weeks, increased difficulty or stress of illness predicted worse outcomes on breast-specific quality of life (95% CI -2.44 to -0.36, p<0.01), breast-specific trial outcome index (95% CI -1.51 to -0.19, p<0.01), social wellbeing (95% CI -0.46 to -0.02, p<0.05), emotional wellbeing (95% CI -0.58 to -0.10, p<0.01), and functional wellbeing (95% CI -0.66 to -0.06, p<0.05). At 12 weeks, increased stress or difficulty of illness predicted worse outcomes in endocrine-specific quality of life (95% CI -2.74 to -0.74, p<0.001), endocrine-specific trial outcome index (95% CI -2.19 to -0.63, p<0.001), breast-specific trial outcome index (95% CI 0.02 to 0.1, p<0.001), physical wellbeing (95% CI -0.55 to -0.11, p<0.01), and social wellbeing (95% CI -0.51 to -0.03, p<0.05). Andersen et al (1998) found that the stress of diagnosis and treatment of breast cancer (n=116) can inhibit cellular immune response including T-cells and N-K cells which may be connected with findings that increased stress predicted poorer outcomes in a range of physical and psychological wellbeing in the current study.

6.6.4 Predictors of outcomes from the intervention group

There were a number of variables which predicted outcomes in the intervention group exposed to MBSR at both eight weeks and 12 weeks which are detailed in Tables 5.18 and 5.19 respectively. The most prevalent of those predictors are discussed below.

6.6.4.1 Predictors of outcomes in the intervention group

Both increased participation in MBSR and increased hours of mindfulness formal home practice predicted better outcomes on a range of measures for physical and psychological wellbeing, the details of which are presented here. At eight weeks, increased hours of formal mindfulness home practice predicted significant improvements in the alleviation of anger (p<0.01) and general wellbeing (p<0.01). At 12 weeks, increased hours of formal mindfulness home practice predicted significant improvements in total mood disturbance (p<0.01), vigour (p<0.01), confusion (p<0.001), endocrine-specific quality of life (p<0.01), endocrine-specific trial outcome index (p<0.01), and general wellbeing (p<0.01). The increased number of weekly sessions attended

predicted significant improvements in breast specific quality of life ($p<0.01$) and breast-specific trial outcome index ($p<0.01$). These results suggest that an increased level of participation in the MBSR programme predicted improvements in outcomes.

6.6.4.2 Time spent participating in MBSR and doing home practice

Time spent participating in MBSR was high and adherence to the programme was good with mean classroom attendance of 2.18 hours per week and the mean number of weekly sessions attended were 6.26 of a possible eight, suggesting high motivation to attend by participants in the intervention group. The length of home practice CDs in this study were 45 minutes which is standard for MBSR course taught at the University of Massachusetts. Over the eight week period, an average of 33 minutes per day of mindfulness practice was done. Including formal mindfulness practice done in the classroom, matching the method used by Speca (2008), it was slightly more than the results in his MBSR study of 32 minutes per day (Speca et al 2000) and was more than six times greater than the daily average of five minutes per day found in breast cancer patients studied by Shapiro et al (2003). Shapiro implied that she expected participants to practise for 30 minutes, but did not state explicitly if there were any home practice tapes given out and if so, how long they were. A personal communication with Speca (2009) revealed that the length of Speca et al's home practice tapes in his study (Speca et al 2000) were 30 minutes with participants being asked to practise for 45 minutes by combining practices and they had leave not to use the tapes if instructions were internalised. Explanations for the high levels of compliance with practice over the eight-week period in the current study may also simply be that participants were motivated and over time felt better for practising mindfulness and also that they were asked to record home practice as part of the study which some participants reported as motivating. Carmody and Baer (2008) found no support for an explanation that more mindful people are more likely to practise meditation when they looked at baseline measures of mindfulness and the extent of home practice.

6.7 Hypothesis 5: Dose related effects of mindfulness

Increased MBSR classroom attendance and mindfulness practice hours will predict improvement in mood state, quality of life and wellbeing in women with stages 0 to III breast cancer in the intervention group, the effects being measured after eight weeks and again after 12 weeks.

Finding that increased mindfulness practice predicted improvements in such diverse aspect of physical or emotional quality of life over time, supported the fifth hypothesis of the study and suggests that its potential benefits of mindfulness practice to be broad (see Tables 5.20 and 5.21 for details). These findings reinforced those of Shapiro et al (2003) that practising mindfulness had a specific therapeutic effect that is not found by only attending the intervention and confirm those in other studies where mindfulness has been found to be beneficial across a range of conditions and symptoms (Baer 2003). Carmody and Baer (2008) found support for the tenet of several mindfulness-based approaches that the regular practice of meditation should cultivate mindfulness skills in everyday life, which in turn should lead to improved psychological functioning such as symptom reduction, reduced stress and enhanced wellbeing. Kabat-Zinn et al (1998a) commented that mindfulness is way of being, a way of living one's life, and as a way of developing alternative generic strategies for coping with life's stresses. It is not seen as a technique for solely coping with a specific problem such as cancer, pain or mental illness. In MBSR, mindfulness practices such as mindfulness meditation and mindful stretching exercises are taught to be practised regularly as a daily discipline (Kabat-Zinn 1990).

The fact that increased hours of MBSR classroom time attended did not predict improvements in social wellbeing compounded the lack of between group differences in these results. This is an area where the quantitative data showed no improvement despite some positive comments from the qualitative data. This may have been a reflection of the tool used or it may have been for other reasons. Social wellbeing for breast cancer patients is known to be an area where support from breast care nurses was inconclusive (Cruickshank et al 2008). It has also been found that social wellbeing is better in breast cancer patients where disease is stable (Frost et al 2000). Disease was stable for most of the participants in the current study, but levels of social wellbeing were still lower than in some other studies, so this area needs further investigation.

6.8 Discussion of qualitative findings

Qualitative data was collected at the end of the MBSR classes and the results analysed were from the intervention group only (n=92). The discussion below about the qualitative data should take this into consideration. Qualitative data was collected for two reasons, to further illuminate the nature of the intervention, as experienced by the participants and also to see if participants considered themselves to have become more mindful.

6.8.1 Becoming more mindful

Following the Transfer Viva in December 2005, an additional question about mindfulness was added to the short proforma given at the end of the eight-week MBSR class during the course of the study. The reason for this was to be able to explore whether doing

MBSR did make participants more mindful. A reduced number of participants from the intervention group (n= 39) answered that question, but all stated that they had experienced a greater degree of mindfulness as a result of participating in MBSR where it was described as 'bringing our attention and awareness to the present moment in a non-judgemental way'. This was supported by findings from the qualitative data that increased present moment awareness, connection and acceptance resulted from MBSR. This is a novel finding in MBSR and cancer studies as mindfulness was not previously measured by Speca et al (2000), Shapiro et al (2003) or Carlson et al (2007) and there are other finding from recent qualitative studies (Mackenzie at al 2007, Dobkin 2008) which found some elements of mindfulness to have been cultivated. Baer et al (2008) commented that most of the newly developed mindfulness scales give a total score on multiple trait-like components of mindfulness including attention, awareness, opening, letting go, non-judging, acceptance and non-aversion, but do not measure them separately. The current study had only one simple question in relation to becoming more mindful, this can be viewed as a limitation. Future studies in MBSR and cancer should include a measurement tool for mindfulness which would enable researchers to evaluate more accurately whether mindfulness has been cultivated and to measure this impact on participants.

It is possible that the way in which mindfulness can be cultivated, that of 'non-doing' may be seen as a tension when trying to explain the mechanism which explains its action. It can be argued that the aspect of non-doing in mindfulness - allowing things to be as they are, acceptance, letting go, resting in awareness - is what enables change to happen (Tolle 2006). Non-doing is an alert process of bringing one's attention and awareness back to the present moment experience again and again, rather than a passive state where the mind wanders aimlessly with no direction.

6.8.2 Key emerging themes from qualitative data

The key themes from participating in MBSR and practising mindfulness reinforced some findings and provided new insights compared to other mindfulness studies in cancer populations (Mackenzie at al 2007, Dobkin 2008) (see Table 6.1). Increased awareness and connection were common to all studies.

6.8.2.1 Being more aware

As a result of being exposed to MBSR, being more aware was found to be the most positive effect by 29.3% (n=27) of participants. This is the process of cultivating moment to moment clear awareness of one's changing inner or outer worlds, including thoughts, emotions, sensations, actions, or surroundings. This unbiased awareness, free from judgements and reactions, is thought to facilitate insights into reality, offering the ability to see phenomena which would otherwise have been obscured from view (Brown et al

2007a) and is central to mindfulness practice. It enables people to make healthier choices for less stressful lives. These findings are supported by Mackenzie et al (2006) who found participants began to see how through mindfulness practice, they could choose to change habitual responses to stress, letting go of patterns that were no longer helpful and Dobkin (2008) found that participants tried to be watchful of the influence of events and circumstances on their lives.

6.8.2.2 Being calmer, centred, at peace, connected and more confident

Being calmer, centred, at peace, connected and more confident was expressed as being beneficial from mindfulness practice in 32.6% (n=30) of participants. Many participants commented about being calmer as a result of mindfulness practice. This was supported by other literature evaluating the effects of mindfulness. As the mind quietens, there is a chance to reperceive (see one's options and reactions), self-regulate (Shapiro et al 2006b) and develop self-control (Mackenzie at al 2006). This can lead to feelings of more self confidence. Connection and acceptance found amongst participants from MBSR reinforces the view that intentionally cultivating non-judgemental attention leads to connection, self-regulation, greater order and health (Shapiro et al 2006b). Mackenzie et al (2006) noted that connecting with others, sharing their cancer and meditation experiences added to the benefit of social support alone.

6.8.2.3 Coping better with stress, anxiety and panic

Coping better with stress, anxiety and panic was experienced by 29.3% (n=27) of participants after MBSR. Through mindfulness, it has been understood that by stepping back from situations and people, attitudes towards them becomes less stressful or difficult, because those tensions will be lacking which so often arise from self reference such as interference, desire or aversion, so life becomes much easier (Nyanaponika 1992). Mackenzie et al (2006) found personal growth enabled MBSR participants to respond differently to their illness and stressful events, identifying some positive benefits. Dobkin (2008) found that through mindfulness, taking responsibility for what could change made stressors easier to cope with, whilst not feeling more stressed when a situation remained unchanged.

6.8.2 4 Acceptance and less judgement

Accepting things as they are and being less judgemental of myself and others was experienced by 19.6% (n=18) participants following MBSR. Acceptance or non-judgement has also been described as experiencing one's situation as it is happening without clinging to it or rejecting it (Leary and Tate 2007). Mindfulness fosters an openness, active participation and ever present curiosity to experience phenomena that arise from moment to moment (Brown et al 2007a) as it is before judgement arises. Dobkin (2008) found that

participants spoke largely of their journey towards acceptance, having first acknowledged that things are not necessarily how one would like them to be, but that they were as deserving of happiness as anyone else.

6.8.2.5 Improved communication and personal relationships

Participants in the current study found that mindfulness helped them cope with life's challenges including improved communication and personal relationships being most beneficial for 17.4% (n=16) of MBSR participants. This finding was supported by results from Mackenzie et al (2006) under the theme of spirituality. Mackenzie et al expressed a greater sense of basic trust, openness and caring from MBSR. Through mindfulness practice, by coming from a place of greater ease from within, people can experience input into interpersonal relationships coming from an overflowing cup (Garrie Rōshi 1998), rather than from one that is depleted or half-empty.

6.8.2.6 The challenges of mindfulness practice

Participants were asked directly about the challenges of mindfulness practice and this has produced new data. Difficulty in finding time to practice and noticing how much the mind wanders from the present were two of the greatest challenges of MSBR found in this study. Finding time and space for oneself is an ongoing challenge in a busy life, no matter the reason, and this can often be as much of a mental or emotional challenge as a physical one. Techniques were discussed in class as to how to work with this and two of the most useful were to ask people to do mindfulness practice as suggested by Kabat-Zinn (2004, personal communication) 'whether they want to/feel like it or not' and also to place time in their diaries for themselves each day, making time for themselves a priority. This view challenges cultural norms where giving time to ourselves ahead of what we perceive the needs of others to be can go against the grain, especially for middle-aged women, many of whom are both mothers and caregivers to the elderly. These complex roles bring their own challenges and feelings of adequacy can act as a mediator for role-specific stress such as these (Franks and Stephens 1992). Feeling more confident (adequate) as a result of giving time to self to practise mindfulness may be one of the mechanisms through which change was achieved.

The wandering mind is common to everyone who cultivates mindfulness which is why the development of concentration is emphasised in the early stages of mindful development (Rahula 1974, Nyanaponika 1992). Whilst the mind never ceases to wander, with practice over time, the spaces between thoughts can increase. This then gives rise to a non-discursive, non-analytical (label and thought free), direct experience of the object of attention (Kabat-Zinn et al 1992). This provides more clarity, stillness and peace in our approach to life.

Table 6.1. Comparisons of themes from qualitative data measuring mindfulness in cancer populations

Current study (n=92)	Mackenzie at al (2007) Mixed cancer patients (n=9)	Dobkin (2008) Completed medical treatment for breast cancer (n=13)
Being more aware	Opening to change	Spirit of openness and connectedness
Being calmer, centred, at peace, connected and more confident	Self-control Shared experience	Regaining and sustaining mindful control
Accepting things as they are, being less judgemental of myself and others		Acceptance
Coping with stress, anxiety and panic	Personal growth	Taking responsibility for what could change
Improved communication and personal relationships	Spirituality	
Making time and creating space for myself		
The value and challenges of mindfulness practice		

6.9 Where MBSR was not helpful

MBSR did not significantly improve social quality of life as measured by FACT-B at eight or twelve weeks, or physical wellbeing at eight weeks. In contrast, there were changes in physical wellbeing in relation to breast-specific and endocrine-specific symptoms. It may be that the physical symptoms measured by FACT had less relevance to this group of survivors, for example, I have nausea, I feel ill, I need to spend time in bed, than they would for those going through treatment such as chemotherapy or radiotherapy (which these participants had completed). Baseline mean (SD) for PWB of this study was 21.88 (4.29) in intervention group and 21.89 (4.35) compared to breast cancer population norms of 21.0 (5.8) suggesting slightly better function in the current study at baseline. Social wellbeing mean (SD) at baseline were worse for intervention 17.59 (5.91) and controls 18.78 (56.01) when compared to the same norms 23.3 (4.2) (Brady et al 1997) and there were no significant between group improvements in the current study over time.

6.10 Study strengths and limitations

6.10.1 Rigour of the study design

This study was conducted as rigorously as possible and is larger, adequately powered and more rigorously evaluated than previous randomised controlled studies involving MBSR and cancer or breast cancer populations (Speca et al 2000, Shapiro et al 2003). Using a mixed methods approach, this study recruited 229 participants and analysed their demographic data, and analysed results from all (n=214) except for the few with missing baseline questionnaire data. This well exceeded the number of 85 participants per arm required for 80% power. The handling of missing data followed the guidelines from the appropriate questionnaire manuals and analysis of results followed rules of Intention To Treat (ITT) with between groups analysis. In the previous randomised controlled study of MSBR and cancer, secondary analysis had been employed to elicit results as these no significance was found under ITT (Speca et al 2000). Univariate, multivariate and stepwise regression was used and reported explicitly in a way that had not been done in such detail in other studies of MSBR and breast cancer (Shapiro et al 2003).

6.10.2 Sampling

The study engaged a convenience sampling strategy of women with stages 0 to III breast cancer between two months and two years post hospital treatment who had previously attended Breast Cancer Haven (BCH) in London for support and complementary therapies, so there was a selection bias in the sample. Using a convenience sampling strategy can be viewed as a limitation. As a self-selected group who had actively sought information, support and complementary therapies and who matched the recruitment criteria, it is not possible to generalise these results to all breast cancer patients, although as previously noted, many of the results confirmed or extended those found in north American studies of MBSR in cancer populations. However, it should be noted that participants were all under the care of NHS Consultant surgeons or oncologists as well as their GPs.

6.10.3 Response to study invitation

Nearly half of those who initially responded to the invitation letter to join the study (n=297) were interested in the study, suggesting the need for stress reduction and self-management programmes in this group despite receiving prior support during breast cancer treatment. This study has therefore raised the question of the extent of ongoing needs of those with breast cancer for additional support and effective ways to self-manage. Rees et al (2000) found 31.5% (n=714) of breast patients in the South Thames region of London had sought complementary therapies following diagnosis suggesting that the response to the study invitation is not atypical of breast patients who actively seek help for themselves. As this sample is not typical of all breast cancer patients in the UK,

the results are not generalisable beyond those attending Breast Cancer Haven or possibly to those who actively seek support and complementary therapies in addition to their medical treatment.

6.10.4 Low age of participants

The mean age of participants at randomisation was 49.5 years, average for attending Breast Cancer Haven in London and much lower than the average age for breast cancer in the UK where 80% of cases occur in women over the age of 50 (Cancer Research UK 2008a). Breast Cancer Haven tends to attract younger women with breast cancer who are interested in psychological support and complementary therapies as has been found in previous studies (Molassiotis et al 2005, Cassileth and Vickers 2005, Downer et al 1994). Increased age at randomisation in this study predicted poorer functional wellbeing after MSBR and at follow-up, poorer physical and functional symptoms relating to breast- and endocrine-specific wellbeing. These results support earlier studies where those (N=105) who received a diagnosis at an older age (>65 years) showed worse physical outcomes than those diagnosed at a younger age (Cimprich et al 2002). These results are in contrast to earlier work (Ganz et al 1998) which suggests that breast cancer survivors (N=864) report more frequent physical and menopausal symptoms than healthy women, but report health-related quality of life and sexual functioning comparable to that of age-matched, healthy women. They also found that some survivors still experience poorer functioning. This area needs more investigation.

6.10.5 Socioeconomic class

Participants' social class was high with over 90% (n=210) participants in the highest social grades AB and C1, thus there was socioeconomic bias in the sample. This reinforces previous findings (Molassiotis et al 2005, Cassileth and Vickers 2005, Downer et al 1994) that people who seek complementary therapies are better educated, of higher socio-economic status, more likely to be female and also younger than those who do not. The question of how to engage those of lower socio-economic groups in supportive services and in research is an important one as socioeconomic inequalities in healthcare are well recognised in all EU countries (Mackenbach et al 1997) at government level; there is a commitment to reduce barriers to health equality (Goddard 2009). Researching the health needs of those from lower socio-economic grades with breast cancer is an ongoing challenge (Miller 2009) without simple solutions. As Breast Cancer Haven services are offered free of charge, as was participation in the research study, the factors which prevented participants from a wider range of socio-economic groups from seeking this support and the opportunity to join this study are not well understood, but as there are government targets to improve access to supportive services for those from lower

socioeconomic groups, there is need for further research to understand how to engage with these groups better to enable them to participate in such programmes as MBSR.

By omission, a limitation of the current study was that no data on educational status and social grade were obtained at recruitment. This information was gathered retrospectively through information from existing BCH Visitor files and where missing, the social grade of participants was estimated from the most prevalent grade of the area in which they lived. These are further limitations of the study and once again have impact on the generalisability of findings beyond the population under study.

6.10.6 Stage of breast cancer

Participants' stage of breast cancer ranged from 0 to III but the highest number of participants 41% (n=94) were diagnosed with stage II breast cancer. Of all participants, 6.2% (n=14) had experienced a recurrence of breast cancer before entering the study and been treated for this. Higher stages of breast cancer predicted poorer scores on general wellbeing after MBSR. Whilst stage of breast cancer is not the same as grade, this may extend findings of other studies finding of poorer quality of life in those with higher grade breast cancers (Northouse et al 2002) as a higher grade of breast cancer suggests more aggressive disease and are more likely to progress to a higher stage indicating worse disease. This area needs more research. These results are therefore not generalisable to people with distant metastatic (Stage IV) breast cancer.

6.10.7 Appropriateness of measurement tools

Two of the main measurement tools of this study were developed in the USA, the Profile of Mood State (POMS) (primary outcome measure) and the breast specific (FACT-B) and endocrine-specific (FACT-ES) quality of life scales (secondary outcome measures). The third was the European-based World Health Organisation (WHO) five-item wellbeing scale. The FACT scales were chosen especially to enable measurement of endocrine symptoms which was not available with the European developed quality of life such as the European Organisation for the Research and Treatment of Cancer (EORTC) QLQ C-30. This could be seen a limitation of this study when trying to compare results to other European studies of quality of life in breast cancer. Another difficulty with using American scales was that a few of the terms may have been less familiar to UK participants, for example 'full of pep' in POMS. A further limitation of the study was the use of the unvalidated Likert-scale stress measurements. As Fallowfield (1995) commented, one of the primary problems about people constructing their own quality of life instruments is that it becomes difficult to pool data for meta-analysis or to compare outcomes across trials and disease states. Not using one of the more recently established mindfulness measurement tools can be seen as a limitation of this study, but at the time of

development of the study, most of the existing mindfulness measures had not been validated, this work came later (Baer et al 2006, 2008).

6.10.8 Impact of timescales of study

The mean period between the finish of the hospital treatment and randomisation was over nine months in each group. That scores at baseline on mood (and other quality of life) were poorer than in breast cancer norms (Cassileth et al 1985) gives testament to the ongoing impact of breast cancer on both physical and psychological aspects of quality of life after treatment finishes (Ganz et al 2002, Whelan et al 2000) or may mean that people coming to Breast Cancer Haven had worse symptoms than the small sample tested by Cassileth. The extent to which participants were randomly allocated to the intervention or control group may have had an effect on scores although scores at baseline did not differ significantly and controls did receive the intervention, although delayed by three months. The short four-week follow-up period is a limitation but was necessarily brief to enable the wait-list control group to start their MBSR programme without too much delay and a longer period was not feasible in the context of doctoral research. Carlson et al (2001) performed a longer six-month follow up of cancer outpatients reported by Speca et al (2000), but found only non-significant improvement in change scores on POMS from the end of MBSR from paired sample t-tests. This is an area that needs further investigation.

6.10.9 Influence of pre-study recruitment interview

The pre-study recruitment interview of up to one hour has to be regarded as part of the therapeutic input in the study. This interview was conducted by the clinician-researcher who also led the MBSR programme. Giving the clinician-researcher time to explain the study in full and listen to any concerns and answer questions from potential participants was seen as an important part in minimizing risk, ensuring safety and, as far as possible, ensuring the appropriate selection of participants as well as helping to minimize dropouts. It may have also led to further trust in the clinician-researcher as well which could have affected results positively, but as it was conducted pre-allocation, it would have equally affected both intervention and control groups.

6.10.10 Strength of control group

The control arm of this study was wait-listed and received no specific intervention during the control period so was the equivalent to treatment as usual or no active intervention. Finding appropriate methods of control, comparable interventions and blinding in pragmatic complementary therapy intervention research is not straight forward and methods used in other complementary therapy studies such as sham acupuncture in acupuncture trials (Lewith et al 2002) is under question. Whilst not ideal, wait-list controls have been used before in MBSR studies (Speca et al 2000, Astin 1997, Shapiro et al

1998). Alternative ‘active controls’ or ‘active placebos’ are traditionally used, but finding ways to mimic effects of complex programmes such as MBSR in a pragmatic trial without having an active ingredient distinguishable by patients is challenging and a subject for further investigation.

6.10.11 Reasons of dropouts

Dropout rates from the current study were low (11 in the intervention group and four controls) similar to results by Speca et al (2000). From data for the intervention group, being a study dropout predicted higher levels of anxiety (95% CI -15.26 to -2.10, $p<0.01$) and worse endocrine symptoms (95% CI -1.88 to 22.36, $p<0.05$) at eight weeks. This reinforced findings by Speca et al (2000) that participants with higher levels of anxiety ($p<0.05$) were more likely to drop out. Dropout rates from the eight-week MBSR in the intervention group, (where four or less sessions were attended) were 16.7% (n=19), with the most common reasons given were work (5), too busy (3), and other life events (3). It is already known that academic performance can be affected by anxiety (Seipp 1991), so it may be that the demands of the eight-week MBSR programme were too much for some more anxious participants. The fact that the current study population was mostly from the higher social classes may have helped adherence as MBSR in low income, multi-ethnic communities of American women with abnormal pap smears found high attrition rates despite financial incentives for participants to attend (Abercrombie et al 2007).

6.10.12 Impact of breast cancer treatment

In the treatment of breast cancer, nearly 40% of participants had undergone mastectomy compared to 60% who had breast conserving surgery. Over 50% of this sample had chemotherapy, over 70% had radiotherapy and over half the study sample had undergone all three treatments of surgery, chemotherapy and radiotherapy and nearly half were on hormonal medication post treatment. Approximately half of those who had neoadjuvant chemotherapy also had adjuvant chemotherapy. The medical treatment received by study participants was standard compared to available UK treatment audit (NHS Breast Screening Programme and Association of Breast Surgery at BASO 2008, Storey 2009). It is known that past chemotherapy (Ganz et al 2002) and radiotherapy (Whelan et al 2000) predict poorer quality of life and that a combination of treatments exacerbates symptoms. More than half of participants (55%) were on long-term endocrine treatments with over 30% on Tamoxifen and over 10% on Arimidex known to impact quality of life (Day et al 1999, Fallowfield et al 2004). This may help explain why baseline levels of mood disturbance, quality of life and wellbeing were lower than norms.

6.10.13 Attendance of the Haven Programme

Attendance of the Haven Programme prior to MBSR was equal between groups prior to the study but those in the intervention group attended a mean of nearly 20 minutes more during the study period which may be accounted for by the fact that coming to BCH for the MBSR programme alerted them to other activities that they could attend at the centre. This may have had a confounding effect on results and a limitation of the study. There was no way of knowing what participants in either the intervention or control groups chose to do outside of MSBR course in terms of other self-management activities undertaken, particularly activities done outside BCH, so there is potential contamination of the study from this. Over the scope of the eight-week MBSR programme, the 20 minutes of additional attendance at the Haven is unlikely to have had a significant impact on outcomes.

6.10.14 Tensions of the clinician-researcher role

Viewed within the predominant positivistic paradigm, another potential limitation of the study was that the clinician-researcher was the same person, both performing the research and delivering the MBSR intervention. The issue under question here is the way in which clinical considerations are united with the rigid methodological demands of quantitative research (Sandahl and Wilberg 2006). There is potential conflict in this role in terms of conducting the study as the integrity of the role of the researcher or of the clinician could be compromised when this role is shared by the same individual. This tension is recognised in the literature and should be performed keeping the roles as separate as possible and maintaining clinical appropriateness (Field and Morse 1985, Chenitz 1986). There were numerous points throughout the study where there was a potential tension between the two roles. The initial letter of invitation to potential participants to join the study came from the clinician-researcher and the follow-up phone contact then came directly to her. Also, conducting the pre-randomisation recruitment interview, a therapeutic encounter, may have influenced participants' decision to join the study. To minimise bias as much as possible, random allocation was performed by staff not involved in the delivery of the intervention as was collection of and data entry from the questionnaires. It has been suggested that being economical with the truth could be a greater dilemma for the researcher-practitioner than an outside researcher (Fraser 1997) so separation of these roles in the areas mentioned above was vital. In order not to compromise the rigour of the study, the clinician-researcher did not have further clinical contact with any of the participants during the course of the study other than clarification and support in the context of the MSBR programme.

Had the interpretative paradigm been dominant in the study then the reflexive principle would have applied and the involvement of the clinician-researcher in the study would

have been a precursor to better understanding the data. In this context, it may have been an advantage in the analysis of the qualitative data, although detailed methodological (reflexive) notes were not kept throughout the whole period of the study.

In this research, even the choice of topic could be seen as a potential source of bias as the clinician-researcher chose the topic that she was interested in. This in itself could be seen as a potential bias from the researcher perspective. People dropping out from the study was also a source of potential conflict as, from a research point of view, there was a desire to keep study numbers up, but from a clinical stance, the most important issue was to care for the needs of the individual.

Sandahl and Wilberg (2006), when leading analytic group psychotherapy and then doing group evaluation and follow-up interviews, commented that:

> 'As clinicians, we know how sensitive patients are to their therapist's needs. It is not unlikely that some of the patients wanted to reward the therapist with a 'happy ending'. The standard questionnaires, however, may be considered relatively reliable' (Sandahl and Wilberg 2006, p. 404).

These comments could be applied directly to this study, where there was some qualitative data collected which participants placed in a box in the classroom on the last week of the course, in addition to the more distant questionnaire data collected by the research assistant.

In this joint role for the clinician-researcher, there is also the disadvantage of balancing the research activities alongside a full-time job (Drucker 1994). This balancing of the clinician-researcher role is complex and one that needs consideration at every moment of the study in order to maintain study rigour.

6.10.15 Understanding the active components of MBSR

MBSR has been described as a multi-component intervention (Speca et al 2000) or a package of care (Smith et al 2005) and it is difficult to isolate the mechanisms of action or specific aspects that account for improvements. The argument against this is that mindfulness, as a 'way of being' or living one's life (Kabat-Zinn 1990) can be effective throughout all techniques delivered and it may not matter whether mindful yoga-based stretches or, for example, mindful Tai Chi is offered. Further dismantling studies to isolate active components are needed to validate this point.

6.10.16 Understanding what mindfulness is

Rigorous papers examining the conceptualisation of mindfulness have only been published recently (Brown et al 2007a) and it was hoped that results from this study would help feed into the development of this conceptualisation. Results from the current study, particularly the key findings from the qualitative data support the conceptual components developed by Brown et al and extend existing findings, providing new insights that MBSR does increase mindfulness in breast cancer survivors.

6.10.17 Ongoing self-management

MBSR is becoming an increasingly popular intervention in healthcare, education, social and business settings since its creation 30 years ago. Reasons for applying it to healthcare and specifically cancer populations and breast cancer survivors as this study shows, is that it can help with physical and psychological side effects of the disease and its treatments as well as providing a way for people to live their lives with less stress. Important factors about the intervention is that it is a time-limited, eight-week self-management programme, taught in a group setting which not only offers the opportunity for those in similar situations to come together, but is more cost effective than individual therapy. In addition, the MSBR programme provided CDs to guide daily home practice which could be used after the programme is finished, providing ongoing self-management to those affected if the techniques have not been internalised. Patient education provides the basis for self-management later performed by patients, making them partners in their own healthcare rather than passive recipients (Creer and Holroyd 1997) and other forms of self-management have been found to improve self-efficacy and reduce health care costs (Lorig et al 2001). The cost effectiveness of MBSR requires further research. This study has shown that it is possible to run MBSR groups effectively with breast cancer survivors eager to find better ways to help themselves whilst living with breast cancer and its possible future sequelae. At Breast Cancer Haven, ongoing fortnightly drop-in MBSR groups have been running since the completion of the study for the benefit of participants who wanted some further support and to introduce mindfulness to those who have not yet done MSBR. Due to time constraints, further eight-week programmes have not been started following the study, but will resume in September 2009.

6.10.18 Limitations of the data collected

Whilst the primary outcome measure (POMS) was a validated tool as were the secondary outcome measures FACT-B and FACT-ES, (a strength of the current study), using two unvalidated Likert scales to measure stress is a limitation. The reason for this is that there may be questions about the validity of the tools, whether they measure what they set out to and also being a newly created tool prevents direct comparisons with the results of other studies in the same area. Limitations of the qualitative data include 1) having added

an additional question part way through the study, 2) using a short proforma that allowed for a moderate amount of qualitative data to be collected, but did not provide the same quantity and depth of information that could have been collected from in depth qualitative interviews.

6.11 Transferability of MBSR to NHS settings

Whilst this programme has been taught to those affected by breast cancer in the voluntary sector, it is conceivable that this programme could be run in the NHS cancer setting as has been done in Wales (Soulsby et al 2007) and in other cancer centres worldwide (Speca et al 2000, Carlson et al 2004). Nurses, psychologists, medical doctors, social workers and other professionals can train in MBSR and other mindfulness-based programmes if they had an existing personal practice of mindfulness meditation at recognised centres locally and internationally (University of Bangor 2009, University of Massachusetts 2009).

6.12 Conclusion of discussion chapter

This chapter has discussed key findings, predictors of outcomes, limitations and generalisability of findings in the context of existing and relevant literature. The fact that research in MBSR and cancer is relatively new and that there are few high quality rigorous trials previously published, gave reason for this study being performed, but also limited the possible extent and depth of discussion of the findings in comparison to other studies. The key conclusions of this study and a summary of the limitations and the key clinical and future research implications will be discussed in the Conclusions Chapter 7.

Chapter 7. Conclusions

7.1 Introduction

This chapter will summarise the key findings and discuss these in the current healthcare context. This study was designed to take into account some of the methodological weaknesses in existing studies as part of its contribution to the area of research. This study reinforced and extended the findings of other studies of MBSR in cancer showing improvements in mood, quality of life including endocrines symptoms and wellbeing in women following treatment for stages 0 to III breast cancer who had attended Breast Cancer Haven. Key limitations are summarised taking into account possible future research that could be performed to address them. Recommendations are made for possible service developments based on these findings.

7.2 Conclusions

Mindfulness-based stress reduction (MBSR) significantly improved mood, quality of life, including endocrine symptoms, and wellbeing for women diagnosed with stages 0 to III breast cancer compared to controls immediately after MBSR at eight weeks and these improvements lasted for the four-week follow-up period. Details of these conclusions linked to the relevant study hypotheses are discussed below.

In relation to mood state, the primary outcome measure for the study, statistically significant improvements were found following MBSR compared to controls in POMS total mood disturbance, and the mood subscales of anxiety, depression, anger, vigour, fatigue and confusion. These results supported the first hypothesis of the study that, as a consequence of being exposed to MBSR, there was an improvement in mood for women with breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks. These results reinforced and extended results found in other studies of MBSR and cancer (Speca et al 2000) by showing a broader range of psychological parameters where MBSR was helpful in women with breast cancer. Baseline levels of total mood disturbance were worse than those in other MBSR and cancer studies for reasons that are not entirely clear. This may have been influenced by the time of recruitment for the study which followed the completion of the breast cancer treatments of surgery, chemotherapy and radiotherapy, a time when emotional issues may come to the surface.

As well as these significant improvements in mood supporting findings from other MBSR and cancer studies (Speca et al 2000), significant improvements in anxiety reinforce and extend findings from some non-cancer studies looking at anxiety and MBSR (Kabat-Zinn et al 1992, Miller et al 1995). This is important as anxiety is a common psychological

problem experienced by people with cancer (Derogatis et al 1983). Improvements in depression reinforced findings from research done specifically with patients with a history of depression using mindfulness-based cognitive therapy (MBCT) (Teasdale et al 2000). Depression is the most common psychological symptom experienced by people with cancer including breast cancer (Spiegal 1996). Finding that MBSR improves anger is useful considering breast cancer and its possible ongoing sequelae. Improvements in vigour and fatigue are important for this group of patients as fatigue is a common consequence of chemotherapy and radiotherapy. Insomnia which can lead to fatigue and reduced vigour can also be a consequence of the side effects of long term endocrine treatments. Improvement in confusion from MBSR is another important finding as a possible side effect of chemotherapy is its effect on cognitive function.

Quality of life was statistically significantly improved following MBSR compared to controls in the areas of breast- and endocrine-specific quality of life both immediately after MBSR, at eight weeks, and at four week follow-up, 12 weeks. In addition there was significant improvement in physical functioning at follow-up, emotional and functional wellbeing at eight and 12 weeks. Social wellbeing was not significantly improved from MBSR at either time point. Breast-specific quality of life and the trial outcome index (including physical and functional dimensions) were significantly improved both statistically following MBSR and at follow up as were endocrine-specific quality of life and the trial outcome index (including physical and functional dimensions). In addition to this, the changes to breast-specific quality of life were clinically significant. These results supported the second hypothesis of the study that as a consequence of being exposed to MBSR, there was an improvement in quality of life including endocrine symptoms for women with stages 0 to III breast cancer in the intervention group compared to controls, the effects being measured after eight weeks and again after 12 weeks. The findings suggest a positive contribution that mindfulness can make to a range of physical and emotional side effects of breast cancer including menopausal symptoms such as hot flushes.

Statistically significant improvements in general wellbeing as a result of MBSR compared to controls indicated the broader benefits of this programme to people affected by breast cancer. This supported the third hypothesis of the study that as a consequence of being exposed to MBSR, there was an improvement in overall wellbeing for women with stages 0 to III breast cancer, the effects being measured after eight weeks and again after 12 weeks. The result from this study suggested that with continued mindfulness practice into the follow-up period, many improvements can be maintained and some may further improve.

The perceived difficulty or stress of breast cancer was statistically significantly reduced supporting the fourth hypothesis of the study in part, that as a consequence of being exposed to MBSR, there was a reduction in stressors for women with stages 0 to III breast cancer relating to breast cancer, the effects being measured after eight weeks and again after 12 weeks. MBSR did not significantly improve the perceived stress of other life events in this study.

Increased hours of formal mindfulness and home practice predicted significant improvements in anger, endocrine-related quality of life, functional wellbeing, and general wellbeing, whilst attending an increased number of hours of classroom time predicted improvements in confusion. These findings supported in part the fifth hypothesis that increased classroom attendance and mindfulness home practice hours predict improvements in mood state, quality of life and well being for women with stages 0 to III breast cancer, measured after eight weeks and again after 12 weeks. Increased hours of formal mindfulness and home practice did not predict significant improvements in overall mood state or most mood state subscales (apart from anger) or in breast-related quality of life.

As these findings show, MBSR was a valuable self-management tool for these breast cancer survivors, reducing physical and emotional symptoms and improving coping skills. Through MBSR and the cultivation of mindfulness and increased awareness, results suggested that participants may have gained clarity and insight enabling conscious choices when responding to events rather than being driven by habitual reactions, thus facilitating positive improvements.

This study reinforced and challenged some findings from an earlier, less rigorous trial and extends those findings to offer new insights into the value of MBSR for women with breast cancer (Shapiro et al 2003). Findings suggest that MBSR might be successfully adopted as part of a survivorship programme for self-selected, and therefore motivated, women with stages 0 to III breast cancer who have finished their main hospital treatment for breast cancer and are looking for ongoing skills to help them live happier and healthier lives.

This study has contributed to the development of knowledge of programmes that can potentially help breast cancer survivors. This evidence will directly contribute to the current *National Cancer Survivorship Initiative* (Department of Health 2009) as the clinician-researcher sits on the Assessment and Care Planning Group of this strategic initiative from the *Cancer Reform Strategy* (Department of Health 2007) to improve the lives of cancer survivors. It is an extension of specialist practice that could be given by

appropriately qualified and experienced health professionals offering programmes for rebuilding lives after treatment and finding new ways to help live with cancer.

7.3 Conclusions on study limitations and implications for further research

Whilst this study was performed as rigorously as possible and is the largest of its kind in the world to date, its key limitations are summarised below along with their implications for future research.

Using a convenience sampling strategy of women attending Breast Cancer Haven limited the possible generalisability of these findings beyond this population and raises questions over transferability of findings to an NHS setting, but having said this, participants were under the care of their NHS specialist medical teams. Participants were younger and of a higher socio-economic group than the population diagnosed with breast cancer across the UK, although very recent figures (Cancer Research UK 2009) suggest that breast cancer is now more common in higher socio-economic groups, primarily due to women taking hormone replacement therapy as well as a few other factors. While the present findings focus on a group known to be attracted to psychological support and complementary therapies, future studies with patients recruited directly from the NHS setting and covering the full range of age and social class may demonstrate wider generalisability and ensure transferability of findings. Indeed, more studies actively including participants from lower socio-economic groupings and ethnic minorities should be considered.

Participants in the study were diagnosed with stages 0 to III breast cancer so results are not generalisable to people with Stage IV breast cancer who have distant metastatic spread. The clinician-researcher is already part of a research team to evaluate MBSR in women with metastatic disease breast cancer commencing in 2010, as she will be able to adapt the MBSR programme to accommodate any physical limitations of this group. Rigorous, adequately powered studies could be extended to other groups of people with cancer and also their carers as well as further qualitative studies.

Two unvalidated Likert-scale measures were used to evaluate illness-related stress and stress from other life events which may make these results difficult to compare with other studies and raise questions about the rigour of their findings. In addition, there was no validated measure of mindfulness used in the current study, as those that are currently available were either in development or unvalidated when this study was designed. Now that these scales are becoming available, future studies in MBSR and cancer should include a validated measurement tool for mindfulness which would enable researchers to evaluate in more depth whether mindfulness has been cultivated and its impact on

participants, as well as being able to make direct comparisons with findings from other studies.

As with the study of other complementary therapies, it is a challenge to find suitable control groups for MBSR other than treatment as usual. As a solution to this, in future quantitative research, it may be helpful to compare MBSR to existing support programmes provided for cancer survivors to establish the most effective self-management approaches.

Questions remain regarding the extent to which improvement is, if at all, maintained in mood post MBSR after the one-month follow-up period demonstrated in the current study. In addition, not measuring the amount of home practice performed in this period was a limitation. It would be helpful to run studies with a follow-up period of longer than four weeks and perform evaluations at six, 12 and 24 months. In doing this, it would be important to measure the amount of ongoing practice done by each participant during the longer follow-up periods.

The combined role of the clinician and researcher can be seen as a limitation of this study even though careful steps were taken to minimise the effect of this on results. It would be valuable to run similar MBSR studies where the researcher had no part in the clinical input of the programme and compare results of both studies. This would help eliminate any potential positive or negative effects that having one person in these two roles may have.

This study did not dismantle the different aspects of MBSR to see what the active components were which could help further understanding as to how and why MBSR improves health. Further comparative and dismantling studies that help to isolate the active components of MBSR would be useful and could be done via more exploratory work in the form of qualitative research and surveys.

In the light of the level of depression found in this population of breast cancer survivors, it is suggested that the Major Depression Inventory (ICD-10) is recommended if the raw WHO five-item wellbeing score is below 13 of if respondents answered 0 or 1 on any of the five items (World Health Organisation Regional Office for Europe 1998). It could be helpful to include the ICD-10 in a future study to more accurately evaluate the level of depression in breast cancer survivors.

The qualitative data collected from this study was limited to a short proforma so further research is needed to see whether this data is saturated and whether themes are sustained. More in-depth qualitative research studies would be helpful in establishing

participants' perceptions of the elements of MBSR that are most effective and give more information about the lived experience of MBSR and how it affects the lives of breast cancer survivors. More data could also be collected from the perspective of the families or those close to the person with breast cancer and from health care professionals to help develop a more rounded body of knowledge from the qualitative data regarding the impact of MBSR on women with breast cancer.

Whilst the impact of MBSR on a range of physical and psychological symptoms have been explored in this study, it would be helpful to explore its impact on other symptoms which are often chronic, debilitating and difficult to manage following breast cancer and other cancer treatments such as peripheral neuropathy and lymphoedema.

This study did not evaluate cost effectiveness of MBSR. In future research, to measure whether participation in MBSR saves other healthcare costs would be important. These costs may include time needed with health care professionals, medication or other more costly interventions given to relieve the possible longer-term side effects of breast cancer and its treatments.

Findings in this study raised a number questions relating to the impact of breast cancer treatment on participants. More research is needed to fully understand the impact on quality of life from receiving both neoadjuvant and adjuvant chemotherapy. Also, gaps in research have been highlighted regarding the level of psychological and physical impact of mastectomy compared to wide local excision or partial mastectomy in different age groups. The question of age and its impact on outcomes after breast cancer may benefit from more investigation, to help find more appropriate ways of managing this.

7.4 Practice, education and policy implications

The practice, education and policy recommendations from this study are that:

1. MBSR programmes should continue at Breast Cancer Haven in London and expand to run at their other Havens in Hereford and Leeds if appropriately qualified staff are available to conduct these programmes.

2. Whilst results cannot be transferred to other settings, there is a possibility that there may be benefits to those in the NHS as most of the participants were NHS patients. MBSR may be considered as a part of the *National Cancer Survivorship Initiative* (NCSI) (Department of Health 2009), as one of the self-management developments for to help breast cancer survivors. The NCSI, which is co-chaired by Macmillan and the Department of Health, aims to improve the quality of life for people living with or beyond cancer (Macmillan Cancer Support 2009). Therefore,

it is worth considering the running of MBSR to other interested women with breast cancer following the completion of their hospital treatment as a way of helping them cope with the ongoing sequelae of breast cancer in other settings across the NHS.

3. It is possible to consider the expansion of conducting MBSR programmes to work with other groups of people including women with stage IV breast cancer and with other cancers based on the results of this and previous research.

4. MBSR training, already available in the UK at the University of Bangor, Wales, could be made available to appropriate health care professionals with the relevant background in mindfulness, group work and practices such as yoga or Tai Chi as in the USA.

It is recognised that many of these research and practice recommendations coming from the current study have resource implications which may affect their possible implementation.

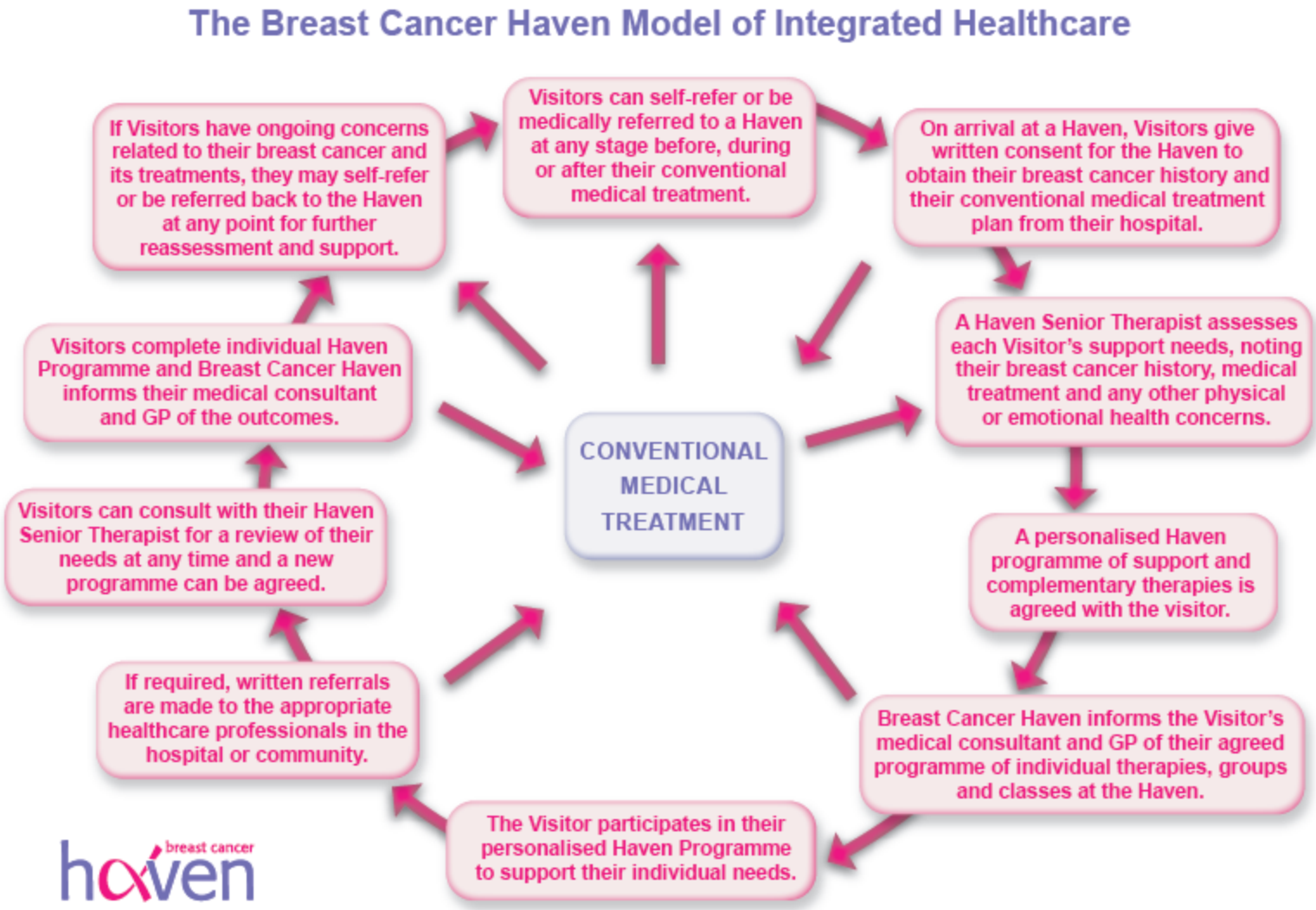
The findings of this study suggest that MBSR can be of benefit to women treated for stages 0 to III breast cancer to alleviate the physical and psychological sequelae of breast cancer treatment. MBSR offers a practical method of self-management to help women cope with their lives in the face of an uncertain future. It may offer one of a range of possible solutions to the Government's Department of Health and Macmillan in the NCSI in helping to improve the lives of those living with and beyond breast cancer.

This study will also contribute to the growing worldwide body of MBSR research, adding to the evidence showing how mindfulness approaches can help people cultivate happier and healthier lives.

Appendix 1. Background literature search strategy

Search Term	Initial search results	Refinement to search Most recent 100 articles taken from all data bases itemised below (where numbers were less than 100 all articles were considered
Quality of life and breast cancer	7059	AMED/ PsychINFO
Insomnia and breast cancer	354	CINAHL/ EMBASE
Fatigue and breast cancer	2477	AMED/CINAHL/Medline/PsychINFO
Pain and breast cancer	3618	AMED/CINAHL/Medline/PsychINFO
Menopaus$ and breast cancer	7198	AMED/CINAHL/PsychINFO
Hot flu$ and breast cancer	1775	AMED/CINAHL/Medline/PsychINFO
Relationship$ and breast cancer	11967	AMED/CINAHL/ PsychINFO
Social and breast cancer	3253	CINAHL/PsychINFO
Function$ and breast cancer	19020	AMED/CINAHL/PsychINFO
General wellbeing and breast cancer	3	AMED/CINAHL/PsychINFO
Wellbeing and breast cancer	726	AMED/CINAHL/PsychINFO
Self management and breast cancer	38	AMED/CINAHL/PsychINFO
Psychoeducation$ and breast cancer	76	AMED/CINAHL/PsychINFO
Stress and breast cancer	2563	AMED/CINAHL/PsychINFO
Work stress and breast cancer	5	AMED/CINAHL/PsychINFO
Occupation$ stress and breast cancer	6	AMED/CINAHL/PsychINFO
Anxiety and breast cancer	1543	AMED/CINAHL/PsychINFO
Depression and breast cancer	2206	AMED/CINAHL/PsychINFO
Anger and breast cancer	95	AMED/CINAHL/PsychINFO
Mood and breast cancer	770	AMED/CINAHL/PsychINFO

Appendix 2. Breast Cancer Haven Model of Integrated Healthcare



Appendix 3. Summary of eight week Mindfulness Based Stress Reduction programme

Week no.	**1**	**2**	**3**	**4**	**5**	**6**	**Day long session (6 hours)**	**7**	**8**
Chief practical elements	Introduce mindful eating Introduce Mindful body scan	Mindful body scan	Introduce Mindful lying stretches. Introduce mindful sitting meditation	Mindful sitting meditation / Fine tune mindful lying stretches	Mindful sitting meditation	Mindful sitting meditation/ Introduce mindful standing stretches	Mindful meditations practised before and i)Walking ii)Loving-kindness iii) Mountain meditation	Discussion of day long Session Mindful sitting meditation	Mindful stretches, body scan and Mindful sitting meditation
Chief theoretical elements	Introduction/ rationale for the MBSR programme. Group rules including confidentiality, not giving advice	Ways of seeing including 9 dots exercise	Discuss pleasant events and responses	Introduce stress physiology and reactivity. Discuss unpleasant events and responses	Introduce reactions and responses to stress	Discuss communications, assertiveness, knowing and expressing feelings. Distinguish passive/aggressive and assertive	Self-observation of thoughts, feelings and bodily sensations. Following instructions, day spent in silence	Starting to think about future practice	Discussion. Note final feedback from the group
Chief home practice elements (aim for 6 days per week)	Mindful body scan CD 45 mins	Mindful body scan CD 45 mins	Mindful body scan CD 45 mins alternate daily with mindful lying stretches CD	Mindful body scan CD 45 mins alternate daily with mindful lying stretches CD	Mindful body scan CD 45 mins OR mindful lying stretches CD	Mindful body scan CD 45 mins OR mindful gentle standing stretches alternate with sitting meditation CD		Do any of the mindfulness practices learned so far without CDs for 45 mins per day	Continue practising with the CDs, choosing element that suit individual

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme

(Santorelli and Kabat-Zinn 2003)

Week	MBSR programme contents
Class 1	Welcome and introductions. The rationale and overview of the whole programme is presented. Introductions and a chance for each person to say why they have come Group rules are outlined (e.g. confidentiality, punctuality, regular attendance, home practice, record keeping). Didactic materials are distributed. Home practice and record keeping are explained. Each session has opportunity for sharing and feedback. Raison-eating exercise: first introduction to mindfulness. Increasing the moment to moment awareness of eating. Home practice and record keeping are explained Introduce Mindful body scan (45 minutes) The mindful body scan is practised intensively for the first 4 weeks of the MBSR programme. It is the first formal mindfulness practice that our participants engage in for a sustained period of time. Along with the mindful sitting meditation, it provides the foundation for all the other mindfulness techniques that they will work with later.
Home practice 1	❑ Do mindful body scan guided by CD for 6/7 days for approximately 45 minutes. ❑ Eat one meal this week mindfully ❑ Do 9 dots exercise

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 2	Do guided body scan for 30-45 minutes Discuss the body scan in small groups, how it went in this session and how the home practice went during the week
Home Practice 2	❑ Do mindful body scan guided by CD for 6/7 days for approximately 45 minutes ❑ Fill out pleasant events calendar for the week, one entry per day ❑ Explore being mindful in routine activities such as brushing teeth, washing dishes, taking a shower, taking out garbage, eating
Class 3	Guided mindful lying stretches (45 minutes) asking participants to avoid any postures that would cause injury or setback. Discuss the experience of mindful stretches and assign homework of alternating mindful body scan and mindful lying stretches with the CD/tape Discuss how home practice went during the week - body scan and lying stretches with focus on awareness of breathing and assign for homework (approximately 5-15 minutes) Go over pleasant events calendar with emphasis on mind-body connection, what people learned about themselves Finish class with short sitting meditation (2-3 minutes)
Home Practice 3	According to exercises given in lessons and guided by the CD, for 6/7 days: ❑ start alternating the mindful body scan one day with the mindful lying stretches the next, during weeks 2 and 3. ❑ Continue to practise mindful sitting meditation, now for fifteen to twenty minutes per day. ❑ Keep a calendar for the week, noting unpleasant events, one entry per day ❑ Make an effort to capture your moments during the day ❑ Mindfulness of going on automatic pilot and when it occurs. What do you most not want to look at?

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 4	Guided Mindful standing stretches (15-20 minutes) Give instructions for sitting positions in sitting meditation Introduce guided Mindful Sitting meditation (10 minutes) Discuss home practice, especially how things went with the mindful lying stretches and the effects of doing mindful stretches on the practice of the mindful body scan. Go over unpleasant events calendar with emphasis on mind-body connection, what people learned about themselves Fine tune mindful stretches instructions as required Introduce concepts of stress physiology and stress reactivity, getting stuck in our lives and how to get unstuck Connect stress with mindfulness meditation practice and mindfulness in every day life Guided sitting meditation (5-10 minutes)
Home Practice 4	According to exercises given in lessons and guided by the CD, for 6/7 days: ❑ Continue alternating the mindful body scan one day with the mindful lying stretches the next, and keep this up during week 4 ❑ Mindful sitting meditation 20 minutes per day, with awareness of breathing and bodily sensations ❑ Be aware of stress reactions during the week, without trying to change them in any way ❑ Be aware of feeling stuck ❑ Awareness of blocking, numbing, shutting off to the moment when it happens this week

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 5	Mindful standing stretches (15 - 20 minutes) Guided mindful sitting meditation (15 - 20 minutes) Discuss the mindful sitting meditation and the mindful lying stretches homework Note that the programme is half over, discuss how it has been so far. Discuss observations of reactions to stressful events Reacting and responding to stress Finish class with short sitting meditation (5 minutes)
Home Practice 5	❑ With the CD for guidance for up to 45 minutes daily mindful sitting meditation alternated with the mindful standing stretches or body scan for 6/7 days ❑ Fill out difficult communications calendar ❑ Bring awareness to moments of reacting and explore options for responding with greater mindfulness and creativity. Do this in meditation practice as well ❑ Practice opening up space for responding in the present moment. Use the breath to slow things down

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 6	Mindful standing stretches for 15-20 minutes Sitting meditation for approximately 25-30 minutes Discuss homework, especially the mindful sitting meditation Discuss the up and coming 6 hour Day of Mindfulness, Discuss difficult communications calendar, examples of how one says 'no' and resistance/difficulty in saying 'no' to some people Discuss stressful communications, assertiveness, knowing and expressing your feelings Introduce standing stretches CD Finish with a short sitting meditation (3-5 minutes)
Home Practice 6	For 6/7 days, with the CD for guidance for up to 45 minutes daily alternate mindful sitting meditation with standing stretches ❑ pay attention to 'what you put into your body', where it comes from, how much, why. Include food, TV, newspapers, bad news, pollution etc ❑ Remind people of the six hour day of mindfulness at the weekend and briefly review how to work with silence

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)	
Week 6	MBSR programme contents
Saturday	**Day of Mindfulness** 1000 – 1005 Mindful sitting in silence for 5 minutes 1005 – 1020 Welcome and ground rules for day in silence (15mins) 1020 –1050 Mindful sitting meditation (30 mins) 1050 –1110Guided mindful lying stretches (20 mins) 1110 – 1115 Short mindful body scan (5 mins) 1115 – 1135 Slow mindful walking meditation (20 mins) 1135 – 1155 Mindful sitting meditation (20 mins) 1155 – 1215 Slow mindful walking meditation (20 mins) 1215 – 1235 Guided mountain meditation (20 mins) 1235 – 1255 Talk (15 mins) 1255 – 1300 Instructions for a silent lunch (5 mins) 1300 – 1400 Silent Lunch and walking outside on own (I hour) 1400 – 1420 Mindful walking at different paces, slow, faster, in different directions – 'an energiser' (20 minutes) 1420 –1450 Loving kindness meditation (30 minutes) 1450 –1510 Short mindful sitting meditation (5mins) alternating with short mindful walking meditation (5mins), and changing again (20 mins total) 1510 – 1525 In dyads: quiet discussion on how the day has been so far (15 mins) 1525 – 1555 Large group discussion on the day 1555 – 1600 Final mindful sitting meditation 1600 – Goodbyes

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 7	Start by getting people to change seats, so change perspectives Mindful standing stretches 15 minutes Sitting meditation for 30 - 40 minutes Discuss the day of mindfulness: reactions, responses, likes and dislikes, feelings afterwards, what you saw, what you learned about yourself Tie this into mindful sitting meditation practice, both formal and informal For this week, home practice without the support of CDs Encourage people to take the same 45 minutes and practise on their own, they decide how what, how much etc Discussion about 'what we take in' and how it affects our health and wellbeing
Home Practice 7	No CDs. For 6/7 days ❑ Practise the formal practices: mindful meditation, mindful stretches, mindful body scan on one's own as best one can. ❑ Informal practice (mindfulness in every day life) practised on your own for preparation for when the course is over ❑ Pay attention to what you put in your body: how much, when, what, how often

Appendix 4. Details of eight week Mindfulness Based Stress Reduction programme (continued)

Week	MBSR programme contents
Class 8	Mindful standing and lying stretches 25 minutes Mindful body scan for 20 minutes Mindful sitting meditation for 35 minutes Small group discussion: thinking back to when you originally came, expectations, why you stayed, expectations, what was learned, costs, sacrifices, obstacles. What strategies have you developed? Touch on practice without CDs Review entire course and focus briefly on main features
Home Practice 8	❑ Go back to the CDs, using whichever techniques you wish. Keep up the practice and make it your own ❑ Formulate three short term and three longer term goals which come out of your direct experience of the programme and your mindfulness practice ❑ Include potential obstacles to reaching these goals and your strategies for working with them to keep the momentum of your practice moving and growing. ❑ Write yourself a letter with what you hope to achieve in the next 6 – 12 months. Keep in a safe place and open it at the appropriate time

Appendix 5. Research and MBSR training, orientation and ongoing training

Courses and Conferences	Date and Location	Duration
Post Graduate Health Science Training	2002-2003 University of Southampton	4 weeks
1. Intensive version of 8-week MBSR programme for health professionals	February 2004, University of Massachusetts Medical School, USA	8 day intensive (96 hours)
2. Participation in 2nd International Mindfulness Conference	March 2004, University of Massachusetts Medical School, USA	3 days
3. Teacher Development Intensive	April 2004, University of Massachusetts Medical School, USA	8 day intensive (96 hours)
4. Participation in 3rd International Mindfulness Conference	March 2005, University of Massachusetts Medical School, USA	3 days
5. MBSR Clinical Supervision	December 2004 – November 2006 ongoing telephone contact with a leading MBSR Teacher Trainer Florence Meleo Meyer, MA, at the University of Massachusetts Medical School, USA	1 hour each session, currently at the end of each 8 week MBSR programme
6. Participation in 5th International Mindfulness Conference	March 2006, University of Massachusetts Medical School, USA	4 days
Participation in a Mindfulness Teachers Retreat	September 2007 Gaia House, Devon.	1 week of mindfulness practice
6. Presentation at the 5th annual international conference 'Integrating mindfulness-based interventions into medicine, healthcare and the larger society	March 2007 University of Massachusetts Medical School, USA	4 days including a one hour presentation of study methodology
Mindfulness Retreat	October 2007 The Orchard, Herefordshire	1 week of mindfulness practice
Mindfulness Retreat	November 2008 The Orchard, Herefordshire	2 weeks of mindfulness practice

Appendix 6. Study Participant Information Sheet

The London Haven
Study Participant Information Sheet (Version 1: 18 6 2004)

1. Title of the research

The evaluation of the therapeutic effectiveness of a Mindfulness Based Stress Reduction programme (MBSR) in women with breast cancer

2. An invitation to join this study

We would like to invite you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear to you of if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

3. What is this study about?

The Mindfulness Based Stress Reduction programme (MBSR) is an eight week training in 'mindfulness', Mindfulness is a form of meditation practice which aims to increase your awareness and attention in the present moment, which may help alleviate stress.
The aim of the MBSR programme is to teach people how to take better care of themselves and live healthier lives.

4. Why have I been chosen for this study?

This study is being offered to Visitors (i.e. patients) attending the London Haven who finished surgery, radiotherapy and /or chemotherapy for breast cancer between two months and two years ago. You will also have attended The Haven Support Workshop and have completed the individual therapy sessions allocated to you by the Nurse/Therapist and possibly attended some Haven groups.
In total, there will be 240 Visitors participating in the study.

5. Do I have to take part?

It is up to you to decide whether or not to take part and have an opportunity to ask questions. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form after you have had a least a day to think about it. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive at The London Haven and you will be able to attend the normal range of programmes on offer.

If you decide to take part, we will inform your GP and hospital Medical Consultant by letter.

6. What will happen to me if I take part?

This study will be comparing learning and practising some exercises to reduce stress with not doing them.
Sometimes, because we do not know which way of treating Visitors is best, we need to make comparisons to see if the new approaches are helpful. You will be randomly allocated into one of two study groups described below, each involving the new exercises, but starting at different times. Randomisation means neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

Participants in both groups of the study will be taught MBSR techniques in an eight week course. The two groups in this study will have exactly the same training. The only difference is that one training group will start right away. The other will start about three and a half months later. Each class is two hours long. There is also a 6 hour day of mindfulness in week six of the programme. On three occasions, you will be sent the same set of questionnaires to fill out and the Research Assistant will contact you by telephone to help you with these if you need it. Each set of questionnaires will take less than half an hour to complete.

If you take part in the study, you will have the following procedures to go complete:

If you are in the first group, starting with MBSR, you will be asked to fill out questionnaires before the course. You will then take the eight week course. After the course is over, and again four weeks later, you will be asked to fill out questionnaires. Each set of questionnaires takes less than half an hour to complete.

If you are in the second group, doing MBSR at a later stage, you will be asked to come to fill out questionnaires immediately, then a second and third time ten and fourteen weeks later. This will be done with assistance on the phone if you need it. After this, you will be able to take the course.

You will be asked to practice the mindfulness techniques you are learning in the course most days at home. You will also be asked to keep a record of your home practice.

7. What else do I have to do?

During the course of the eight week programme, you may be asked to notice how ‘mindful’ or in other words ‘how present and aware you are in each moment’ in the course of your normal everyday activities. There are not other restrictions or additions to your life apart from this.

You can stop participating at any time. Your decision to withdraw from the study will not affect your care at the London Haven in any way.

Appendix 6. Study Participant Information Sheet (continued)

8. The procedure being tested is the Mindfulness Based Stress Reduction (MBSR) programme.

It is delivered in an eight week course of two hours per week and one six hour day of Mindfulness in week six of the course to broaden and deepen the practice. During this time the formal practices of 1) mindful body scan (taking the focus of attention through the body), 2) mindful sitting meditation (involving awareness of breathing)
3) mindful simple gentle slow stretches will be learned. In addition to this, there will be the opportunity to develop informal mindfulness practices in your everyday life such as when eating and walking. Learning these MBSR techniques may help you become more aware of stress in your life and be able to cope it more quickly and effectively. In addition to this, there will be some discussions about stress and the stress response, communication and perceptions in life.

9. What are the alternatives?

If you chose not to enter the study, then you will be welcome to continue coming to the normal programme of supportive and complementary therapies offered at The London Haven.

10. What are the risks of taking part in the MBSR programme?

There are no serious or non-reversible risks or side effects associated with the procedures included in this study.

Minor risks which may occur include:

Participants may feel frustrated during mindfulness practice because their mind wanders. They may feel minor stress due to the need to include daily practice of mindfulness or they may feel some physical discomfort during sitting meditation and will be encouraged to change position if this happens.

Participants may be unable to do some of the gentle stretches that are part of several classes. These stretches are less strenuous than climbing up a flight of stairs and are not meant to increase strength or stamina. They are for the purpose of becoming aware of sensations in different parts of your body. Participants will be reminded not to stretch to the point of discomfort and alternative mindfulness activities may be available instead of the stretches.

Another potential risk is the release of private information. To minimise the risk of releasing sensitive personal or family information, we have developed strict guidelines to protect privacy of medical and personal information.

Sometimes there may be feelings of sadness, anger, or anxiety associated with experiences that you may think about as you complete questionnaires or participate in training exercises. If talking or thinking about your experiences makes you unusually anxious, you will be offered the support of counselling services if the interview causes any bad feelings for you. You are free to decline to answer any questions on the questionnaire or in the interviews. You have the right to skip any question on the questionnaire if you want to.

For the reasons described above, the Researcher will observe you closely while participating in the programme described and, if you have any concerns notify the Researcher immediately. Her name is Caroline Hoffman and her phone number is 020 7384 0007. She can also be contacted for more information regarding any concerns you may have about risks and side effects.

11. What are the possible disadvantages of taking part?

There are no known disadvantages in taking part in the MBSR study, except for the time that you will be asked to commit.

12. What are the possible benefits of taking part?

If you agree to take part in this study, there may or may not be direct medical benefit to you. Benefits may include more positive mood, decreased feelings of stress, and having more energy. We hope the information learned from this study will benefit other people with breast cancer in the future.

13. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your researcher will make arrangements for your care to continue with the normal Haven programme. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information, your researcher might consider it to be in your best interests to withdraw you from the study. She will explain the reasons and arrange for your care to continue.

14. What happens when the research study stops?

Once the research study stops, if successful, it is anticipated that the MBSR programme will continue to run for Visitors to The London Haven. Research participants may choose to repeat the programme at a later date or to attend a Day of Mindfulness that will be offered at regular intervals at The London Haven.

15. What if something goes wrong?

In the unlikely event you are harmed by taking part in this research project, there are no special compensation arrangements. It is not the policy of Breast Cancer Haven or the University of Southampton to compensate human subjects in the event that the research results in injury. Breast Cancer Haven, in fulfilling its public responsibility, has provided public and professional liability insurance coverage for any injury in the event such injury is caused by negligence of Breast Cancer Haven or its staff. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study,

complaints can be sent to The Chief Executive Officer at Breast Cancer Haven. This statement is not to be construed as an admission of liability.

16. Will my taking part in the study be kept confidential?

Information produced by this study will be stored in the Researcher's locked file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate secure location. It is normal for study data to be transferred to computer and it is important that this transfer is carried out accurately. Independent specialists usually do this. Confidentiality is always assured and your name and address is not transferred to computer with the data. In the storage of information there will be full adherence to the current Data Protection Act. Information contained in your records with your name on it may not be given to anyone not connected with the study without your written consent.

17. What will happen to the results of the research study?

The results of the research will be published in a medical book or journal and used for teaching purposes. When the study is completed, there will be copies of the published results available at the Haven and as a participant, you will be invited to a presentation at The London Haven to have these explained. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

18. Who is organising and funding the research?

The research is being organised by Breast Cancer Haven and the University of Southampton. The Researcher is an employee of Breast Cancer Haven and is a part-time Doctor of Philosophy student at the University of Southampton. The Researcher is not being paid for including you in this study.

19. Who has reviewed this study?

The Riverside Research Ethics Committee has approved this study.

20. Contact for further information

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enrol or continue to participate in this study, you may contact The Chief Executive Officer of Breast Cancer Haven on telephone 020 7384 0000.
You may ask more questions about this study at any time. To do so, please contact Caroline Hoffman on telephone 020 7384 0007 or email cjh@breastcancerhaven.org.uk.

Thank you again for reading this information and for considering taking part in this study.

Appendix 7. Study Participant Consent Form

Study Number: RREC 04/Q0401/58.
Patient Identification Number for this trial: XXXXX

CONSENT FORM V1: Date:17 06 04

Title of Project: The evaluation of the therapeutic effectiveness of a Mindfulness Based Stress Reduction programme (MBSR) in women with Stages I – III breast cancer

Name of Researcher: Caroline Hoffman
Therapies Director
Breast Cancer Haven
Effie Road
London
SW6 1TB

Please initial box

1. ☐ I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study and have had the opportunity to ask questions.

2. ☐ I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. ☐ I understand that sections of any of my medical notes may be looked at by responsible individuals from Breast Cancer Haven or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study. ☐

Name of Visitor	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 for Visitor; 1 for researcher; 1 to be kept with Breast Cancer Haven clinical notes

Appendix 8. Project Plan 2004 – 2010

An evaluation of the effectiveness of MBSR in women with breast cancer:

Date	Action
06/04 – 08/04	Ethics Application to Riverside Research Ethics Committee and approved
11/04	Research Assistant commenced at Breast Cancer Haven
01/05 – 03/05	Clinician-researcher led MBSR programme with Haven staff
04/05 – 11/06	Intervention and Data Collection 14 x eight-week cycles were run avoiding major holiday periods.
02/06 – 02/07	Data entry
02/07 - 02/08	Data analysis
03/08 – 08/09	Write up of thesis and submission
02/10 onwards	Submission for publication to journals
04/10 onwards	Presentations of research at conferences

Appendix 9. Two day Haven Introductory Programme

Day 1

1000 – 1010 Welcome to the Haven by Therapies Director

1010 –1045 General and personal introductions
with Senior Group Therapist for the Haven, Introductory Programme Leader

1045 – 1100 A short relaxation exercise

1100 – 1115 Break

1115 – 1200 Ongoing Skills Development - Visitors with Senior Group Therapist
Supporting the Carer (Lilac Room), Carers with Therapies Director/Nurse

1200 – 1300 Introduction to Nutrition with Nutritionist

1300 – 1400 Lunch

1400 – 1600 Introduction to personal imagery and the imagination for self-healing with Senior Group Therapist (including tea break)

- The connection between mind, body, emotions and spirit
- Movement and breath
- Meditation

1600 Finish

Day 2

1000 – 1200 Ongoing Skills Development with Senior Group Therapist
(including a break)

1200 – 1300 Introduction to Therapies at the Haven with the Therapies Director

1300 – 1400 Lunch

1400 - 1430 Session on minimising risks in your environment with Nutritionist

1500- 1550 Group discussion and relaxation

1550 –1600 Review of the 2 day programme with Senior Group Therapist
Completion of evaluation forms

1600 Finish

Appendix 10. Other aspects of the Haven Programme

2) 1:1 Assessment with Senior Therapist to agree a personalised treatment programme of individual sessions, groups and classes

3) 12 hours of individual therapy time as agreed with Senior Therapist

4) Attendance of groups and classes

5) Reviews with Senior Therapist as required

Table A 4.6.1. Individual and Group Therapies offered at the London Haven

Individual therapies at The London Haven	**Group therapies at The London Haven**
Acupuncture	Alexander Technique
Aromatherapy	Art Therapy
Alexander Technique	Ear Acupuncture
Counselling	Introductory two-day workshop
Emotional Freedom Technique	Hair and makeup classes
Hands on healing	Looking good, feeling better
Homeopathy	Lymphoedema Awareness Classes
Kinesiology	Energy Meditation
Medical Herbalism	Qi gong
NES Energetic Analysis	Stretch and relax
Nutritional advice	Support groups
Reflexology	Yoga (breast cancer specific exercises)
Reiki	
Shiatsu	

Appendix 11. Letter of invitation to participate in the study

Date

Name
Address

Our Ref XXXXX

Dear

Invitation to be part of a research study at Breast Cancer Haven

I am writing to invite you to come and discuss your possible participation in a research study involving a novel participatory self-help programme that I will be leading at The London Haven during both 2005 and 2006.

The programme is called the Mindfulness-Based Stress Reduction programme (MBSR). It is an eight week participatory educational programme. The commitment for the programme is 2 hours per week for 8 weeks plus one Saturday of 6 hours duration which falls in week 6 of the programme. There is a choice of Tuesday evenings or Wednesday mornings for the programme for the regular weekly groups.

Mindfulness refers to developing attention and awareness in the present moment. The aim of MBSR is to teach people how to take better care of themselves and live healthier lives. It includes elements that may boost energy levels and relieve stress.

MBSR has been used in over 240 major medical centres worldwide, but has little used to date in the UK. This study is important as it will add to research looking at ways that people, like you, who have had cancer treatment, can develop health promoting skills.

There will be no charge for participating in this study and for attending the programme.

I would be delighted if you would contact me to make an appointment to come and discuss your possible participation in this study further.

With all best wishes.

Yours sincerely

Caroline Hoffman
Therapies Director
Breast Cancer Haven
Tel 020 7384 0007
Email cjh@breastcancerhaven.org.uk

Appendix 12. Leaflet explaining MBSR and study to participants sent with letter of invitation

Appendix 13. MBSR recruitment interview contents

Name Ref Date

Current health status

Breast cancer status

Date hospital treatment finished

Current Treatments

Current Side Effects

Other symptoms (including psychological/)

Menopause –date/symptoms/drug induced?

Current complementary / supportive therapies / activities

Past complementary therapies/support from the Haven

Why do you want to do Stress Reduction Programme?

Any Questions?

Explain MBSR programme structure, contents and commitment and questionnaires

---

MBSR Cycle:

Day and time preferred

Does participant have a CD Player?

Consent form and pre paid envelope given?

Information sheet given?

Appendix 14. Letter sent to hospital consultants and GPs of participants

11 April 2005

Dear

Research trial: An evaluation study of the therapeutic effective of a Mindfulness Based Stress Reduction programme (MBSR) in women with Stages 0 – 3 breast cancer at The London Haven

I am writing to inform you that your patient, Mrs X, DOB…, address…, has agreed to participate in the above mentioned study which is part of my PhD research at the Faculty of Medicine, Health and Life Sciences at the University of Southampton.

It is a study which involves participation in an eight week stress reduction programme for two hours per week. The programme is based on 'Mindfulness' which aims to increase awareness and attention in the present moment to promote overall wellbeing. It involves the core elements of 1) mindful body scan (taking the focus of attention through the body) 2) mindful sitting meditation (involving awareness of breathing) and 3) mindful gentle slow stretches. There is also a six hour day of mindfulness practice in week 6 of the programme. The aim of the programme is to offer self-management skills to participants which may support them in leading healthier lives and to better manage life's stressors.

MBSR is now offered in over 240 health establishments world-wide with patients in a variety of health care settings. It was developed by Dr Jon Kabat-Zinn at the University of Massachusetts Medical Centre, USA over 20 years ago.

Evaluation of the therapeutic effectiveness using some standard measures including Profile of Mood States (POMS), Functional Assessment of Cancer Therapy-Breast plus Endocrine symptom subscale (FACT-B plus ES) and World Health Organisation -5 item-Wellbeing (WHO-5) measure and will be performed pre- and post-intervention.

If you would like to know more about the study or know any reason why your patient should not participate, please do not hesitate to contact me.

Yours sincerely

Caroline Hoffman
Therapies Director
Breast Cancer Haven

Tel 020 7384 0007 (direct line)
Fax 020 7384 0002
Email cjh@breastcancerhaven.org.uk

Appendix 15. Participant measurement tools

Thank you for taking the time to fill out these questionnaires. It takes about 20 - 25 minutes to complete. Please put an answer to each question, even if the question seems to have been asked before.

If you have any difficulties at all, please contact the Research Assistant, Julia Hyde, on tel 020 7384 0044 who can help you. She will telephone you anyway to see how you are getting on completing the form. Please return the questionnaire in the Stamped Addressed Envelope provided.

Your help with this is greatly appreciated.

Section 1: Your personal details

Your name……

Your date of birth……

Today's date……

Questionnaire No. 1 2 3 (OFFICE USE ONLY)

1. Are you having treatment for your breast cancer at present? Yes No (Please circle)

If Yes, what?

……

2. On a score of 0 – 10, how difficult or stressful is your illness for you at the moment? (Please circle)

0 1 2 3 4 5 6 7 8 9 10

Not stressful at all **Extremely stressful**

3. Apart from your illness, have you had any recent event in your life which has affected you strongly or been particularly stressful? (Please circle)

0 1 2 3 4 5 6 7 8 9 10

Not stressful at all **Extremely stressful**

If Yes, please say what, and if more than one, please put all down all of them; please add the date the event happened

Event **When happened**

……
……
……
……
……
……

Section 2: Your mood (Profile of Mood States (POMS)

Below is a list of words that describe feelings people have. Please circle one of the numbers next to each word to best describe <u>how you have been feeling during the past week including today</u>:

	not at all	a little	moderately	quite a lot	extremely		not at all	a little	moderately	quite a lot	extremely
Friendly	0	1	2	3	4	Spiteful	0	1	2	3	4
Tense	0	1	2	3	4	Sympathetic	0	1	2	3	4
Angry	0	1	2	3	4	Uneasy	0	1	2	3	4
Worn out	0	1	2	3	4	Restless	0	1	2	3	4
Unhappy	0	1	2	3	4	Unable to concentrate	0	1	2	3	4
Clear-headed	0	1	2	3	4	Fatigued	0	1	2	3	4
Lively	0	1	2	3	4	Helpful	0	1	2	3	4
Confused	0	1	2	3	4	Annoyed	0	1	2	3	4
Sorry for things done	0	1	2	3	4	Discouraged	0	1	2	3	4
Shaky	0	1	2	3	4	Resentful	0	1	2	3	4
Listless	0	1	2	3	4	Nervous	0	1	2	3	4
Peeved	0	1	2	3	4	Lonely	0	1	2	3	4
Considerate	0	1	2	3	4	Miserable	0	1	2	3	4
Sad	0	1	2	3	4	Muddled	0	1	2	3	4
Active	0	1	2	3	4	Cheerful	0	1	2	3	4
On edge	0	1	2	3	4	Bitter	0	1	2	3	4
Grouchy	0	1	2	3	4	Exhausted	0	1	2	3	4
Blue	0	1	2	3	4	Anxious	0	1	2	3	4
Energetic	0	1	2	3	4	Ready to fight	0	1	2	3	4
Panicky	0	1	2	3	4	Good-natured	0	1	2	3	4
Hopeless	0	1	2	3	4	Gloomy	0	1	2	3	4
Relaxed	0	1	2	3	4	Desperate	0	1	2	3	4
Unworthy	0	1	2	3	4	Sluggish	0	1	2	3	4

	not at all	a little	moderately	quite a lot	extremely
Rebellious	0	1	2	3	4
Helpless	0	1	2	3	4
Weary	0	1	2	3	4
Bewildered	0	1	2	3	4
Alert	0	1	2	3	4
Deceived	0	1	2	3	4
Furious	0	1	2	3	4
Efficient	0	1	2	3	4
Trusting	0	1	2	3	4
Full of pep	0	1	2	3	4

	not at all	a little	moderately	quite a lot	extremely
Bad-tempered	0	1	2	3	4
Worthless	0	1	2	3	4
Forgetful	0	1	2	3	4
Carefree	0	1	2	3	4
Terrified	0	1	2	3	4
Guilty	0	1	2	3	4
Vigorous	0	1	2	3	4
Uncertain about things	0	1	2	3	4
Bushed	0	1	2	3	4

Please turn over

Section 3: Your quality of life (FACT-B and FACT-ES subscale)

Below is a list of statements that other people with your illness have said are important. By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

<u>Physical Well-being</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I have lack of energy……	0	1	2	3	4
I have nausea……	0	1	2	3	4
Because of my physical condition, I have trouble meeting the needs of my family…	0	1	2	3	4
I have pain……..	0	1	2	3	4
I am bothered by side effects of treatment……	0	1	2	3	4
I feel ill……	0	1	2	3	4
I am forced to spend time in bed……	0	1	2	3	4

<u>Social/Family Well-being</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I feel close to my friends……..	0	1	2	3	4
I get emotional support from my family….	0	1	2	3	4
I get support from my friends……..	0	1	2	3	4
My family has accepted my illness……..	0	1	2	3	4
I am satisfied with family communication about my illness……	0	1	2	3	4
I feel close to my partner (or the person who is my main support)…….	0	1	2	3	4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ and go to the next section.					
I am satisfied with my sex life…….	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

<u>Emotional Well-being</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I feel sad……	0	1	2	3	4
I feel satisfied with how I am coping with my illness ……	0	1	2	3	4
I am losing hope in the fight against my illness……..	0	1	2	3	4
I feel nervous……	0	1	2	3	4
I worry about dying……...	0	1	2	3	4
I worry that my condition will get worse…	0	1	2	3	4

<u>Functional Well-being</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I am able to work (including work at home) ……	0	1	2	3	4
My work (include work at home) is fulfilling……..	0	1	2	3	4
I am able to enjoy my life……	0	1	2	3	4
I have accepted my illness……..	0	1	2	3	4
I am sleeping well……	0	1	2	3	4
I am enjoying the things I usually do for fun……...	0	1	2	3	4
I am content with the quality of my life right now……	0	1	2	3	4

Please turn over

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

<u>Additional Concerns</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I have been short of breath…….	0	1	2	3	4
I am self-conscious about the way I dress……...	0	1	2	3	4
One or both of my arms are swollen and tender…….	0	1	2	3	4
I feel sexually attractive……...	0	1	2	3	4
I am bothered about hair loss…….	0	1	2	3	4
I worry that other members of my family might someday get the same illness I have……	0	1	2	3	4
I worry about the effect of stress on my illness…….	0	1	2	3	4
I am bothered by changes in weight…….	0	1	2	3	4
I am able to feel like a woman……	0	1	2	3	4
I have certain parts of my body where I experience significant pain…….	0	1	2	3	4
I have hot flushes…….	0	1	2	3	4
I have cold sweats……	0	1	2	3	4
I have night sweats……...	0	1	2	3	4
I have vaginal discharge…….	0	1	2	3	4
I have vaginal itching/irritation……	0	1	2	3	4

Please turn over

By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days.</u>

<u>Additional Concerns (continued)</u>

	Not at all	A little bit	Some what	Quite a bit	Very much
I have vaginal bleeding or spotting……	0	1	2	3	4
I have vaginal dryness……..	0	1	2	3	4
I have pain or discomfort with intercourse	0	1	2	3	4
I have lost interest in sex……..	0	1	2	3	4
I have gained weight……	0	1	2	3	4
I feel light-headed (dizzy)……	0	1	2	3	4
I have been vomiting……	0	1	2	3	4
I have diarrhoea……	0	1	2	3	4
I get headaches……	0	1	2	3	4
I feel bloated…….	0	1	2	3	4
I have breast sensitivity/tenderness……..	0	1	2	3	4
I have mood swings…….	0	1	2	3	4
I am irritable……..	0	1	2	3	4
I have pain in my joints……	0	1	2	3	4

Please turn over

Section 4: Your well-being (WHO – 5)

For each of the five statements below, please put a circle round one number, which is closest to how you have been feeling over the last week. Notice that the higher numbers mean better well-being.

Over the last week	All the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I feel cheerful and in good spirits……	5	4	3	2	1	0
I feel calm and relaxed…..	5	4	3	2	1	0
I feel active and vigorous……	5	4	3	2	1	0
I wake up feeling fresh and rested……	5	4	3	2	1	0
My daily life is filled with things that interest me….	5	4	3	2	1	0

Thank you very much indeed for your help with this research study.

Appendix 16. Feedback form given out at Week 8 (final MBSR class)

Name……
Date……..

1. As stated in class, **Mindfulness is described as 'bringing our attention and awareness to the present moment in a non-judgemental way'.**

1.1.Do you believe you have experienced a greater degree of Mindfulness as a result of participating in the stress reduction programme?

Yes No (Please circle the answer)

1.2. Can you give some examples in your life where this has occurred?

……
……
……
……
……
……
……

2. Please write down the most positive effect that this eight-week programme and mindfulness practice has had in your life?

……
……
……
……
……
……
……

3. Please write down what you found the most challenging about the programme and the mindfulness practice

……
……
……
……
……
……
……

4. Please add any other comments about the programme that you would like in the space below

……
……
……
……
……
……
……

Appendix 17. Home practice instructions and record sheet for MBSR home practice

Home Practice for MBSR Class 1 (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

According to exercises given in class and following the CDs, for 6/7 days:

- Do body scan guided by CD daily for approximately 45 minutes
- Eat one meal this week mindfully
- Do 9 dots exercise
- Read A Contemporary Fable: Upstream/Downstream
- Please fill in home practice sheet attached for week one and return to the box in the classroom on week 2.

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column.*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Record Sheet

Date X **Week X**

Name_____

Day of week	Details of home practice undertaken	Time taken for home practice	Any comments or observations you want to make about home practice
Wed			
Thurs			
Fri			
Sat			
Sun			
Mon			
Tues			

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 2: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

According to exercises given in class and following the CDs, for 6/7 days:

- Fill out pleasant events calendar for the week, one entry per day
- Do body scan for approximately 45 minutes
- Explore being mindful in routine activities such as brushing teeth, washing dishes, taking a shower, taking out garbage, eating a meal
- Please fill in home practice sheet attached for week one and return to the box in the classroom on week 3.

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 3: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

According to exercises given in lessons and following the CDs, for 6/7 days*:*

- Start alternating the body scan one day with the sequence of mindful lying stretches the next, and keep this up during week 3.
- Practise mindful sitting meditation for 5 - 15 minutes per day.
- Keep a calendar for the week, noting unpleasant events, one entry per day
- Make an effort to capture your moments during the day
- Mindfulness of 'going on automatic pilot' and noticing when it occurs
- Ask yourself, what do you most not want to look at?

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 4: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

***According to exercises given in lessons and following the CDs, for 6/7 days**:*

- Continue alternating the body scan one day with the sequence of mindful lying stretches the next, and keep this up during week 4
- Do the sitting meditation for 10 - 20 minutes per day, with awareness of breathing and bodily sensations
- Be aware of stress reactions during the week, without trying to change them in any way
- Be aware of feeling stuck when it happens this week
- Bring awareness to blocking, numbing, shutting off to the moment when it happens this week

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 5: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

According to exercises given in lessons and following the CDs, for 6/7 days*:*

- Do the mindful sitting meditation with the CD for guidance for up to 45 minutes one day alternating it with either the lying stretches or body scan the next day
- Fill out the difficult communications calendar
- Bring awareness to moments of reacting and explore options for responding with greater mindfulness and creativity. Do this in meditation practice as well
- Practice opening up space for responding in the present moment. Use the breath to slow things down
- Bring awareness of blocking, numbing, shutting off to the moment when it happens this week

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 6: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

***According to exercises given in lessons and following the CDs, for 6/7 days**:*

- Alternate mindful sitting meditation with mindful standing stretches each day this week
- Pay attention to 'what you put into your body', where it comes from, how much and why. Include food, TV, newspapers, bad news, pollution etc
- The six hour day of mindfulness is this Saturday, (Insert date) from 10.00 am until 4.00pm
- Please bring lunch, wear loose layered clothing on Saturday

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 7: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

According to exercises given in lessons and following the CDs, for 6/7 days*:*

- Practice the formal mindfulness practice: meditation, standing or lying stretches, body scan on one's own as best one can for approximately 45 minutes per day.
- Informal practice (mindfulness in every day life) practised on your own for preparation for when the course is over
- Pay attention to what you put in your body: how much, when, what, how often

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 17. Home practice instructions and record sheet for MBSR home practice (continued)

Home Practice for MBSR Class 8: (Insert date here)

If you have any queries or difficulties with the home practice, please do not hesitate to call Caroline Hoffman on 020 7384 0007 or email cjh@breastcancerhaven.org.uk

Home Practice Instructions

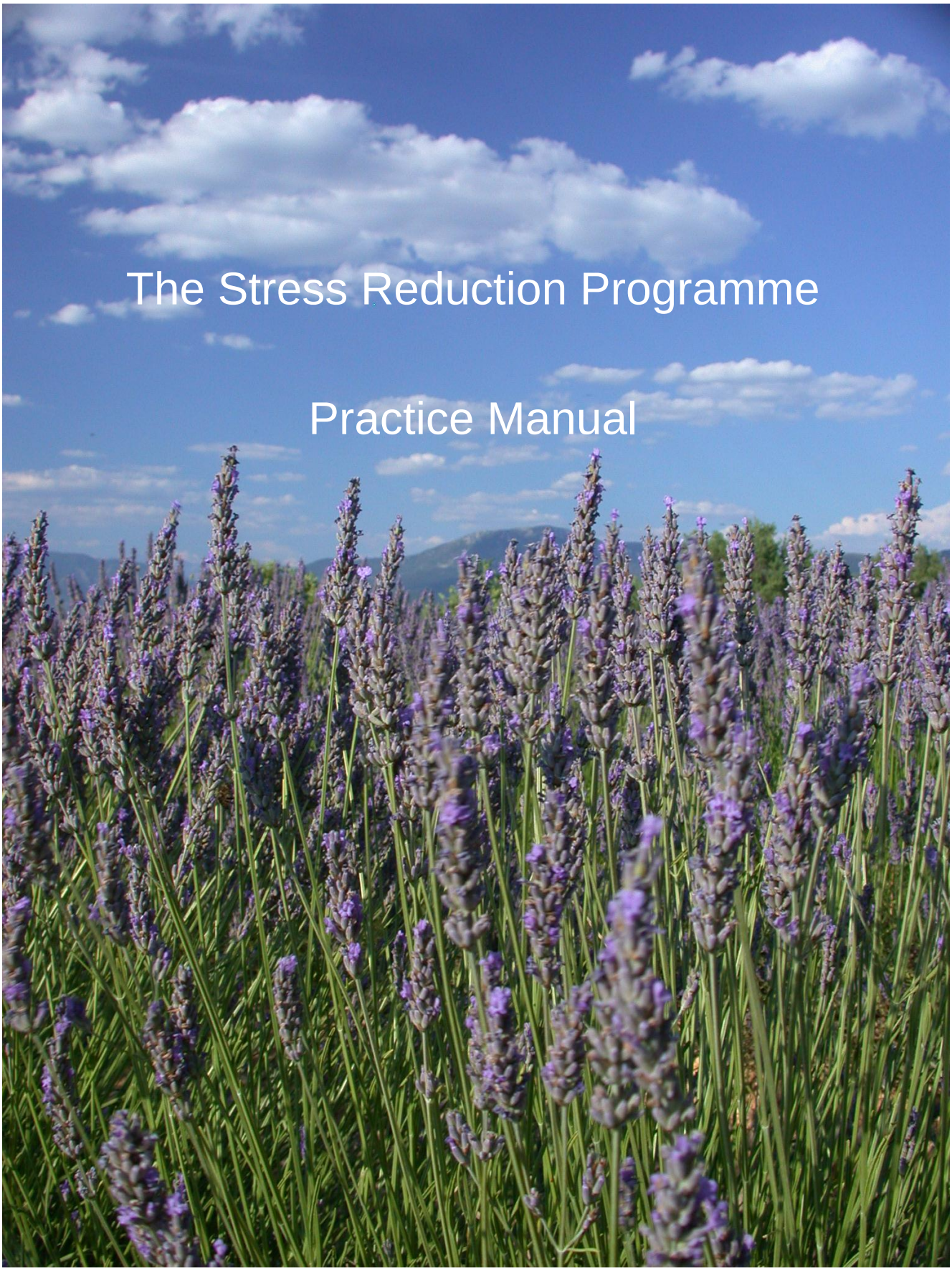
***According to exercises given in lessons and following the CDs, for 6/7 days**:*

- Go back to the CDs, using whichever mindfulness practices you wish. Keep up the practice and make it your own.
- Identify three short term and three longer term goals which come out of your direct experience of the MBSR programme and your mindfulness practice and write them down.
- Also write down any potential obstacles to reaching these goals and your strategies for working with them to keep the momentum of your practice moving and growing.
- Write yourself a letter about what you what to achieve over the next six to twelve months. Keep the letter and open it in six to twelve months time.

On the home work sheet

1. *Please make sure you fill in your name*
2. *Write in the boxes as instructed as to what practices you have done e.g. body scan, mindful sitting meditation*
3. *Please record how many minutes they took*
4. *Please add any comments about the home practice in the third column*

Appendix 18. The Stress Reduction Programme Practice Manual



The Stress Reduction Programme Practice Manual

Mindfulness is about being fully awake in our lives. It is about perceiving the exquisite vividness of each moment.
We feel more alive.
We also gain immediate access to our own powerful inner resources for insight, transformation, and healing.

Jon Kabat-Zinn
Founder of the Centre for Mindfulness,
Medicine, Health Care and Society

This practice manual is
used with the kind permission of

University of Massachusetts Medical School,
Worcester, Mass, USA.
Other elements have been added by Caroline Hoffman,
Therapies Director, Breast Cancer Haven.

Table of Contents

Tips for the Body Scan

1. Regardless of what happens (fall asleep, lose concentration, keep thinking of other things), just do it! These are your experiences in the moment. Just be aware of them.

2. If your mind is wandering a lot, simply note the thoughts (as passing events) and then bring the mind gently back to the body scan.

3. Let go of ideas of "success", "failure", "doing it really well," or "trying to purify the body". This is not a competition. It is not a skill for which you need to strive. The only discipline involved is regular and frequent practice. Just do it with an attitude of openness and curiosity.

4. Let go of any expectations about what the body scan will do for you. Imagine it as a seed you have planted. The more you poke around and interfere, the less it will be able to develop. So with the body scan, just give it the right conditions - peace and quiet, regular and frequent practice. That is all. The more you try to influence what it will do for you, the less it will do.

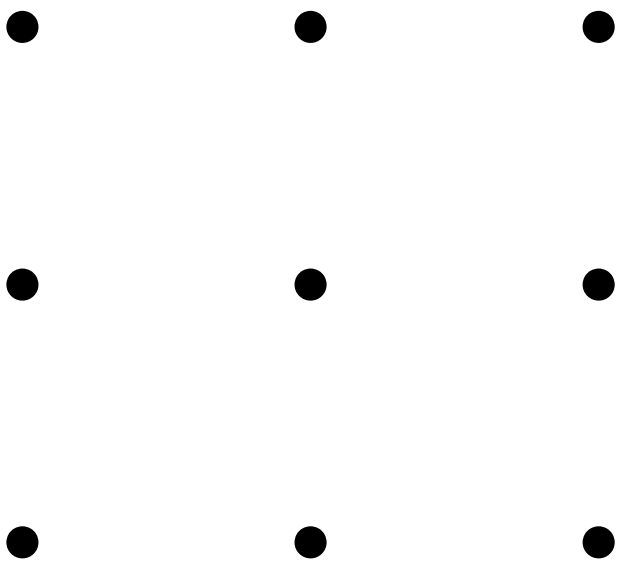
5. Try approaching your experience in each moment with the attitude: "OK that's just the way things are right now". If you try to fight off unpleasant thoughts, feelings or body sensations, the upsetting feelings will only distract you from doing anything else. Be aware, be non-striving, be in the moment, accept things as they are. Just do it.

From Segal,Z., Williams J.M. G. and Teasdale, J.D. (2002) *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse.* New York: Guilford Press

Ways of Seeing

Nine Dots

Connect up all these dots with four straight lines without lifting the pencil, and without retracing over any of the lines.



A Contemporary Fable

Upstream /Downstream

It was many years ago that the villagers of Downstream recall spotting the first body in the river. Some old timers remember how spartan were the facilities and procedures for managing that sort of thing. Sometimes, they say, it would take hours to pull 10 people from the river, and even then only a few would survive.

Though the number of victims in the river has greatly increased in recent years, the good folks of Downstream have responded admirably to the challenge. Their rescue system is clearly second to none: most people discovered in the swirling waters are reached within 20 minutes – many less than 10. Only a small number drown each day before help arrives – a big improvement from the way it used to be.

Talk to the people of Downstream and they'll speak with pride about the new hospital by the edge of the waters, the flotilla of rescue boats ready for service at a moment's notice, the comprehensive health plans for coordinating all the manpower involved, and the large numbers of highly trained and dedicated swimmers always ready to risk their lives to save victims from the raging currents. Sure it costs a lot but, say the Downstreamers, what else can decent people do except provide whatever is necessary when human lives are at stake.

Oh, a few people in Downstream have raised the question now and again, but most folks show little interest in what's happening Upstream. It seems that there's so much to do to help those in the river that nobody's got time to check how all those bodies are getting there in the first place. That's the way things are, sometimes.

Ardell, D.B. (1979) *High Level Wellness: An Alternative to Doctors, Drugs and Disease.* New York: Bantam Books

Awareness of Pleasant and Unpleasant Events

If I had my life to live over

If I had my life to live over, I'd like to make more mistakes next time. I'd relax, I would limber up. I would be sillier than I had been this trip. I would take fewer things seriously. I would take more chances. I would climb more mountains and swim more rivers. I would eat more ice-cream and less beans. I would perhaps have more actual troubles, but I'd have fewer imaginary ones.

You see, I'm one of those people who live sensibly and sanely hour after hour, day after day. Oh, I've had my moments, and if I had to do it over again, I'd have more of them. In fact, I'd try to have nothing else. Just moments, one after another, instead of living so many years ahead of each day. I've been one of those persons who never goes anywhere without a thermometer, a hot water bottle, a raincoat, and a parachute. If I had to do it again, I would travel lighter that I have.

If I had my life to live over, I would start barefoot earlier in the spring and stay that way until late in the fall. I would go to more dances. I would ride more merry-go-rounds. I would pick more daisies.

Nadine Stair
85 years old
Louisville, Kentucky

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

Pleasant Events

What was the experience?	**Were you aware of the pleasant feelings *while* the event was happening?**	**How did your body feel, in detail, during this experience?**	**What moods, feelings and thoughts accompanied this event?**	**What thoughts are in your mind now as you write this event?**
Monday				
Tuesday				
Wednesday				
Thursday				

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

Pleasant Events

What was the experience?	**Were you aware of the pleasant feelings *while* the event was happening?**	**How did your body feel, in detail, during this experience?**	**What moods, feelings and thoughts accompanied this event?**	**What thoughts are in your mind now as you write this event?**
Friday				
Saturday				
Sunday				

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

Unpleasant Events

What was the experience?	**Were you aware of the unpleasant feelings *while* the event was happening?**	**How did your body feel, in detail, during this experience?**	**What moods, feelings and thoughts accompanied this event?**	**What thoughts are in your mind now as you write this event?**
Monday				
Tuesday				
Wednesday				
Thursday				

Unpleasant Events

What was the experience?	**Were you aware of the unpleasant feelings *while* the event was happening?**	**How did your body feel, in detail, during this experience?**	**What moods, feelings and thoughts accompanied this event?**	**What thoughts are in your mind now as you write this event?**
Friday				
Saturday				
Sunday				

Mindful Stretches

Mindful Stretches

Many of us are reluctant to exercise because it involves discomfort or strain, or requires special equipment or others to work out with, or going to a special place to do it. If this has been the case for you, then mindful stretches may be just the practice you have been waiting for.

The word ‘mindful’ implies harnessing together and a unifying of body and mind. Mindful stretches are a form of moving meditation, and when done regularly, is an excellent mind/body discipline for people who wish to move towards a greater level of health.

Mindful stretches consist of postures done mindfully and with awareness of breathing. They are easily learned and have a dramatic effect if practised regularly. The ones we are doing are extremely gentle. Regular practice will increase your musculoskeletal flexibility, strength, and balance, as well as help you to enter states of deep relaxation and awareness. Many people experience a greater serenity about life in general, improved circulation, a firmer, trimmer figure, and less illness as a result.

In practising mindful stretches, you are advised to practise in the same way as you do when meditating, namely maintaining moment to moment awareness and not striving to get somewhere, just allowing yourself to be as you are, and letting go of any judging of yourself. Move slowly and consciously.

Mindful stretching involves exploring your limits but not pushing beyond them. Instead, you play with dwelling at the boundary and breathe. This requires honouring your body and the “messages” it gives you about when to stop and when to avoid doing a posture because of your particular health condition.

Mindful stretching involves no special equipment and can be done almost anywhere. You can learn from the accompanying CDs and then later you can go on and practise without the CDs and apply the principles to other forms of exercise that you might do.

Adapted from Kabat-Zinn, J. (1990) *Full Catastrophe Living: How to cope with stress, pain and illness using mindfulness meditation*. New York: Delacorte.

Mindful Lying Stretches

1. Relaxation Pose

2. Stretching entire

3. Lower back press

4a. Sweeping

4b. Sweeping arms

4c. Sweeping arms

5a. Single arm shoulder stretch (both sides)

5b. Single arm shoulder stretch (both sides)

Example of knees bend up and feet flat on the floor

6a. Folded arms shoulder

6b. Folded arms shoulder

7. Hugging knees to the chest

8. Head to knee pose (both sides)

9a. Rotating leg in hip joint (both sides)

9b. Rotating leg in hip joint (both sides)

10. Diamond pose

11. Gentle spinal twist (both sides)

12a. Head to leg (both sides)

12b. Head to leg (both sides)

12c. Head to leg (both sides)

13. Lying on front

14. Leg raises (both sides)

15. Head raises

16. Relaxation

Mindful Standing Stretches

1 Standing
like a mountain

1 Standing
Like a mountain

2 Stretching
The whole body

3a) Stretching
the sides
of the body

3b)
Stretching
of the body

4
Stretching
sideways

5a) Moving the
arms like a bird

5b) Moving the
arms like a bird

6 Sideways
stretch

11 Standing
like a mountain

12 Balance

13 Standing
like a mountain

14a) Twist
from the neck

14b) Twist
from the waist

14b) Twist
from the ankles

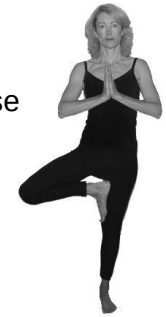
15a) Forward

15b) Forward bend

15c) Forward bend

16 Chair pose

17a) Tree pose



17b) Tree pose

18 Sitting

19a) Opening the hips

19b) Opening the hips

19c) Opening the hips

20a) Forward

20b) Forward

20c) Forward bend

21 Hugging knees to chest

22 Relaxation pose

Mindful Sitting Meditation

Mindfulness Meditation Sitting Positions

1 Chair sitting
Hands in lap

Chair sitting
ands on thigh

3 Chair sitting
Side view

4 Sitting on a
cushion
Hands in lap

5 Sitting on a
cushion
Side view

6 Kneeling
position

7 Kneeling
Position
Side view

Mindfulness of the Breath Tip Sheet

Focusing on the breath

- Brings you back to this very moment - the here and now
- Is always available as an anchor and haven, no matter where you are
- Can actually change your experience by connecting you with a wider space and broader perspective from which to view things

Basics

It helps to adopt an erect and dignified posture, with your head, neck, and back aligned vertically - the physical counterpart of the inner attitudes of self-reliance, self-acceptance, patience, and alert attention that we are cultivating.

Practice on a chair or on the floor. If you use a chair, choose one that has a straight back and allows your feet to be flat on the floor. If at all possible, sit away from the back of the chair so that your spine is self-supporting.

If you choose to sit on the floor, do so on a firm thick cushion (or a pillow folded over once or twice), which raises your buttocks off the floor 3 to 6 inches.

The Three Minute Breathing Space

Use this method as often as you like to help you step out of automatic pilot. It is like a compressed version of your sitting practice.

Take your seat.

Sink into the sensations of sitting and of your body awareness.

Ask yourself: What is here now?

Allow yourself to accept what is going on in this moment, including thoughts, feelings, sensations and emotions. Notice it all….

Bring your awareness to your breath at the nostrils, chest or belly, wherever it is most vivid.

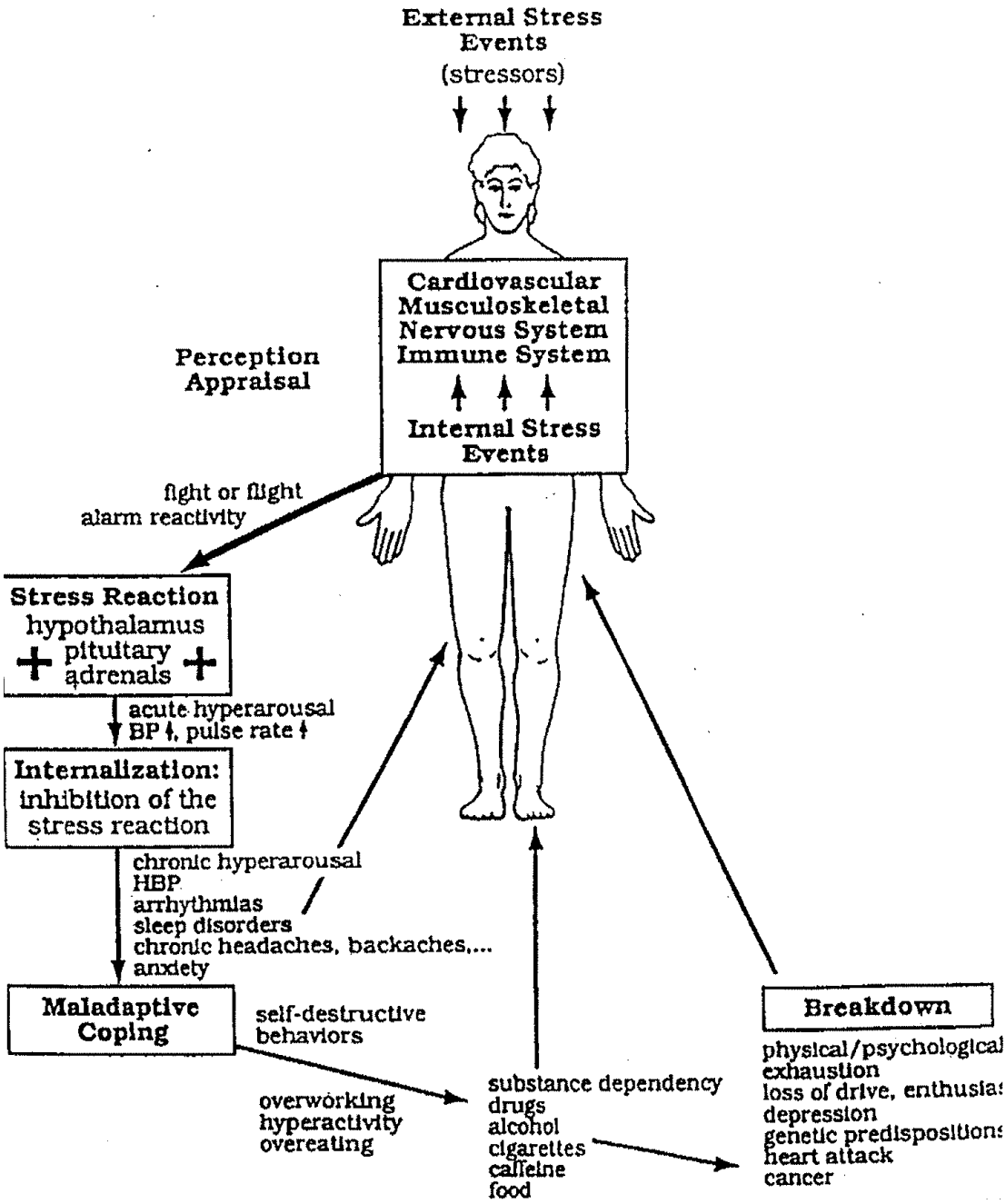
Expand your awareness to your body as a whole.

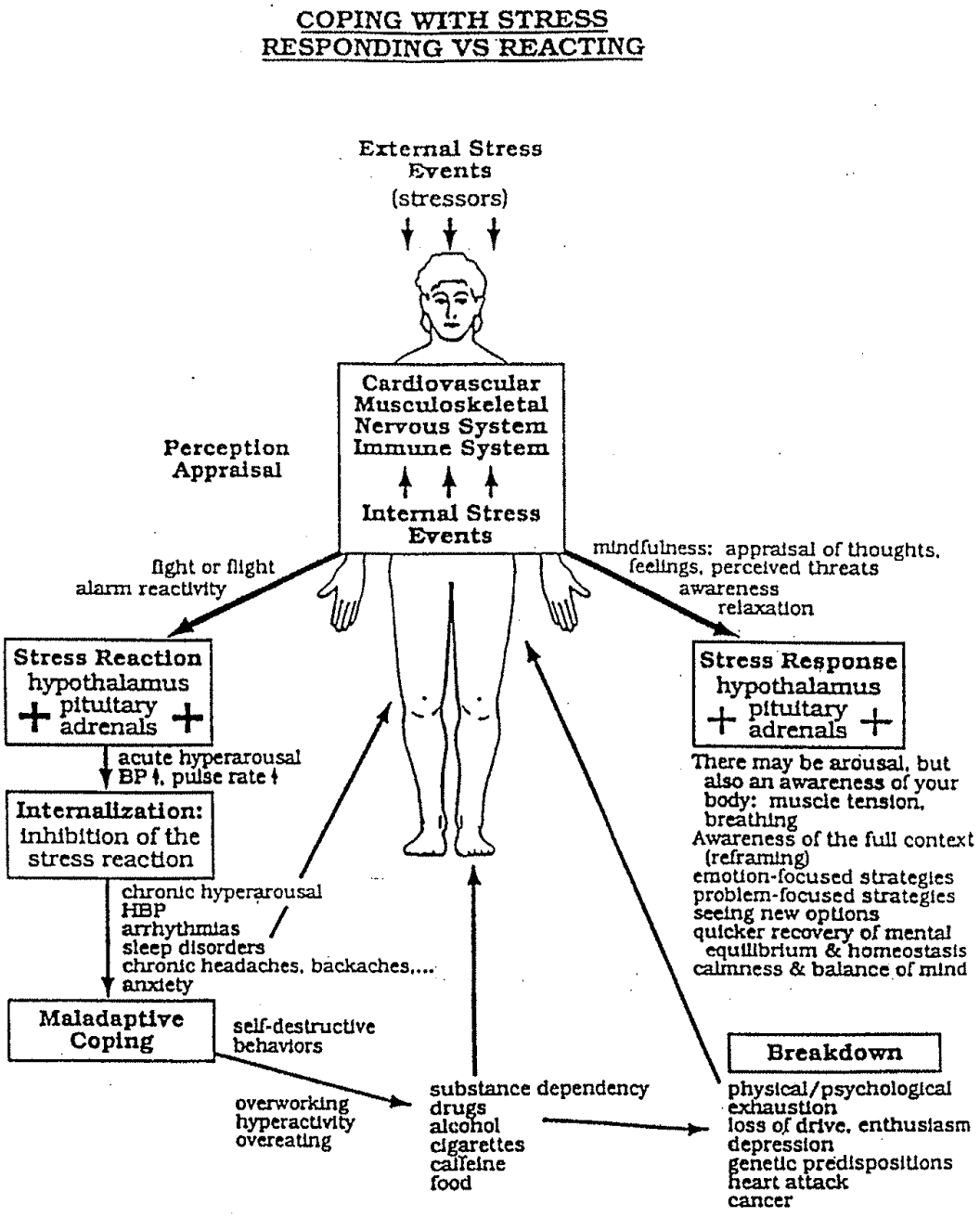
Sit in this compassionate and non-judgmental way for 3 minutes.

Do this exercise several times a day and it can become a nourishing interval in your day.

Stress,
Stress Reactivity
and
Stress Hardiness

THE STRESS REACTION CYCLE




COPING WITH STRESS
RESPONDING VS REACTING
External Stress Events
(stressors)
Cardiovascular
Musculoskeletal
Nervous System
Immune System
Internal Stress Events
Perception
Appraisal
fight or flight
alarm reactivity
mindfulness: appraisal of thoughts, feelings, perceived threats
awareness
relaxation
Stress Reaction
hypothalamus
pituitary
adrenals
acute hyperarousal
BP ↑, pulse rate ↑
Internalization:
inhibition of the stress reaction
chronic hyperarousal
HBP
arrhythmias
sleep disorders
chronic headaches, backaches,...
anxiety
Maladaptive Coping
self-destructive behaviors
overworking
hyperactivity
overeating
substance dependency
drugs
alcohol
cigarettes
caffeine
food
Stress Response
hypothalamus
pituitary
adrenals
There may be arousal, but also an awareness of your body: muscle tension, breathing
Awareness of the full context (reframing)
emotion-focused strategies
problem-focused strategies
seeing new options
quicker recovery of mental equilibrium & homeostasis
calmness & balance of mind
Breakdown
physical/psychological exhaustion
loss of drive, enthusiasm
depression
genetic predispositions
heart attack
cancer

Mindfulness and Mastery in the workplace:
21 ways to reduce stress during the workday

The following *21 ways are simply a roadmap. Allow your curiosity and the sense of possibility to unfold as you explore the territory, discovering your own "ways".*

1. Take 5-30 minutes in the morning to be quiet and meditate – sit or lie down and be with yourself…gaze out the window, listen to the sounds of nature or take a slow quiet walk.

2. While your car is warming up or while waiting for the bus or train or getting on your bike, try taking a minute to quietly pay attention to your breathing.

3. While driving, become aware of body tension, e.g. hands wrapped tightly around the steering wheel, raised shoulders, stomach tight, etc., consciously working at releasing, dissolving that tension…Does being this tense help you to drive better or get there any faster? What does if feel like to relax and drive or sit, stand or wait?

4. Decide not to play the radio and be with yourself.

5. On the motorway, experiment with driving in the left lane, going a little below the speed limit.

6. Pay attention to your breathing and to the sky…trees, or quality of your mind when stopped at a red light or in a traffic jam.

7. Take a moment to orientate yourself to your workday once you park your car at the workplace or walking from the bus or train. Use that walk to step into your life. To know where you are and where you are going.

8. While sitting at your desk, keyboard etc, paying attention to bodily sensations, again consciously attempting to relax and rid yourself of excess tension.

9. Using your breaks to truly relax rather than simply "pausing".

10. At lunch, changing your environment can be helpful.

11. Try closing your door (if you have one) and take some time to consciously relax.

12. Decide to "STOP" for 1-3 minutes every hour during the workday. Become aware of your breathing and bodily sensations, allowing the mind to settle in as a time to regroup and recoup.

13. Use the everyday cues in your environment as reminders to “centre” yourself, e.g. the ringing telephone, sitting down at the computer terminal etc.

14. Take some time at lunch or other moments in the day to speak with close associates. Try choosing topics that are not necessarily work related.

15. Choose to eat one or two lunches per week in silence. Use this as a time to eat slowly and be with yourself.

16. At the end of the workday, try retracing today’s activities acknowledging and congratulating yourself for what you have accomplished and then make a list *for tomorrow*. You’ve done enough for today!

17. Pay attention to the walk to the car, bus or train or bike– breathing in the crisp or warm air. Feel the cold or warmth of your body. What might happen if you opened to and accepted these environmental conditions rather than resisting them? Listen to the sounds outside your workplace. Can you walk without feeling rushed? What happens if you slow down?

18. At the end of the workday, while your car is warming up, sit quietly and consciously make the transition from work to home – take a moment to simply *be* – **enjoy it for a moment**. Like most of us, you’re heading into your next full-time job – home!

19. While driving, walking to the bus or train or biking, notice if you are rushing. What does this feel like? What could you do about it? Remember that you’ve got more control than you might imagine.

20. When you pull into the driveway or park on the street, take a minute to orientate yourself to being with your family or to entering your home.

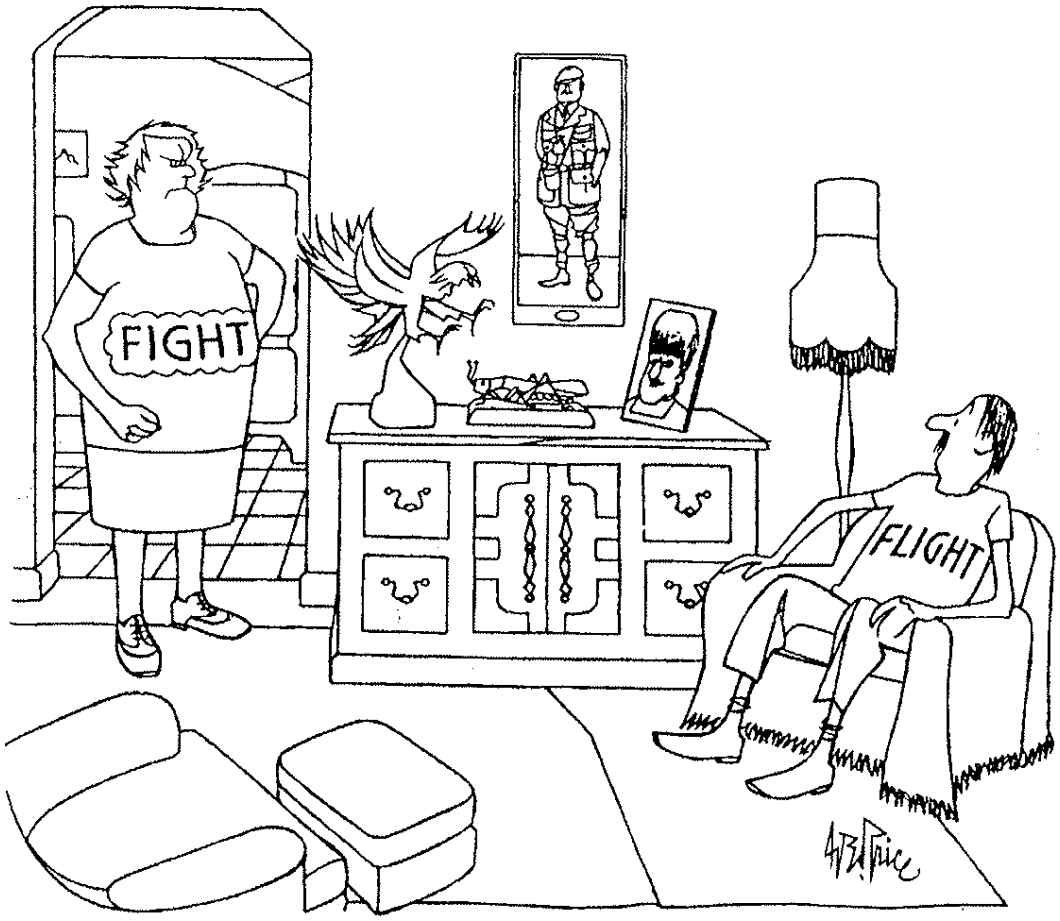
21. Try changing out of work clothes when you get home. This simple act may help you to make a smoother transition into your next “role” – much of the time you can probably “spare” five minutes to do this. Say hello to each of your family members or to the people you live with. Take a moment to look into their eyes. If possible, make the time to take 5 – 10 minutes to be quiet and still. If you live alone, feel what it is like to enter the quietness of your home, the feeling of entering your own environment.

Saki Santorelli,

Director of the Centre for Mindfulness,

Medicine, Health Care and Society

Communication



- New Yorker Magazine

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

Communication Exercises

Describe the communication. With whom? What subject?	**How did the difficulty come about?**	**What did you want from the person or situation? What did you actually get?**	**How did you feel during and after this time?**	**Have you resolved this issue yet?**
Monday				
Tuesday				
Wednesday				
Thursday				

Communication Exercises

Describe the communication. With whom? What subject?	**How did the difficulty come about?**	**What did you want from the person or situation? What did you actually get?**	**How did you feel during and after this time?**	**Have you resolved this issue yet?**
Friday				
Saturday				
Sunday				

A Comparison of Passive, Assertive and Aggressive Behaviours

Verbal Behaviours

Passive	Assertive	Aggressive
You avoid saying what you want, think or feel. If you do then you say them in such a way that you put yourself down. Apologetic words with hidden meanings are frequent. A smoke screen of vague words or silence. "Well…", "I mean…", "I guess…", and "I'm sorry". You allow others to choose for you.	You say what you honestly want, think and feel in direct and helpful ways. You make your own choices. You communicate with tact and humour. You use "I" statements. Your words are clear and well chosen.	You say what you want, think and feel but at the expense of others. You use "loaded words" and "you" statements that label and blame. You are full of threats and accusations and apply one-upmanship.

Non-verbal behaviours

Passive	Assertive	Aggressive
You use actions instead of words. You hope someone will guess what you want. You look as if you don't mean what you say. Your voice is weak, hesitant and soft. You whisper in a monotone. Your eyes are to the side or downcast. You nod your head to almost anything anyone says. You sit or stand as far away as you can from the other person. You don't know what to do with your hands and they are trembling and clammy. You look uncomfortable, shuffle, and are tense and inhibited.	You listen closely. Your manner is calm and assured. You communicate caring and strength. Your voice is firm, warm and expressive. You look directly at the other person but you don't stare. You face the person, your hands are relaxed. You hold your head erect and lean towards the other person. You have a relaxed expression.	You make an exaggerated show of strength. You are flippant. You have an air of superiority. Your voice is tense, loud, cold and demanding. You are "deadly quiet". Your eyes are narrow, cold and staring. You almost see through the other people. You take a macho fight stance. Your hands are on your hips and you are inches from the other people. Your hands are in fists or your fingers are pointed at the other person. You appear tense and angry.

Your apparent goals and feelings

Goals

Passive	Assertive	Aggressive
To please, to be liked	To communicate, to be respected	To dominate or humiliate

Feelings

Passive	Assertive	Aggressive
You feel anxious, ignored, hurt, manipulated, and disappointed with yourself. You are often angry and resentful later.	You feel confident and successful. You feel good about yourself at that time and later. You feel in control, you have self-respect and you are goal-orientated.	You feel self-righteous, controlling and superior. Sometimes you feel embarrassed or selfish later

Your apparent payoffs

Passive	Assertive	Aggressive
You avoid unpleasant situations, conflicts, short-term tensions and confrontation. You don't have to take responsibility for your choices.	You feel good. You feel respected by others. Your self-confidence improves. You make your own choices. Your relationships with others are improved. You have very little physical distress now or later. You are in touch with your feelings.	You get some anger off your chest. You get a feeling of control. You feel superior.

The effects on others

Their feelings

Passive	Assertive	Aggressive
They feel guilty, superior, frustrated or even angry.	They feel respected or valued. They feel free to express themselves.	They feel humiliated, depreciated or hurt.

Their feelings towards you

Passive	Assertive	Aggressive
They feel irritated. They pity and depreciate you. They feel frustrated and disgusted with you. They lose respect for you because you are a pushover and someone who does not know where he stands.	They usually respect, trust or value you. They know where you stand.	They feel hurt, defensive, humiliated or angry. They resent, distrust and fear you. They may want revenge.

Probable outcomes of each type of behaviour

Passive	Assertive	Aggressive
You don't get what you want. If you do get your own way, it is indirect. You feel emotionally dishonest. Others achieve their goals at your expense. Your hands are violated. Your anger builds up and you either push it down or redirect it towards other people who are less powerful. You may find yourself procrastinating, suffering in silence, doing things half-heartedly, being sloppy or becoming forgetful. You get manoeuvred. Loneliness and isolation may become part of your life.	You often get what you want if it is reasonable. You often achieve your goals. You gain self-respect. You feel good. You convert win-loose to win-win. The outcome is determined by above-board negotiations. Your rights and other's rights are respected.	You often get what you want but at the expense of others. You hurt others by making choices for them and infantilizing them. Others may feel a right to "get even". You may have increased difficulty with relaxing and "unwinding" later.

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

Directions:

Label each of the following as either assertive (AS) passive

(P) or aggressive (AG)

The situation might be	**What you say and do**
1. You are watching a movie, but people seated in front of you are making it hard to hear	You sit and fume, clearing your throat occasionally
2. At a meeting one person often interrupts you when you are speaking	You look at the person and say firmly, I would like to finish what I am saying"
3. You'd like a pay rise	You shuffle into your bosses office and say, "Do you think that, ah, you could see your way clear to giving me a raise?"
4. You have talked with your boss about a helpful suggestion for organising work in the office. He says that he thinks it is a good idea and that he will ask someone else to put the change into effect	You put your hands on your hips and shout, "This was my suggestion, and I'll not stand for someone else getting the credit for it".
5. You are looking forward to a quiet night alone. A relative calls and asks you to babysit.	You communicate caring, but strength as you say, " I put aside tonight for myself and I won't be able to babysit"
6. Your parents or in-laws call and they tell you they are dropping by. You are busy.	In a very loud voice you say, "you always call two minutes before you are here and expect me to drop everything
7. Two workers in your office are talking about personal matters. The work has been piling up. Others have been complaining. You are their supervisor.	You call the offenders together, lean towards them and say, "I know how easy it is for time to slip by when you are talking to your friends. But work is piling up. I would like you to use the 20 minute break for personal conversation.
8. A good friend is always late for things you plan to do together. You have not said anything for several weeks.	When your friend arrives you look like you are ready to explode. You say "You are never on time".
9. A date and time are set for a weekly meeting. The time is not convenient for you. The times are set when it is impossible for you to make the meetings regularly.	When asked about the time you look down and almost whisper "Well, I guess it is OK. I'm not going to be able to come very often, but if it fits everyone else's schedule, its OK with me.
10. You are the only woman (or man) in a group of men (or women). You are asked to be the secretary of the meetings.	You respond, "I'm willing to do my share and take notes at this time. I'd like others to take their turn".

Answers to the review questions:

1. P. 2. AS 3. P 4. AG 5. AS 6. AG 7. AS 8. AG 9. P 10. AS

Reprinted from Charlesworth, E. and Nathan, R. (1882) *Stress Management: A comprehensive guide to wellness*. Texas: Biobehavioral Press.

Mindful Walking Tip Sheet

1. Find a place where you can walk up and down, without feeling concerned about whether people can see you. It can be inside or outside.

2. Stand at one end of your walk, with your feet parallel to each other, about 4-6 inches apart, and your knees unlocked, so that they can gently flex. Allow your arms to hang loosely by your sides, or hold your hands loosely together. Direct your gaze, softly, straight ahead.

3. Bring the focus of your awareness to the bottoms of your feet, getting a direct sense of the physical sensations of the contact of the feet with the ground and the weight of your body transmitted through your legs and feet to the ground. You may find it helpful to flex your knees slightly a few times to get a clearer sense of the sensations in the feet and legs.

4. When you are ready, transfer the weight of the body into the right leg, noticing the changing pattern of physical sensations in the legs and feet as the left leg empties and the right leg takes over the support of the rest of the body.

5. With the left leg empty, allow the left heel to rise slowly from the floor, noticing the sensation in the calf muscles as you do so, and continue, allowing the whole of the left foot to lift gently until only the toes are in contact with the floor. Allow the rest of the bottom of the left foot to make contact with the floor as you transfer the weight of the body into the left leg and foot, aware of the increasing physical sensations in the left leg and foot, and of the emptying of the right leg and right heel leaving the floor.

6. With the weight fully transferred to the left leg, allow the rest of the right foot to lift, and move it slowly forward, aware of the changing patterns of physical sensations in the foot and leg as you do so. Focusing your attention on the right heel as it makes contact with the ground, transfer the weight of the body into the right foot as it is placed gently on the ground, aware of the shifting pattern of physical sensations in the two legs and feet.

7. In this way, slowly move from one end of your walk to the other, aware particularly of the sensations in the bottoms of the feet and heels as they make contact with the floor, and of the sensations in the muscles of the legs as they swing forward.

8. At the end of your walk, turn slowly around, aware of and appreciating the complex pattern of movements through which the body changes direction, and continue walking.

9. Walk up and down in this way, being aware, as best you can, of physical sensations in the feet and legs, and of the contact of the feet with the floor. Keep your gaze directed softly ahead.

10. When you notice that the mind has wandered away from awareness of the sensations of walking, gently escort the focus of attention back to the sensations in the feet and legs, using the sensations as the feet contact the floor, in particular, as an anchor to reconnect with the present moment, just as you used the breath in the sitting meditation.

11. Continue to walk for 10-15 minutes, or longer if you wish.

Appendix 18. The Stress Reduction Programme Practice Manual (continued)

12. To begin with, walk at a pace that is slower than usual, to give yourself a better chance to be fully aware of the sensations of walking. Once you feel comfortable walking slowly with awareness, you can experiment as well with walking at faster speeds, up to and beyond normal walking speed. If you are feeling particularly agitated, it may be helpful to begin walking fast, with awareness, and to slow down naturally as you settle.

13. As often as you can, bring the same kind of awareness that you cultivate in walking meditation to your normal, everyday experiences of walking.

From Segal,Z., Williams J.M. G. and Teasdale, J.D. (2002) *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse.* New York: Guilford Press

Dimensions of Wellness

Spiritual

- Finding meaning and purpose in life
- Celebrating values
- Developing ways to feel joyful and committed to life
- Allowing yourself quiet time for connection and reflection

Physical

- Good nutrition, adequate sleep
- Minimisation/avoidance of behaviours which are harmful (e.g. tobacco, drugs or alcohol)
- Maintaining strength, cardiovascular fitness and flexibility
- Getting out in fresh air and amongst nature
- Detoxing from time to time

Social

- Contributing to the community –people and environment
- Developing and maintaining healthy relationships within your community
- Giving yourself time to have fun with others
- Seeing the funny side of life

Emotional

- Awareness and acceptance of feelings
- Managing stress with healthy coping strategies
- Feeling free to express yourself
- Being able to be yourself

Occupational

- Gaining satisfaction and enrichment from work
- Contributing to a healthy work environment
- Working at an even pace, not overworking
- Having outlets for self-expression and creativity

Intellectual

- Engaging the mind in creative, stimulating mental activities
- Improving skills, expanding knowledge

Wellness is the conscious commitment to growth and improvement in all areas of our lives. It enables us to love our lives just as they are.

Appendix 19. Mindfulness audio CDs for home practice

See inside back cover of thesis for four mindfulness CDs:

1. Mindful body scan
2. Mindful lying stretches
3. Mindful sitting meditation
4. Mindful standing stretches

Appendix 20. MBSR Programme Cycles for 2005 – 2006

2005

Jan					**Feb**				**Mar**		Easter25/28		**Apr**				**May**					**Jun**			
3	10	17	24	31	7	14	21	28	7	14	21	28	4	11	18	25	2	9	16	23	30	6	13	20	27
New Year		**Pilot Cycle**								**Pilot Follow up**				**Spring Cycle 1**								**Follow up 1**			
Weeks		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	7	8	10	11	12

Jul				**Aug**					**Sep**				**Oct**					**Nov**				**Dec**			
4	11	18	25	1	8	15	22	29	5	12	19	26	3	10	17	24	31	7	14	21	28	5	12	19	26
Summer cycle 2								**Follow up 2**				**Autumn cycle 3**								**Follow up 3**				Xmas	
1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12		

2006

Jan					**Feb**				**Mar**				**Apr**	Easter14/17			**May**					**Jun**			
2	9	16	23	30	6	13	20	27	6	13	20	27	3	10	17	24	1	8	15	22	29	5	12	19	26
New Year		**Winter Cycle 4**								**Follow up 4**						**Spring Cycle 5**								**Follow**	
		1	2	3	4	5	6	7	8	9	10	11	12			1	2	3	4	5	6	7	8	9	10

Jul					**Aug**				**Sep**				**Oct**					**Nov**			
3	10	17	24	31	7	14	21	28	4	11	18	25	2	9	16	23	30	6	13	20	27
Up 5		**Summer Cycle 6**								**Follow up 6**				**Autumn Cycle 7**							
11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8

Appendix 21. Coding of data

Chart A. MBSR Baseline Database Coding Chart

	Variable name	Variable/ field description	Value labels
1.	studyno	MBSR Study ID No.	Cycle, I or C, three digit number
2.	age	Age of participant at randomisation	In years
3.	occupation	Participant occupation	Text
4.	ses1	Socio economic status analytic classes	Large employers and higher managerial occupations = 1.1 Higher professional occupations = 1.2 Low managerial and professional occupations = 2 Intermediate occupations = 3 Small employers and own account workers = 4 Lower supervisory and technical occupations = 5 Semi-routine occupations = 6 Routine occupations = 7 Never worked and long-term unemployed = 8 Not classified = 88
5.	ses2	Socio economic status operational categories	Employers in large organisations = 1 Higher managerial occupations = 2 Higher professional occupations = 3.1, 3.2, 3.3, 3.4 Lower professional and higher technical occupations = 4.1, 4.2, 4.3, 4.4 Lower managerial occupations = 5 Higher supervisory occupations = 6 Intermediate occupations = 7.1, 7.2, 7.3, 7.4 Employers in small occupations = 8.1, 8.2 Own account workers = 9.1, 9.2 Lower supervisory occupations = 10 Lower technical occupations = 11.1, 11.2 Semi-routine occupations = 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7 Routine occupations = 13.1, 13.2, 13.3, 13.4, 13.5 Full time students = 15 Occupations not stated or inadequately described = 16 Never worked and long-term unemployed = 17

Appendix 21. Coding of data (continued)

6.	staging	Stage of breast cancer at randomisation	Stage 0 = 0 Stage 1 = 1 Stage 2 = 2 Stage 3 = 3
7.	recurrence	Has the participant suffered a recurrence of breast cancer?	Yes = 1 No = 2
8.	surgery	Did the participant have surgery for breast cancer?	Yes = 1 No = 2
9.	wlepart	Frequency of wide local excision/ partial mastectomy	0 1 2 etc
10	mastect	Frequency of mastectomy	0 1 2
11	reconstruct	Frequency of reconstruction	0 1 2 etc
12	chemo	Did the participant have chemotherapy for breast cancer?	Yes = 1 No = 2
13	neochemo	Neoadjuvant chemotherapy	Yes = 1 No = 2
14	neocycle	No of neoadjuvant cycles	
15	adjchemo	Adjuvant chemotherapy	Yes = 1 No = 2
16	adjcycle	No of adjuvant cycles	
17	radio	Did the participant have radiotherapy for breast cancer?	Yes = 1 No = 2
18	treatfin	Date breast cancer treatment finished	Text: month/year
19	hormonetx	Was the participant prescribed hormone treatment for breast cancer?	Yes = 1 No = 2
20	hormonetype	Type of hormone treatment prescribed	1= Anastrozole (Arimidex®) 2= Exemestane (Aromasin®) 3= Fulvestrant (Faslodex®) 4= Goserelin (Zoladex®) 5= Letrozole (Femara®) 6= Medroxyprogesterone acetate (Depo-Provera®, Farlutal®, Provera®) 7= Megestrol acetate (Megace®) 8= Tamoxifen® 9= Toremifene (Fareston®)
21	hormonetype2	Type of hormone treatment prescribed	Ditto

Appendix 21. Coding of data (continued)

22	herceptin	Was the participant prescribed Herceptin?	Yes = 1 No = 2
23	pretherapy	Total number of Haven programme hours pre MBSR teaching programme	
24	duringther	Total number of Haven programme hours during MBSR teaching programme	
25	postther	Total number of Haven programme hours after MBSR teaching programme	
26	randomise	Date participant randomised into study	Date dd/mm/yy
27	cycleallo	MBSR recruitment cycle participant allocated to.	Spring 2005 = 1 Summer 2005 = 2 Autumn 2005 = 3 Winter 2006 = 4 Spring 2006 = 5 Summer 2006 = 6
28	groupatt	MBSR teaching cycle participant allocated to	Spring 2005 = 1 Summer 2005 = 2 Autumn 2005 = 3 Winter 2006 = 4 Spring 2006 = 5 Summer 2006 = 6 Autumn 2006 = 7
29	q1complete	Did participant complete study Q1?	Yes = 1 No = 2
30	q1ontime	Did participant complete Q1 on time?	Yes = 1 No = 2 Not applicable = 88
31	q2complete	Did participant complete study Q2?	Yes = 1 No = 2
32	q2ontime	Did participant complete Q2 on time?	Yes = 1 No = 2 Not applicable = 88
33	q3complete	Did participant complete study Q3?	Yes = 1 No = 2
34	q3ontime	Did participant complete Q3 on time?	Yes = 1 No = 2 Not applicable = 88
35	intercont	Is the participant intervention or control?	Intervention = 1 Control = 2
36	havenid2	Haven Visitor No	
37	studyno2	MBSR Study ID No.	
38	totalhrs	Total hours of MBSR teaching programme attended by participant	

Appendix 21. Coding of data (continued)

39	totalwks	Total number of weekly MBSR sessions attended by participant	
40	saturday	Did the participant attend the Saturday workshop?	Yes = 1 No = 2
41	classdrop	Did the participant drop out of the MBSR teaching programme?	Yes = 1 No = 2
42	reasonclass	Reason the participant dropped out of MBSR teaching programme	MBSR not suitable = 1 Illness other than cancer = 2 Breast cancer = 3 Too busy = 4 Other life events = 5 Forgot = 6 Away = 7 Work = 8 Does not want to be around others with breast cancer = 9 Travel/ weather = 10 Moved away = 11 Deceased = 12 Not applicable = 88
43	dropout	Did the participant drop out of the study?	Yes = 1 No = 2
44	reasondrop	Reason the participant dropped out of the study	MBSR not suitable = 1 Illness other than cancer = 2 Breast cancer = 3 Too busy = 4 Other life events = 5 Forgot = 6 Away = 7 Work = 8 Does not want to be around others with breast cancer = 9 Travel/ weather = 10 Moved away = 11 Deceased = 12 No study Qs = 13 Study Q1 only = 14 No study Q1 = 15 No study Q2 = 16 Distress at filling in Qs = 17 Not applicable = 88
45	homepract	Total number of formal MBSR home practice hours carried out by participant	
46	Randdatemin ustxfin	Time between treatment finish and randomisation in months	

Appendix 21. Coding of data (continued)

47	Trandtoq1	Time between randomisation and starting study (Q1) in months	

Missing dated coded as: 9,99,999, 'missing'

Appendix 22. MBSR study questionnaire coding chart

	Variable/ field name	**Variable/ field description**	**Value labels** (0 = No in Access, 2 = No in SPSS)
1	acparid	Access database participant ID (autonumber)	
2	studyid	MBSR Study ID No	
3	*acqueid*	*Access database questionnaire ID (autonumber) only used in access database*	
4	intcont	Is the participant an intervention or control?	1 = intervention 2 = control
5	blankqu	Is the questionnaire missing?	0 = No **(NB 2 = No in SPSS)** 1 = yes
6	dateque	Date questionnaire completed by participant	dd/mm/yyyy
7	questno	Questionnaire number (assessment time point)	1 = Q1 2 = Q2 3 = Q3
8	bctreat	Q1 Treatment for breast cancer?	0 = No 1 = yes
9	treat10	If yes treatment 1	0= None 1= Anastrozole (Arimidex®) 2= Exemestane (Aromasin®) 3= Fulvestrant (Faslodex®) 4= Goserelin (Zoladex®) 5= Letrozole (Femara®) 6= Medroxyprogesterone acetate (Depo-Provera®, Farlutal®, Provera®) 7= Megestrol acetate (Megace®) 8= Tamoxifen® 9= Toremifene (Fareston®) 10= Trastuzumab (Herceptin®) 11= Radiotherapy 12= Surgery (not reconstruction) 13= Chemotherapy 14= disodium pamidronate (Aredia Dry Powder®) 15= ibandronic acid (Bondronat®) 16= sodium clodronate (Bonefos®, Loron®) 17= zoledronic acid (Zometa®) 18= Other 19 = Hormone but does not say which 20 = Reconstruction surgery
10	treat20	If yes treatment 2	Ditto
11	treat30	If yes treatment 3	Ditto
12	stressf	Q2 How stressful is your illness? (if more than one circled take most conservative answer)	Range 0 – 10 (0= Not stressful at all, 10 = Extremely stressful)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

13	stevent	Q3 Have you had recent life event? (if more than one circled take most conservative answer)	Range 0 – 10 (0= Not stressful at all, 10 = Extremely stressful)
14	event10	Recent life event example 1	1= Bereavement 2= Marital/relationship problems 3= Ill health (family/ friend) 4= Caring for ill/ disabled family member/ friend 5= Other family issues (examples include children starting school and ex-partner's relationship with child) 6= Financial concerns 7= Made redundant/sacked/retired from job/ looking for a new job 8= Stress associated with work/educational/other activities 9= Dispute with neighbour/ family/ friend 10= Moving home/ problems with home 11= Other 12 = ill health (self)
15	dateev1	Date of life event 1	Text
16	event20	Recent life event example 2	Ditto categories
17	dateev2	Date of life event 2	Text
18	event30	Recent life event example 3	Ditto categories
19	dateev3	Date of life event 3	Text
20	event40	Recent life event example 4	Ditto categories
21	dateev4	Date of life event 4	Text
22	event50	Recent life event example 5	Ditto categories
23	dateev5	Date of life event 5	Text
24	event60	Recent life event example 6	Ditto categories
25	dateev6	Date of life event 6	Text
26	event70	Recent life event example 7	Ditto categories
27	dateev7	Date of life event 7	Text
28	event80	Recent life event example 8	Ditto categories
29	dateev8	Date of life event 8	Text
30	pom01fx	POMS item 1 Friendly (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
31	pom02tt	POMS item 2 Tense (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
32	pom03aa	POMS item 3 Angry (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
33	pom04wf	POMS item 4 Worn out (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
34	pom05ud	POMS item 5 Unhappy (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
35	pom06cx	POMS item 6 Clear-headed (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
36	pom07lv	POMS item 7 Lively (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
37	pom08cc	POMS item 8 Confused (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

38	pom09sd	POMS item 9 Sorry (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
39	pom10st	POMS item 10 Shaky (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
40	pom11lf	POMS item 11 Listless (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
41	pom12pa	POMS item 12 Peeved (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
42	pom13ex	POMS item 13 Considerate (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
43	pom14sd	POMS item 14 Sad (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
44	pom15av	POMS item 15 Active (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
45	pom16ot	POMS item 16 On edge (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
46	pom17ga	POMS item 17 Grouchy (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
47	pom18bd	POMS item 18 Blue (Depression subscale)	Range 0 – 4 (0 = Not al all, 4 = Extremely)
48	pom19ev	POMS item 19 Energetic (Vigor subscale)	Range 0 – 4 (0 = Not al all, 4 = Extremely)
49	pom20pt	POMS item 20 Panicky (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
50	pom21hd	POMS item 21 Hopeless (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
51	pom22rt	POMS item 22 Relaxed (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
52	pom23wd	POMS item 23 Unworthy (Depression subscale)	Range 0 – 4 (0 = Not al all, 4 = Extremely)
53	pom24sa	POMS item 24 Spiteful (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
54	pom25sx	POMS item 25 Sympathetic (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
55	pom26ut	POMS item 26 Uneasy (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
56	pom27lt	POMS item 27 Restless (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
57	pom28uc	POMS item 28 Unable to concentrate (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
58	pom29ff	POMS item 29 Fatigued (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
59	pom30hx	POMS item 30 helpful (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
60	pom31na	POMS item 31 Annoyed (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
61	pom32dd	POMS item 32 Discouraged (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
62	pom33ra	POMS item 33 Resentful (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
63	pom34nt	POMS item 34 Nervous (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

64	pom35ld	POMS item 35 Lonely (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
65	pom36md	POMS item 36 Miserable (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
66	pom37mc	POMS item 37 Muddled (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
67	pom38cv	POMS item 38 Cheerful (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
68	pom39ba	POMS item 39 Bitter (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
69	pom40ef	POMS item 40 Exhausted (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
70	pom41at	POMS item 41 Anxious (Tension subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
71	pom42fa	POMS item 42 Ready to fight (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
72	pom43gx	POMS item 43 Good natured (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
73	pom44gd	POMS item 44 Gloomy (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
74	pom45pd	POMS item 45 Desperate (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
75	pom46sf	POMS item 46 Sluggish (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
76	pom47ea	POMS item 47 Rebellious (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
77	pom48ed	POMS item 48 Helpless (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
78	pom49yf	POMS item 49 Weary (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
79	pom50bc	POMS item 50 Bewildered (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
80	pom51tv	POMS item 51 Alert (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
81	pom52da	POMS item 52 Deceived (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
82	pom53sa	POMS item 53 Furious (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
83	pom54ec	POMS item 54 Efficient (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
84	pom55tx	POMS item 55 Trusting (no subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
85	pom56pv	POMS item 56 Full of pep (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
86	pom57ma	POMS item 57 Bad-tempered (Anger subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
87	pom58od	POMS item 58 Worthless (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
88	pom59lc	POMS item 59 Forgetful (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
89	pom60fv	POMS item 60 Carefree (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

90	pom61td	POMS item 61 Terrified (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
91	pom62yd	POMS item 62 Guilty (Depression subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
92	pom63vv	POMS item 63 Vigorous (Vigor subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
93	pom64nc	POMS item 64 Uncertain about things (Confusion subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
94	pom65bf	POMS item 65 Bushed (Fatigue subscale)	Range 0 – 4 (0 = Not at all, 4 = Extremely)
95	fgp01pe	FACT Physical wellbeing GP1 lack energy	Range 0 - 4 (0=Not at all, 4 = Very much)
96	fgp02pn	FACT Physical wellbeing GP2 nausea	Range 0 - 4 (0=Not at all, 4 = Very much)
97	fgp03pf	FACT Physical wellbeing GP3 family	Range 0-4 (0=Not at all, 4 = Very much)
98	fgp04pp	FACT Physical wellbeing GP4 pain	Range 0-4 (0=Not at all, 4 = Very much)
99	fgp05ps	FACT Physical wellbeing GP5 side effects	Range 0-4 (0=Not at all, 4 = Very much)
100	fgp06pi	FACT Physical wellbeing GP6 ill	Range 0-4 (0=Not at all, 4 = Very much)
101	fgp07pb	FACT Physical wellbeing GP7 bed	Range 0-4 (0=Not at all, 4 = Very much)
102	fgs01sf	FACT Social/Family Wellbeing GS1 friends	Range 0-4 (0=Not at all, 4 = Very much)
103	fgs02se	FACT Social/Family Wellbeing GS2 emotional	Range 0-4 (0=Not at all, 4 = Very much)
104	fgs03ss	FACT Social/Family Wellbeing GS3 support	Range 0-4 (0=Not at all, 4 = Very much)
105	fgs04si	FACT Social/Family Wellbeing GS4 illness	Range 0-4 (0=Not at all, 4 = Very much)
106	fgs05sc	FACT Social/Family Wellbeing GS5 communication	Range 0-4 (0=Not at all, 4 = Very much)
107	fgs06sp	FACT Social/Family Wellbeing GS6 partner	Range 0-4 (0=Not at all, 4 = Very much)
108	fgs07sx	FACT Social/Family Wellbeing GS7 sex	Range 0-4 (0=Not at all, 4 = Very much)
109	fge01es	FACT Emotional Wellbeing GE1 sad	Range 0-4 (0=Not at all, 4 = Very much)
110	fge02ec	FACT Emotional Wellbeing GE2 coping	Range 0-4 (0=Not at all, 4 = Very much)
111	fge03eh	FACT Emotional Wellbeing GE3 hope	Range 0-4 (0=Not at all, 4 = Very much)
112	fge04en	FACT Emotional Wellbeing GE4 nervous	Range 0-4 (0=Not at all, 4 = Very much)
113	fge05ed	FACT Emotional Wellbeing GE5 dying	Range 0-4 (0=Not at all, 4 = Very much)
114	fge06ew	FACT Emotional Wellbeing GE6 worse	Range 0-4 (0=Not at all, 4 = Very much)
115	fgf01fw	FACT Functional Wellbeing GF1 work	Range 0-4 (0=Not at all, 4 = Very much)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

116	fgf02ff	FACT Functional Wellbeing GF2 fulfilling	Range 0-4 (0=Not at all, 4 = Very much)
117	fgf03fl	FACT Functional Wellbeing GF3 life	Range 0-4 (0=Not at all, 4 = Very much)
118	fgf04fi	FACT Functional Wellbeing GF4 illness	Range 0-4 (0=Not at all, 4 = Very much)
119	fgf05fs	FACT Functional Wellbeing GF5 sleeping	Range 0-4 (0=Not at all, 4 = Very much)
120	fgf06fe	FACT Functional Wellbeing GF6 enjoying	Range 0-4 (0=Not at all, 4 = Very much)
121	fgf07fq	FACT Functional Wellbeing GF7 quality	Range 0-4 (0=Not at all, 4 = Very much)
122	fbs01bb	FACT Breast Specific Additional Concerns B1 breath	Range 0-4 (0=Not at all, 4 = Very much)
123	fbs02bd	FACT Breast Specific Additional Concerns B2 dress	Range 0-4 (0=Not at all, 4 = Very much)
124	fbs03ba	FACT Breast Specific Additional Concerns B3 arms	Range 0-4 (0=Not at all, 4 = Very much)
125	fbs04bs	FACT Breast Specific Additional Concerns B4 sexually	Range 0-4 (0=Not at all, 4 = Very much)
126	fbs05bh	FACT Breast Specific Additional Concerns B5 hair loss	Range 0-4 (0=Not at all, 4 = Very much)
127	fbs06bf	FACT Breast Specific Additional Concerns B6 family	Range 0-4 (0=Not at all, 4 = Very much)
128	fbs07bi	FACT Breast Specific Additional Concerns B7 illness	Range 0-4 (0=Not at all, 4 = Very much)
129	fbs08bc	FACT Breast Specific Additional Concerns B8 changes	Range 0-4 (0=Not at all, 4 = Very much)
130	fbs09bw	FACT Breast Specific Additional Concerns B9 woman	Range 0-4 (0=Not at all, 4 = Very much)
131	fbsp2bp	FACT Breast Specific Additional Concerns P2 pain	Range 0-4 (0=Not at all, 4 = Very much)
132	fes01ef	FACT Endocrine Specific (ES) symptoms ES1 flushes	Range 0-4 (0=Not at all, 4 = Very much)
133	fes02es	FACT Endocrine Specific (ES) symptoms ES2 sweats	Range 0-4 (0=Not at all, 4 = Very much)
134	fes03en	FACT Endocrine Specific (ES) symptoms ES3 night sweats	Range 0-4 (0=Not at all, 4 = Very much)
135	fes04ed	FACT Endocrine Specific (ES) symptoms ES4 discharge	Range 0-4 (0=Not at all, 4 = Very much)
136	fes05ei	FACT Endocrine Specific (ES) symptoms ES5 itching	Range 0-4 (0=Not at all, 4 = Very much)
137	fes06eb	FACT Endocrine Specific (ES) symptoms ES6 bleeding	Range 0-4 (0=Not at all, 4 = Very much)
138	fes07ev	FACT Endocrine Specific (ES) symptoms ES7 vaginal dryness	Range 0-4 (0=Not at all, 4 = Very much)
139	fes08ep	FACT Endocrine Specific (ES) symptoms ES8 pain	Range 0-4 (0=Not at all, 4 = Very much)
140	fes09ex	FACT Endocrine Specific (ES) symptoms ES9 sex	Range 0-4 (0=Not at all, 4 = Very much)
141	fes10ew	FACT Endocrine Specific (ES) symptoms ES10 weight	Range 0-4 (0=Not at all, 4 = Very much)

Appendix 22. MBSR Study Questionnaire Coding Chart (continued)

142	fean9ed	FACT Endocrine Specific (ES) symptoms An9 light-headed (dizzy)	Range 0-4 (0=Not at all, 4 = Very much)
143	feso2ev	FACT Endocrine Specific (ES) symptoms O2 vomiting	Range 0-4 (0=Not at all, 4 = Very much)
144	fesc5ed	FACT Endocrine Specific (ES) symptoms C5 diarrhoea	Range 0-4 (0=Not at all, 4 = Very much)
145	fean10h	FACT Endocrine Specific (ES) symptoms An10 headaches	Range 0-4 (0=Not at all, 4 = Very much)
146	ftax1eb	FACT Endocrine Specific (ES) symptoms Tax 1 bloated	Range 0-4 (0=Not at all, 4 = Very much)
147	fes11es	FACT Endocrine Specific (ES) symptoms ES11 sensitivity	Range 0-4 (0=Not at all, 4 = Very much)
148	fes12em	FACT Endocrine Specific (ES) symptoms ES12 mood swings	Range 0-4 (0=Not at all, 4 = Very much)
149	fes13ei	FACT Endocrine Specific (ES) symptoms ES13 irritable	Range 0-4 (0=Not at all, 4 = Very much)
150	fbrm1ej	FACT Endocrine Specific (ES) symptoms BRM1 joints	Range 0-4 (0=Not at all, 4 = Very much)
151	wb01che	Wellbeing cheerful	Range 0-5 (0 = At no time, 5 = All the time)
152	wb02rel	Wellbeing relaxed	Range 0-5 (0 = At no time, 5 = All the time)
153	wb03act	Wellbeing active	Range 0-5 (0 = At no time, 5 = All the time)
154	wb04fre	Wellbeing fresh	Range 0-5 (0 = At no time, 5 = All the time)
155	wb05int	Wellbeing interest	Range 0-5 (0 = At no time, 5 = All the time)

Missing values = 9,99,999, ‘missing’, or blank cell.

Appendix 23. Independent variables grouped for the multiple regression

1. Age and socioeconomic status
2. Breast cancer staging and treatment:
    a. breast cancer staging
    b. surgery
    c. wide local excision/partial mastectomy
    d. mastectomy
    e. reconstruction
    f. neoadjuvent chemotherapy (pre-surgery)
    g. number of neoadjuvent chemotherapy cycles
    h. adjuvant chemotherapy (post surgery)
    i. number of adjuvant chemotherapy cycles
    j. radiotherapy
    k. hormonal treatment
    l. first type of hormone treatment
    m. second type of hormone treatment
    n. Herceptin
3. Date between treatment finish and randomisation
4. Date between randomisation and questionnaire 1.
5. Breast Cancer Haven treatment
    a. Hours prior to week 0
    b. Hours between weeks 0 - 8
    c. Hours during weeks 8 - 12
6. How difficult or stressful is your illness for you at the moment?
7. Apart from your illness, have you had any recent event in your life which has affected you strongly or been particularly stressful?
8. Study dropout
9. Reason for study dropout

Groupings applicable to the intervention group only

1. Attendance of MBSR group
    - Total hours attended
    - Total number of weekly sessions
    - Saturday attended
2. Class dropout

    Reason for class dropout

Appendix 24. Individual variable, multivariate and stepwise regression predictors of T2 POMS Total Mood Disturbance

	Individual variables			Multivariate			Stepwise		
	Adjusted R^2	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 POMS TMD	0.26	0.51	0.59***	0.28	0.47	0.06***	0.38	0.24	0.08**
Intervention or control group	0.30	15.30	4.29***	0.28	17.43	4.47***		18.07	4.18***
Age at randomisation	0.25	0.00	0.24	0.28	-0.01	0.26	-	-	-
Socioeconomic status analytic classes	0.23	-0.06	0.07	0.28	-0.06	0.07	-	-	-
Breast cancer staging	0.25	-0.89	2.60	0.33	-7.55	3.23*	-	-	-
Breast cancer local recurrence	0.26	-5.04	9.18		10.87	10.07	-	-	-
Breast surgery	0.26	1.31	32.18	-	-	-	-	-	-
WLE/ Partial mastectomy	0.26	-4.30	3.44		3.28	4.49	-	-	-
Mastectomy	0.28	11.12	3.73**		19.62	6.32		11.23	3.60**
Breast reconstruction	0.26	4.42	3.38		-6.80	4.65	-	-	-
Chemotherapy	0.26	-4.18	4.41		6.70	16.90	-	-	-
Neoadjuvant Chemotherapy	0.26	-9.32	6.58		38.62	23.14	-	-	-
Neoadjuvant chemotherapy cycles (number)	0.26	1.76	1.05		9.99	4.33*	-	-	-
Adjuvant chemotherapy	0.25	-1.83	4.42		-12.36	18.36	-	-	-
Adjuvant chemotherapy cycles (number)	0.26	0.08	0.66		0.09	1.84	-	-	-
Radiotherapy	0.26	7.02	5.21		6.29	0.04	-	-	-
Treatment finish to randomisation (months)	0.26	-0.22	0.39		-0.04	0.40	-	-	-
Endocrine treatment	0.25	2.28	4.44		0.12	29.10	-	-	-
Herceptin	0.25	0.25	12.41		7.51	12.73	-	-	-
Haven Programme hours before Q1	0.26	-0.10	0.14	0.30	-0.13	0.15	-	-	-
Haven Programme hours from Q1 to Q2	0.27	1.05	1.01		2.73	1.42	-	-	-
Haven Programme hours from Q2 to Q3	0.26	-0.83	1.540		-2.20	1.95	-	-	-
Randomisation to Q1 (months)	0.25	012	1.63	0.29	0.36	1.65	-	-	-
MBSR cycle allocation	0.26	-1.07	1.22		-0.96	1.22	-	-	-
Study dropout	0.26	-9.88	11.55		32.80	37.59	-	-	-
Difficulty /stress of illness	0.46	8.64	0.91***	0.33	3.93	1.19***	-	-	-
Stressful life events	0.26	-1.16	0.79		-1.29	0.75	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 25. Individual variable, multivariate and stepwise regression predictors of T3 POMS Total Mood Disturbance

	Individual variables			Multivariate			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adj'd R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 POMS Total Mood Disturbance	0.27	0.50	0.06***	0.26	0.47	0.06	0.40	0.29	0.07***
Intervention or control group	0.31	12.91	4.11**	0.26	13.70	4.47		16.37	3.97***
Age at randomisation	0.27	-0.65	0.23	0.26	-0.10	0.24	-	-	-
Socioeconomic status analytic classes	0.24	-0.06	0.06	0.26	-0.06	0.06	-	-	-
Breast cancer staging	0.28	1.41	2.47	0.32	-2.97	3.17	-	-	-
Breast cancer local recurrence	0.28	-5.54	8.75		9.20	9.76	-	-	-
Breast surgery	0.27	-9.23	30.68	-	-	-	-	-	-
WLE/ partial mastectomy	0.28	-1.24	3.29		6.96	4.35	-	-	-
Mastectomy	0.30	10.04	3.56**		16.62	6.13**		10.29	3.41**
Breast reconstruction	0.29	5.68	3.22		-1.85	4051	-	-	-
Chemotherapy	0.28	-4.65	4.20		-4.30	16.38	-	-	-
Neoadjuvant chemotherapy	0.28	-6.41	6.29		50.09	22.43*	-	-	-
Neoajduvant chemo cycles (number)	0.28	1.53	1.01		9.71	4.20*	-	-	-
Adjuvant chemotherapy	0.28	-1.59	4.22		-5.94	17.80	-	-	-
Adjuvant chemo cycles (number)	0.27	0.11	0.63		-0.83	1.78	-	-	-
Radiotherapy	0.28	7.78	4.96		4.15	6.09	-	-	-
Treatment finish to randomisation (months)	0.28	-0.22	0.37		0.02	0.39	-	-	-
Endocrine treatment	0.28	0.79	4.22		-4.80	28.20	-	-	-
Herceptin	0.28	0.63	11.80		2.47	12.34	-	-	-
Haven Programme hours before Q1	0.28	-0.08	0.14	0.30	-0.11	0.14	-	-	-
Haven Programme hours from Q1 to Q2	0.27	0.16	1.06		-0.14	1.37	-	-	-
Haven Programme hours from Q2 to Q3	0.28	0.90	1.47		1.89	1.88	-	-	-
Randomisation to Q1 (months)	0.28	2.25	1.55	0.30	2.45	1.57	-	-	-
MBSR cycle allocation	0.27	0.02	1.1		-0.89	1.17	-	-	-
Study dropout	0.28	-11.41	11.01		45.88	35.79	-	-	-
Difficulty or stress of illness	0.30	3.21	1.14**	0.33	3.61	1.14	-	-	-
Stressful life events	0.28	0.31	0.75		0.189	0.72	-	-	-

*****$p < 0.05$, ******$p < 0.01$, ******* $p < 0.001$; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 26. Individual variable, multivariate and stepwise regression predictors of T2 POMS Tension-Anxiety subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Tension-Anxiety	0.18	0.43	0.06***	0.22	0.42	0.06***	0.24	0.29	0.07***
Intervention or control group	0.21	2.93	0.88***	0.22	3.38	0.93***		2.93	0.88***
Age at randomisation	0.18	-0.00	0.05	0.22	-0.001	0.05	-	-	-
Socioeconomic status analytic classes	0.18	-0.01	0.01	0.22	-0.01	0.01	-	-	-
Breast cancer staging	0.17	-0.07	0.53	0.21	-1.12	0.68	-	-	-
Breast cancer local recurrence	0.17	0.23	1.90		2.01	2.15	-	-	-
Breast surgery	0.17	-2.36	6.61	-	-	-	-	-	-
WLE/ Partial mastectomy	0.18	-1.08	0.70		-0.36	0.95	-	-	-
Mastectomy	0.18	1.41	0.78		1.80	1.34	-	-	-
Breast reconstruction	0.17	0.53	0.70		-0.99	0.99	-	-	-
Chemotherapy	0.17	-0.73	0.91		3.58	0.10	-	-	-
Neoadjuvant chemotherapy	0.18	-1.44	1.36		2.08	4091	-	-	-
Neoadjuvant chemo cycles (number)	0.18	0.23	0.22		0.94	0.92	-	-	-
Adjuvant Chemotherapy	0.17	-0.50	0.91		-0.15	3.91	-	-	-
Adjuvant chemo cycles (number)	0.18	0.07	0.13		0.34	0.39	-	-	-
Radiotherapy	0.18	1.50	1.06		1.19	1.34	-	-	-
Treatment finish to randomisation (months)	0.17	-0.03	0.08		-0.02	0.09	-	-	-
Endocrine treatment	0.17	0.12	0.91		5.10	6.19	-	-	-
Herceptin	0.17	-1.85	2.54		-0.63	2.70	-	-	-
Haven Programme hours before Q1	0.17	-0.01	0.03	0.21	-0.01	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.17	0.17	0.23		0.40	0.29	-	-	-
Haven Programme hours from Q2 to Q3	0.17	-0.09	0.31		-0.30	0.40	-	-	-
Randomisation to Q1 (months)	0.18	-0.31	0.34	0.22	-0.22	0.34	-	-	-
MBSR cycle allocation	0.18	-0.43	0.25		-0.37	0.25	-	-	-
Study dropout	0.18	-2.17	2.37		6.18	7.70	-	-	-
Difficulty or stress of illness	0.20	0.66	0.23**	0.24	0.74	0.23**	-	-	-
Stressful life events	0.17	-0.15	0.16		0.39	0.07***	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 27. Individual variable, multivariate and stepwise regression predictors of T3 POMS Tension-Anxiety subscale

	Individual variable			Multivariate			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Tension-Anxiety	0.18	0.41	0.06***	0.19	0.37	0.06***	0.26	0.33	0.07***
Intervention or control	0.20	2.30	0.84**	0.19	2.70	0.92**		2.38	0.83**
Age at randomisation	0.17	-0.00	0.04	0.19	-0.01	0.05	-	-	-
Socioeconomic status analytic classes	0.16	-0.02	0.01		-0.02	0.01	-	-	-
Breast cancer staging	0.17	0.25	0.50	0.20	-0.38	0.65	-	-	-
Breast cancer local recurrence	0.18	-2.96	1.79		-1.23	2.05	-	-	-
Breast surgery	0.18	-5.08	6.27	-	-	-	-	-	-
WLE/ Partial mastectomy	0.17	-0.10	0.67		0.96	0.90	-	-	-
Mastectomy	0.19	1.62	0.73*		1.80	1.28		1.65	0.72*
Breast reconstruction	0.18	1.13	0.66		-0.03	0.94	-	-	-
Chemotherapy	0.18	-0.78	0.86		-1.71	3.42	-	-	-
Neoadjuvant Chemotherapy	0.18	-1.08	1.19		7.85	4.69	-	-	-
Neoadjuvant chemo cycles (number)	0.17	0.26	0.21		1.45	0.88	-	-	-
Adjuvant chemotherapy	0.18	-0.16	0.86		0.34	3.73	-	-	-
Adjuvant chemo cycles (number)	0.17	0.02	0.13		-0.08	0.37	-	-	-
Radiotherapy	0.18	1.58	1.01		1.29	1.28	-	-	-
Treatment finish to randomisation (months)	0.17	-0.03	0.08		0.03	0.08	-	-	-
Endocrine treatment	0.18	0.65	0.86		-2.12	5.91	-	-	-
Herceptin	0.18	-1.24	2.41		-1.63	2.57	-	-	-
Haven Programme hours before Q1	0.17	0.01	0.03				-	-	-
Haven Programme hours from Q1 to Q2	0.18	0.13	0.22		-0.10	0.28	-	-	-
Haven Programme hours from Q2 to Q3	0.18	0.42	0.30		0.59	0.38	-	-	-
Time from randomisation to Q1 (months)	0.17	0.16	0.32	0.20	0.24	0.32	-	-	-
MBSR cycle allocation	0.17	-0.10	0.24		-0.08	0.24	-	-	-
Study dropout	0.18	-2.53	2.25		8.02	7.41	-	-	-
Difficulty or stress of illness	0.19	0.48	0.22*	0.22	0.47	0.22*	-	-	-
Stressful life events	0.18	0.26	0.15		0.22	0.15	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from the univiariate multivariate analyses included in stepwise

Appendix 28. Individual variable, multivariate and stepwise regression predictors of T2 POMS Depression-Dejection subscale

	Individual variable			multivariate			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Depression-Dejection	0.31	0.562	0.057***	0.29	0.51	0.06***	0.39	0.35	0.08***
Intervention or control	0.33	3.39	1.36*	0.29	4.24	1.49**		5.06	1.37***
Age at randomisation	0.31	0.03	0.08	0.29	0.03	0.08	-	-	-
Socioeconomic status analytic classes	0.27	-0.02	0.02		-0.02	0.02	-	-	-
Breast cancer staging	0.31	-0.10	0.80	0.37	-2.12	1.01		-	-
Breast cancer local recurrence	0.31	-1.54	2.86		3.59	3.16	-	-	-
Breast surgery	0.31	3.49	10.02	-	-	-	-	-	-
WLE/ Partial mastectomy	0.31	-0.85	1.07		1.99	1.40	-	-	-
Mastectomy	0.33	3.26	1.16**		6.58	1.98***		2.78	1.17*
Breast reconstruction	0.31	0.90	1.06		-2.74	1.46	-	-	-
Chemotherapy	0.31	-0.71	1.37		2.21	5.29	-	-	-
Neoadjuvant Chemotherapy	0.32	-3.87	2.04		11.75	7.27	-	-	-
Neoadjuvant chemo cycles (number)	0.32	0.73	0.33*		3.27	1.36*		0.76	0.33*
Adjuvant Chemotherapy	0.31	0.64	1.37		-1.15	5.75	-	-	-
Adjuvant chemo cycles (number)	0.30	-0.08	0.20		0.31	0.58	-	-	-
Radiotherapy	0.31	2.24	1.62		1.72	1.97	-	-	-
Treatment finish to randomisation (months)	0.31	-0.10	0.12		-0.07	0.13	-	-	-
Endocrine treatment	0.30	-0.48	1.38		1.95	9.13	-	-	-
Herceptin	0.30	-0.10	3.87		2.42	3.99	-	-	-
Haven Programme hours before Q1	0.31	-0.04	0.05	0.33	-0.05	0.05	-	-	-
Haven Programme hours from Q1 to Q2	0.31	0.28	0.35		0.76	0.45	-	-	-
Haven Programme hours from Q2 to Q3	0.31	-0.21	0.48		-0.57	0.61	-	-	-
Time from randomisation to Q1 (months)	0.31	0.06	0.51	0.32	0.11	0.52	-	-	-
MBSR cycle allocation	0.31	-0.09	0.38		-0.06	0.39	-	-	-
Study dropout	0.31	-2.51	3.60		7.70	11.96	-	-	-
Difficulty or stress of illness	0.33	0.96	0.36**	0.35	1.12	0.37	-	-	-
Stressful life events	0.31	-0.32	0.24		-0.38	0.24	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 29. Individual variable, multivariate and stepwise regression predictors of T3 POMS Depression-Dejection subscale

	Individual variable			Multivariate			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Depression-Dejection	0.29	0.50	0.05***	0.25	0.44	0.06***	0.39	0.31	0.07***
Intervention or control	0.30	2.32	1.29	0.25	2.68	1.39		3.94	1.27**
Age at randomisation	0.29	-0.01	0.07	0.25	-0.03	0.08	-	-	-
Socioeconomic status analytic classes	0.24	-0.02	0.02		-0.02	0.02	-	-	-
Breast cancer staging	0.29	0.41	0.76	0.33	-1.08	0.96	-	-	-
Breast cancer local recurrence	0.29	-0.47	2.69		3.95	3.01	-	-	-
Breast surgery	0.29	10.90	9.40	-	-	-	-	-	-
WLE/ Partial mastectomy	0.29	-0.39	1.00		2.31	1.33	-	-	-
Mastectomy	0.31	2.67	1.10*		6.10	1.89***	-	-	-
Breast reconstruction	0.29	0.62	0.99		-1.98	1.39	-	-	-
Chemotherapy	0.29	-1.08	1.29		-0.68	5.05	-	-	-
Neoadjuvant chemotherapy	0.29	-2.68	1.93		14.74	6.93*	-	-	-
Neoadjuvant chemo cycles (number)	0.30	0.59	0.31		3.03	1.30*		0.70	0.30*
Adjuvant Chemotherapy	0.29	0.20	1.29		-0.23	5.48	-	-	-
Adjuvant chemo cycles (number)	0.28	-0.02	0.19		0.00	0.55	-	-	-
Radiotherapy	0.29	1.78	1.53		1.06	1.88	-	-	-
Treatment finish to randomisation (months)	0.29	-0.10	0.11		-0.06	0.12	-	-	-
Endocrine treatment	0.29	-0.20	1.29		0.03	8.70	-	-	-
Herceptin	0.29	2.29	3.62		2.93	3.80	-	-	-
Haven Programme hours before Q1	0.29	-0.03*	0.04	0.30	-0.05*	0.05	-	-	-
Haven Programme hours from Q1 to Q2	0.29	0.21	0.33		0.06	0.43	-	-	-
Haven Programme hours from Q2 to Q3	0.29	0.51	0.45		0.69	0.58	-	-	-
Time from randomisation to Q1 (months)	0.29	0.53	0.48	0.29	0.63	0.49	-	-	-
MBSR cycle allocation	0.29	-0.03	0.36		-0.04	0.37	-	-	-
Study dropout	0.29	-2.90	3.39		8.76	11.27	-	-	-
Difficulty or stress of illness	0.33	1.23	0.33***	0.34	1.32	0.34***	-	-	-
Stressful life events	0.29	0.18	0.23		0.08	0.22	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 30. Individual variable, multivariate and stepwise regression predictors of T2 POMS Anger-Hostility subscale

	Individual variable			Multivariate			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Anger-Hostility	0.20	0.45	0.06***				0.28	0.31	0.07***
Intervention or control	0.21	1.96	1.02	0.21	2.04	1.07		2.3	0.99*
Age at randomisation	0.20	-0.02	0.06	0.21	-0.02	0.06	-	-	-
Socioeconomic status analytic classes	0.20	-0.013	0.02		-0.01	0.02	-	-	-
Breast cancer staging	0.20	-0.19	0.60	0.24	-0.67	0.76	-	-	-
Breast cancer local recurrence	0.20	-0.77	2.14		1.64	2.39	-	-	-
Breast surgery	0.20	1.31	7.50	-	-	-	-	-	-
WLE/ Partial mastectomy	0.22	-2.03	0.79**		-1.06	1.06	-	-	-
Mastectomy	0.23	2.75	0.87**		2.77	1.50		2.82	0.85***
Breast reconstruction	0.22	1.90	0.78		0.45	1.10	-	-	-
Chemotherapy	0.20	0.13	1.03		-2.17	4.00	-	-	-
Neoadjuvant Chemotherapy	0.20	-1.61	1.54		3.18	5.49	-	-	-
Neoadjuvant chemo cycles (number)	0.20	0.27	0.25		0.57	1.03	-	-	-
Adjuvant Chemotherapy	0.20	0.89	1.02		-1.84	4.34	-	-	-
Adjuvant chemo cycles (number)	0.20	0.21	0.15		-0.68	0.44	-	-	-
Radiotherapy	0.21	2.32	1.21		-0.42	1.49	-	-	-
T1 Anger-Hostility									
Treatment finish to randomisation (months)	0.20	0.06	0.09		0.06	0.10	-	-	-
Endocrine treatment	0.20	0.87	1.02		-11.51	6.89	-	-	-
Herceptin	0.19	1.12	2.87		1.8	3.00	-	-	-
Haven Programme hours before Q1	0.20	-0.03	0.03	0.20	-0.03	0.04	-	-	-
Haven Programme hours from Q1 to Q2	0.20	-0.08	0.26		0.19	0.34	-	-	-
Haven Programme hours from Q2 to Q3	0.20	-0.35	0.36		-0.36	0.46	-	-	-
Time from randomisation to Q1 (months)	0.20	0.34	0.38	0.21	0.45	0.39	-	-	-
MBSR cycle allocation	0.20	-0.35	0.28		-0.38	0.29	-	-	-
Study dropout	0.20	-2.50	2.70		9.84	8.95	-	-	-
Difficulty or stress of illness	0.23	0.77	0.25	0.24	0.86	0.26	-	-	-
Stressful life events	0.20	-0.09	0.18		-0.20	0.17	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 31. Individual variable, multivariate and stepwise regression predictors of T3 POMS Anger-Hostility subscale

	Individual variable			Multiple			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Anger-Hostility	0.34	0.56	0.05***				0.47	0.67	0.08***
Intervention or control	0.36	2.69	0.89**	0.34	2.58	0.93**		3.19	0.84***
Age at randomisation	0.34	-0.05	0.05	0.34	-0.06	0.05	-	-	-
Socioeconomic status analytic classes	0.32	-0.02	0.14		-0.02	0.01	-	-	-
Breast cancer staging	0.33	0.47	0.53	0.40	0.05	0.66	-	-	-
Breast cancer local recurrence	0.34	-0.95	1.89		1.94	2.08	-	-	-
Breast surgery	0.33	-5.70	6.62	-	-	-	-	-	-
WLE/ Partial mastectomy	0.33	-0.31	0.71		1.06	0.92	-	-	-
Mastectomy	0.36	2.23	0.77**		2.45	1.31		2.39	0.72***
Breast reconstruction	0.36	2.04	0.69**		0.93	0.96	-	-	-
Chemotherapy	0.33	-0.73	0.91		-1.24	3.48	-	-	-
Neoadjuvant Chemotherapy	0.33	-0.53	1.36		8.26	4.78	-	-	-
Neoadjuvant chemo cycles (number)	0.33	0.17	0.22		1.44	0.89	-	-	-
Adjuvant Chemotherapy	0.33	-0.21	0.91		-1.24	3.78	-	-	-
Adjuvant chemo cycles (number)	0.33	0.01	0.14		-0.33	0.38	-	-	-
Radiotherapy	0.35	2.47	1.07*		1.17	1.30	-	-	-
Treatment finish to randomisation (months)	0.33	-0.05	0.08		0.00	0.08		0.84	0.31**
Endocrine treatment	0.34	0.84	0.91		-9.92	6.00	-	-	-
Herceptin	0.34	-2.01	2.54		-1.57	2.62	-	-	-
Haven Programme hours before Q1	0.33	-0.01	0.03	0.36	-0.02	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.33	0.11	0.23		-0.12	0.30	-	-	-
Haven Programme hours from Q2 to Q3	0.34	0.46	0.32		0.72	0.40	-	-	-
Time from randomisation to Q1 (months)	0.36	1.00	0.33**	0.40	1.04	0.33**		0.84	0.31**
MBSR cycle allocation	0.34	0.44	0.25		0.39	0.24	-	-	-
Study dropout	0.34	-2.74	2.38		9.94	7.58	-	-	-
Difficulty or stress of illness	0.35	0.24	0.23	0.37	0.26	0.23	-	-	-
Stressful life events	0.34	0.13	0.15		0.11	0.15	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 32. Individual variable, multivariate and stepwise regression predictors of T2 POMS Vigour-Activity subscale

	Individual variable			multivariate			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Vigour-Activity	0.26	0.52	0.06***	0.26	0.49	0.82**	0.31	0.32	0.08**
Intervention or control	0.29	2.21	0.74**		2.35	0.82**		2.16	0.73**
Age at randomisation	0.26	0.27	0.04	0.26	0.02	0.05	-	-	-
Socioeconomic status analytic classes	0.23	-0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.26	-0.40	0.44	0.30	-1.47	0.57**	-	-	-
Breast cancer local recurrence	0.26	-1.88	1.58		-0.30	1.78	-	-	-
Breast surgery	0.26	-3.98	5.55	-	-	-	-	-	-
WLE/ Partial mastectomy	0.26	0.18	0.59		0.68	0.79	-	-	-
Mastectomy	0.26	0.76	0.66		2.42	1012	-	-	-
Breast reconstruction	0.26	-0.13	0.59		-1.56	0.83	-	-	-
Chemotherapy	0.27	-0.74	2.76		-0.77	2.99	-	-	-
Neoadjuvant Chemotherapy	0.26	-0.14	1.14		6.95	4.10	-	-	-
Neoadjuvant chemo cycles (number)	0.26	0.08	0.18		1.32	0.77	-	-	-
Adjuvant Chemotherapy	0.26	-0.69	0.77		0.20	3.28	-	-	-
Adjuvant chemo cycles (number)	0.27	0.09	0.11		0.16	0.33	-	-	-
Radiotherapy	0.26	-0.46	0.90		-0.10	1.12	-	-	-
Treatment finish to randomisation (months)	0.26	-0.09	0.07		-0.05	0.07	-	-	-
Endocrine treatment	0.26	0.50	0.77		3.14	5.15	-	-	-
Herceptin	0.25	0.30	2.14		1.30	2.26	-	-	-
Haven Programme hours before Q1	0.26	0.02	0.03	0.29	0.01	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.26	0.30	0.19		0.44	0.25	-	-	-
Haven Programme hours from Q2 to Q3	0.26	0.08	0.27		-0.26	0.34	-	-	-
Time from randomisation to Q1 (months)	0.26	0.00	0.28	0.26	-0.04	0.29	-	-	-
MBSR cycle allocation	0.26	-0.01	0.21	0.29	-0.03	0.21	-	-	-
Study dropout	0.26	0.13	2.00		5.61	6.57	-	-	-
Difficulty or stress of illness	0.26	0.08	0.20	-	-	-	-	-	-
Stressful life events	0.26	-0.09	0.13	-	-	-	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 33. Individual variable, multivariate and stepwise regression predictors of T3 POMS Vigour-Activity subscale

	Individual variable			multivariate			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Vigour-Activity	0.25	0.52	0.06***	0.51	0.50	0.06***	0.32	0.39	0.08***
Intervention or control	0.29	2.63	0.75***	0.27	0.28	0.83***		2.74	0.76***
Age at randomisation	0.25	0.000	0.04	0.27	-0.02	0.05	-	-	-
Socioeconomic status analytic classes	0.24	0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.25	-0.05	0.46	0.27	-0.56	0.59	-	-	-
Breast cancer local recurrence	0.25	0.23	1.62		1.53	1.86	-	-	-
Breast surgery	0.25	-2.89	5.68	-	-	-	-	-	-
WLE/ Partial mastectomy	0.25	0.03	0.61		0.72	0.82	-	-	-
Mastectomy	0.25	0.62	0.67		1.91	1.17	-	-	-
Breast reconstruction	0.25	0.21	0.60		-0.50	0.86	-	-	-
Chemotherapy	0.25	-0.26	0.78		-1.86	3.11	-	-	-
Neoadjuvant chemotherapy	0.25	0.41	1.17		7.39	4.27	-	-	-
Neoadjuvant chemo cycles (number)	0.25	0.00	0.19		1.06	0.80	-	-	-
Adjuvant Chemotherapy	0.25	-0.31	0.79		-0.63	3.42	-	-	-
Adjuvant chemo cycles (number)	0.26	0.00	0.12		-0.25	0.34	-	-	-
Radiotherapy	0.25	0.36	0.92		0.02	1.16	-	-	-
Treatment finish to randomisation (months)	0.25	0.05	0.07		0.08	0.07	-	-	-
Endocrine treatment	0.25	-0.32	0.79		2.00	5.36	-	-	-
Herceptin	0.25	-0.58	2.20		-0.90	2.35	-	-	-
Haven Programme hours before Q1	0.25	-0.01	0.03	0.28	0.00	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.25	-0.18	0.20		-0.04	0.25	-	-	-
Haven Programme hours from Q2 to Q3	0.26	-0.32	0.27		-0.20	0.35	-	-	-
Time from randomisation to Q1 (months)	0.25	0.18	0.29	0.27	0.15	0.29	-	-	-
MBSR cycle allocation	0.25	-0.13	0.22		-0.17	0.22	-	-	-
Study dropout	0.25	0.01	2.05		7.27	6.67	-	-	-
Difficulty or stress of illness	0.27	0.44	0.20	0.32	0.50	0.20	-	-	-
Stressful life events	0.26	-0.02	0.13		-0.07	0.13	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 34. Individual variable, multivariate and stepwise regression predictors of T2 POMS Fatigue-Inertia subscale

	Individual variable			multivariate			stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Fatigue-Inertia	0.18	0.42	0.06***	0.18	0.38	0.07***	0.27	0.28	0.07***
Intervention or control	0.21	0.22	2.67		2.89	0.91**		3.29	0.84***
Age at randomisation	0.17	-0.02	0.05	0.18	-0.02	0.05	-	-	-
Socioeconomic status analytic classes	0.14	-0.01	0.01		-0.01	0.01	-	-	-
Breast cancer staging	0.17	-0.13	0.50	0.29	-1.51	0.60*	-	-	-
Breast cancer local recurrence	0.17	-0.13	1.78		2.76	1.88	-	-	-
Breast surgery	0.17	5.84	6.21	-	-	-	-	-	-
WLE/ Partial mastectomy	0.17	-0.30	0.66		1.26	0.83	-	-	-
Mastectomy	0.19	1.42	0.73	3.42	1.18	0.004		-	-
Breast reconstruction	0.17	0.50	0.66	-1.33	0.87	0.128*		-	-
Chemotherapy	0.18	-1.17	0.85	3.93	3.16	0.215*		-	-
Neoadjuvant Chemotherapy	0.18	-2.11	1.27	11.55	4.33**	0.008		-	-
Neoadjuvant chemo cycles (number)	0.19	0.44	0.20*	3.04	0.81	0.000		0.62	0.20**
Adjuvant Chemotherapy	0.18	-0.87	0.85	-4.74	3.45	0.171*		-	-
Adjuvant chemo cycles (number)	0.19	0.08	0.13	0.18	0.34	0.602*		-	-
Radiotherapy	0.17	0.33	1.01	0.26	1.18	0.823*		-	-
Treatment finish to randomisation (months)	0.17	-0.04	0.08	0.03	0.08	0.650*		-	-
Endocrine treatment	0.17	0.90	0.85	-0.10	5.43	0.985*		-	-
Herceptin	0.18	0.40	2.40	2.03	2.39	0.397*		-	-
Haven Programme hours before Q1	0.18	-0.03	0.03	-0.05	0.03	0.114*		-	-
Haven Programme hours from Q1 to Q2	0.18	0.37	0.21	0.76	0.27**	0.006		-	-
Haven Programme hours from Q2 to Q3	0.17	-0.05	0.30	0.47	0.37	0.206*		-	-
Time from randomisation to Q1 (months)	0.17	-0.19	0.32	-0.17	0.32	0.576*		-	-
MBSR cycle allocation	0.17	-0.11	0.24	-0.08	0.24	0.741*		-	-
Study dropout	0.17	-1.54	2.23	3.13	7.31	0.669*		-	-
Difficulty or stress of illness	0.18	0.38	0.22	0.53	0.21*	0.015		-	-
Stressful life events	0.19	-0.19	0.15	-0.24	0.14	0.096*		-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 35. Individual variable, multivariate and stepwise regression predictors of T3 POMS Fatigue-Inertia subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Fatigue-Inertia	0.23	0.48	0.06***	0.21	0.45	0.07***	0.29	0.48	0.06***
Intervention or control	0.24	1.84	0.82*		2.00	0.91*		2.51	0.82**
Age at randomisation	0.23	-0.02	0.05	0.21	0.01	0.05	-	-	-
Socioeconomic status analytic classes	0.19	-0.01	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.23	0.50	0.49	0.27	-0.42	0.62	-	-	-
Breast cancer local recurrence	0.23	0.11	1.73		2.90	1.94	-	-	-
Breast surgery	0.23	-2.20	6.07	-	-	-	-	-	-
WLE/ Partial mastectomy	0.23	-0.32	0.65		1.26	0.86	-	-	-
Mastectomy	0.25	1.69	0.71*		2.69	1.22		1.67	0.71*
Breast reconstruction	0.23	0.92	0.64		-0.26	0.90	-	-	-
Chemotherapy	0.23	-1.33	0.83		0.83	3.26	-	-	-
Neoadjuvant chemotherapy	0.23	-1.87	1.24		8.56	4.47	-	-	-
Neoadjuvant chemo cycles (number)	0.24	0.38	0.20		1.97	0.84		0.41	0.20*
Adjuvant Chemotherapy	0.23	-0.82	0.83		-3.32	3.56	-	-	-
Adjuvant chemo cycles (number)	0.23	0.07	0.12		-0.19	0.36	-	-	-
Radiotherapy	0.23	0.93	0.98		0.42	1.21	-	-	-
Treatment finish to randomisation (months)	0.23	-0.04	0.07		0.00	0.08	-	-	-
Endocrine treatment	0.23	-0.42	0.83		3.30	5.61	-	-	-
Herceptin	0.23	1.86	2.33		3.58	2.47	-	-	-
Haven Programme hours before Q1	0.23	-0.04	0.03	0.24	-0.04	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.23	-0.12	0.21		0.02	0.27	-	-	-
Haven Programme hours from Q2 to Q3	0.23	-0.19	0.29		-0.02	0.37	-	-	-
Time from randomisation to Q1 (months)	0.23	0.32	0.31	0.24	0.33	0.31	-	-	-
MBSR cycle allocation	0.23	-0.10	0.23		-0.16	0.23	-	-	-
Study dropout	0.23	-1.35	2.18		9.62	7.18	-	-	-
Difficulty or stress of illness	0.23	0.27	0.21	0.27	0.41	0.21	-	-	-
Stressful life events	0.24	-0.16	0.14		-0.20	0.14	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 36. Individual variable, multivariate and stepwise regression predictors of T2 POMS Confusion-Bewilderment subscale

	Individual variables			Multivariate			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Confusion-Bewilderment	0.34	0.54	0.05***	0.37	0.51	0.05***	0.42	0.42	0.06***
Intervention or control	0.37	1.91	0.56***		2.20	0.59***		2.30	0.57***
Age at randomisation	0.34	-0.01	0.03	0.37	-0.01	0.03	-	-	-
Socioeconomic status analytic classes	0.33	-0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.34	-0.17	0.54	0.40	-0.80	0.42	-	-	-
Breast cancer local recurrence	0.34	-1.20	1.19		0.90	1.32			
Breast surgery	0.34	-3.42	4.20	-	-	-	-	-	-
WLE/ Partial mastectomy	0.34	-0.34	0.45		0.54	0.59	-	-	-
Mastectomy	0.37	1.55	0.48**		2.45	0.83**		1.70	0.49***
Breast reconstruction	0.35	0.86	0.44*		-0.51	0.61	-	-	-
Chemotherapy Neoadjuvant	0.34	-0.71	00.57		1.84	2.22	-	-	-
Chemotherapy	0.34	-0.06	0.86		3.69	3.03	-	-	-
Neoadjuvant chemo cycles (number)	0.34	0.00	0.14		0.92	0.57	-	-	-
Adjuvant Chemotherapy	0.35	-1.01	0.57		-4.27	2.40	-	-	-
Adjuvant chemo cycles (number)	0.35	0.09	0.09		-0.20	0.24	-	-	-
Radiotherapy	0.35	1.15	0.68		0.45	0.82	-	-	-
Treatment finish to randomisation (months)	0.34	-0.01	0.05		0.01	0.05	-	-	-
Endocrine treatment	0.34	0.57	0.58		1.21	3.82	-	-	-
Herceptin	0.34	0.28	1.62		0.46	1.67	-	-	-
Haven Programme hrs before Q1	0.34	-0.01	0.02	0.37	-0.01	0.02	-	-	-
Haven Programme hrs from Q1 to Q2	0.34	0.01	0.15		-0.22	0.19	-	-	-
Haven Programme hrs from Q2 to Q3	0.34	-0.23	0.20		-0.32	0.26	-	-	-
Time from randomisation to Q1 (months)	0.34	0.23	0.21	0.37	0.29	0.21	-	-	-
MBSR cycle allocation	0.34	-0.11	0.16		-0.08	0.16	-	-	-
Study dropout	0.34	-1.53	1.50		1.22	4.89	-	-	-
Difficulty or stress of illness	0.35	0.31	0.15*	0.40	0.39	0.15**	-	-	-
Stressful life events	0.35	-0.20	0.10*		-0.23	0.10*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 37. Individual variable, multivariate and stepwise regression predictors of T3 POMS Confusion-Bewilderment subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Confusion-Bewilderment	0.35	0.55	0.05***	0.35	0.54	0.06***	0.42	0.42	0.06***
Intervention or control	0.35	1.09	0.56*		1.03	0.62		2.30	0.57***
Age at randomisation	0.35	0.01	0.03	0.35	0.02	0.03	-	-	-
Socioeconomic status analytic classes	0.34	0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.35	-0.08	0.33	0.36	-0.53	0.43	-	-	-
Breast cancer local recurrence	0.36	-1.76	1.17		-0.06	1.35	-	-	-
Breast surgery	0.35	-5.18	4.13	-	-	-	-	-	-
WLE/ Partial mastectomy	0.35	0.06	0.44		0.81	0.61	-	-	-
Mastectomy	0.37	1.16	0.48*		1.78	0.85*		1.70	0.49***
Breast reconstruction	0.36	0.72	0.44		-0.04	0.63	-	-	-
Chemotherapy	0.35	-0.48	0.57		0.54	2.28	-	-	-
Neoadjuvant chemotherapy	0.35	-0.54	0.85		2.93	3.11	-	-	-
Neoadjuvant chemo cycles (number)	0.35	0.11	0.14		0.70	0.58	-	-	-
Adjuvant Chemotherapy	0.35	-0.36	0.57		-0.73	2.46	-	-	-
Adjuvant chemo cycles (number)	0.35	0.06	0.08		0.07	0.25	-	-	-
Radiotherapy	0.35	0.48	0.67		0.09	0.85	-	-	-
Treatment finish to randomis (months)	0.36	-0.05	0.05		-0.03	0.05	-	-	-
Endocrine treatment	0.3	0.16	0.57		1.58	3.91	-	-	-
Herceptin	0.35	0.40	1.59		-0.14	1.72	-	-	-
Haven Programme hours before Q1	0.35	-0.01	0.02	0.35	-0.01	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.35	0.01	0.14		0.03	0.19	-	-	-
Haven Programme hours from Q2 to Q3	0.35	0.02	0.20		0.0.7	0.26	-	-	-
Time from randomisation to Q1 (months)	0.35	0.00	0.21	0.36	0.03	0.22	-	-	-
MBSR cycle allocation	0.35	-0.03	0.16		0.00	0.16	-	-	-
Study dropout	0.35	-1.85	1.48		2.10	4.93	-	-	-
Difficulty or stress of illness	0.35	0.18	0.15	0.36	0.22	0.15	-	-	-
Stressful life events	0.35	-0.04	0.10		-0.06	0.10	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 38. Individual variable, multivariate and stepwise regression predictors of T2 FACT-ES

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES	0.59	0.80	0.05	0.57	0.77	0.05***	0.64	0.92	0.07***
Intervention or control group	0.61	-7.66	1.88***		-7.75	2.07***		-8.99	1.89***
Age at randomisation	0.59	-0.12	0.11		-0.08	0.12	-	-	-
Socioeconomic status analytic classes	0.54	-0.01	0.03		-0.01	0.03	-	-	-
Breast cancer staging	0.58	0.88	1.15	0.64	3.30	1.39*	-	-	-
Breast cancer local recurrence	0.58	3.20	4.04		-2.30	4.37	-	-	-
Breast surgery	0.58	-0.62	14.15	-	-	-	-	-	-
WLE/ Partial mastectomy	0.58	-1.12	1.52		-3.74	1.94	-	-	-
Mastectomy	0.59	-2.49	1.68		-5.76	2.79*	-	-	-
Breast reconstruction	0.59	-2.21	1.56		-0.09	2.14	-	-	-
Chemotherapy	0.58	1.42	0.03		-0.31	7.43	-	-	-
Neoadjuvant Chemotherapy	0.58	2.36	2.96		-9.21	10.11	-	-	-
Neoadjuvant chemo cycles (number)	0.59	-0.44	-0.04		-3.04	1.89	-	-	-
Adjuvant Chemotherapy	0.58	1.26	1.97		1.43	8.12	-	-	-
Adjuvant chemo cycles (number)	0.59	-0.14	0.29		-0.48	0.85	-	-	-
Radiotherapy	0.58	-0.616	2.357		1.29	2.81	-	-	-
Treatment finish - randomisation (months)	0.59	-0.12	0.17		-0.29	0.18	-	-	-
Herceptin	0.58	0.83	5.87		1.72	5.83	-	-	-
Haven Programme hours before Q1	0.58	0.00	0.06	0.62	0.20	0.07	-	-	-
Haven Programme hours from Q1 to Q2	0.59	-0.67	0.49		-1.30	0.62*	-	-	-
Haven Programme hours from Q2 to Q3	0.58	0.14	0.68		0.95	0.85	-	-	-
Time from randomisation to Q1 (months)	0.59	0.71	0.73	0.61	0.78	0.72	-	-	-
MBSR cycle allocation	0.58	0.11	0.55		-0.04	0.54			
Study dropout	0.59	5.81	5.08		7.33	5.49	-	-	-
Difficulty or stress of illness	0.59	-0.54	0.58	0.63	-0.69	0.57	-	-	-
Stressful life events	0.60	0.78	0.33*		0.79	0.32*	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 39. Individual variable, multivariate and stepwise regression predictors of T3 FACT-ES

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES	0.58	0.75	0.04***	0.59	-8.02	1.97***	0.67	0.77	0.06***
Intervention or control group	0.62	-7.98	1.78***		-8.02	1.97***		-9.12	1.68***
Age at randomisation	0.58	-0.01	0.10		0.01	0.11	-	-	-
Socioeconomic status analytic classes	0.55	-0.01	0.03		-0.01	0.03	-	-	-
Breast cancer staging	0.58	0.27	1.10	0.65	2.73	1.29*	-	-	-
Breast cancer local recurrence	0.58	1.47	3.86		-7.20	4.05	-	-	-
Breast surgery	0.58	5.22	13.53	-	-	-	-	-	-
WLE/ Partial mastectomy	0.58	-1.48	1.45		-5.40	1.80**		-3.30	1.56*
Mastectomy	0.59	-3.44	1.59*		-10.05	2.58***		-5.36	1.71**
Breast reconstruction	0.58	-1.66	1.49		1.83	1.98	-	-	-
Chemotherapy	0.58	0.64	1.90		1.36	6.88	-	-	-
Neoadjuvant chemotherapy	0.58	0.81	2.82		-16.65	9.36	-	-	-
Neoadjuvant chemo cycles (number)	0.58	-0.31	0.45		-3.53	1.75	-	-	-
Adjuvant Chemotherapy	0.58	0.20	1.89		-5.17	7.51	-	-	-
Adjuvant chemo cycles (number)	0.58	-0.10	0.28		-0.92	0.78	-	-	-
Radiotherapy	0.58	-0.79	2.25		0.97	2.60	-	-	-
Treatment finish - randomisation (months)	0.58	-0.003	0.17		-0.12	0.16	-	-	-
Endocrine treatment	0.59	2.92	1.85		19.46	11.67	-	-	-
Herceptin	0.58	1.17	5.57		2.57	5.39	-	-	-
Haven Programme hours before Q1	0.58	0.00	0.06	0.61	0.00	0.06	-	-	-
Haven Programme hours from Q1 to Q2	0.58	0.20	0.47		0.13	0.59	-	-	-
Haven Programme hours from Q2 to Q3	0.58	0.22	0.65		-0.16	0.814	-	-	-
Time from randomisation to Q1 (months)	0.58	0.39	0.70	0.62	0.51	0.68	-	-	-
MBSR cycle allocation	0.58	-0.03	0.52		-0.14	0.51	-	-	-
Study dropout	0.58	6.36	4.86		8.38	4.68	-	-	-
Difficulty or stress of illness	0.60	-1.46	0.54*	0.65	-1.63	0.53**		-1.74	0.50***
Stressful life events	0.59	0.46	0.32		0.55	0.30	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 40. Individual variable, multivariate and stepwise regression predictors of T2 FACT-ES TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES TOI	0.59	0.80	0.05***	0.57	0.75	0.05***	0.64	0.89	0.06***
Intervention or control group	0.62	-5.65	1.40***		-5.6	1.52***		-6.46	1.37***
Age at randomisation	0.59	-0.09	0.08		-0.05	0.08	-	-	-
Socioeconomic status analytic classes	0.55	-0.02	0.02		-0.02	0.02	-	-	-
Breast cancer staging	0.59	0.94	0.85	0.65	2.86	1.03**	-	-	-
Breast cancer local recurrence	0.59	2.60	0.30		-1.51	3.22	-	-	-
Breast surgery	0.59	5.97	10.58	-	-	-	-	-	-
WLE/ Partial mastectomy	0.59	-1.03	1.13		-2.84	1.42*	-	-	-
Mastectomy	0.59	-1.52	1.25		-4.15	2.03*	-	-	-
Breast reconstruction	0.59	-1.33	1.12		0.38	1.49	-	-	-
Chemotherapy	0.59	10.7	1.47		-0.46	5.41	-	-	-
Neoadjuvant chemotherapy	0.59	0.86	2.18		-6.61	7.46	-	-	-
Neoadjuvant chemo cycles (number)	0.59	-0.37	0.34		-2.13	1.39	-	-	-
Adjuvant Chemotherapy	0.59	1.38	1.47		1.55	5.93	-	-	-
Adjuvant chemo cycles (number)	0.59	-0.15	0.22		-0.39	0.62	-	-	-
Radiotherapy	0.59	0.37	1.74		1.40	2.05	-	-	-
Treatment finish - randomisation (months)	0.59	-0.09	0.13		-0.23	0.13	-	-	-
Endocrine treatment	0.59	1.23	1.45		22.47	9.31*	-	-	-
Herceptin	0.59	1.46	4.05		0.72	4.10	-	-	-
Haven Programme hours before	0.59	0.01	0.05	0.62	0.02	0.05	-	-	-
Haven Programme hours from Q1 to Q2	0.59	-0.41	0.37		-0.96	0.46*	-	-	-
Haven Programme hrs from Q2 to Q3	0.59	0.28	0.50		0.87	0.63	-	-	-
Time from randomisation to Q1 (months)	0.59	0.59	0.54	0.62	0.65	0.54	-	-	-
MBSR cycle allocation	0.59	0.21	0.41		0.102	0.399	-	-	-
Study dropout	0.59	4.42	3.81		5.05	4.11	-	-	-
Difficulty or stress of illness	0.59	-0.02	0.40	0.63	-0.10	0.39	-	-	-
Stressful life events	0.60	0.44	0.24		0.42	0.24	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 41. Individual variable, multivariate and stepwise regression predictors of T3 FACT-ES TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES TOI	0.59	0.78	0.05***	0.58	0.74	0.05***	0.68	1.07	0.12***
Intervention or control group	0. 62	-5.67	1.36***		-5.31	1.48***		-6.29	1.27***
Age at randomisation	0.59	-0.06	0.08		-0.05	0.08		-0.15	0.07*
Socioeconomic status analytic classes	0.55	-0.02	0.02		-0.02	0.02	-	-	-
Breast cancer staging	0.59	-0.01	0.83		1.95	0.98*	-	-	-
Breast cancer local recurrence	0.59	1.13	0.30		-5.98	3.08	-	-	-
Breast surgery	0.59	13.75	10.29	-	-	-	-	-	-
WLE/ Partial mastectomy	0.59	-1.04	1.10		-4.22	1.36**		-2.52	1.18*
Mastectomy	0.59	-2.42	1.21*		-7.36	1.95***		-4.38	1.31***
Breast reconstruction	0.59	-0.84	1.09		1.85	1.43	-	-	-
Chemotherapy	0.59	0.89	1.43		1.69	5.18	-	-	-
Neoadjuvant Chemotherapy	0.59	1.67	2.12		-9.83	7.14	-	-	-
Neoadjuvant chemo cycles (number)	0.59	-0.37	0.34		-2.27	1.33	-	-	-
Adjuvant Chemotherapy	0.59	0.36	1.44		-4.05	5.68	-	-	-
Adjuvant chemo cycles (number)	0.59	-0.07	0.21		-0.62	0.60	-	-	-
Radiotherapy	0.59	-0.01	1.70		00.64	1.96	-	-	-
Treatment finish–randomis (months)	0.59	-0.01	0.13		-0.120	0.13	-	-	-
Endocrine treatment	0.60	2.31	1.39		15.35	8.91	-	-	-
Herceptin	0.60	0.75	0.39		0.32	3.93	-	-	-
Haven Programme hours before Q1	0.59	0.01	0.05	0.61	-5.55	1.38***	-	-	-
Haven Programme hours from Q1 to Q2	0.59	0.32	0.36		0.03	0.46	-	-	-
Haven Programme hours from Q2 to Q3	0.59	0.63	0.49		0.44	0.62	-	-	-
Time from randomisation to Q1 (months)	0.59	0.194	0.53	0.62	0.28	0.52	-	-	-
MBSR cycle allocation	0.59	0.02	0.40		-0.06	0.39			
Study dropout	0.59	4.73	3.71		6.27	3.60	-	-	-
Difficulty or stress of illness	0.60	-0.68	0.38	0.65	-0.77	0.37*		-1.41	0.387***
Stressful life events	0.61	0.30	0.24		0.36	0.23		-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 42. Individual variable, multivariate and stepwise regression predictors of T2 FACT-B

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B	0.60	0.80	0.05***	0.57	0.78	0.05***	0.66	0.81	0.07***
Intervention or control group	0.63	0.80	0.04***		-7.00	1.88***		-8.04	1.65***
Age at randomisation	0.60	-0.91	0.10		-0.06	0.10	-	-	-
Socioeconomic status analytic classes	0.54	0.01	0.03		0.01	0.03	-	-	-
Breast cancer staging	0.60	0.91	1.04	0.64	3.44	1.27**	-	-	-
Breast cancer local recurrence	0.60	2.56	3.75		-3.09	4.06	-	-	-
Breast surgery	0.60	-9.36	12.63	-	-	-	-	-	-
WLE/ Partial mastectomy	0.60	-6-0.61	1.36		-3.53	1.75	-	-	-
Mastectomy	0.60	-2.72	1.50		-6.22	2.51		-2.86	1.42*
Breast reconstruction	0.60	-1.92	1.40		1.04	1.92	-	-	-
Chemotherapy	0.60	1.55	1.77		-0.57	6.70	-	-	-
Neoadjuvant chemotherapy	0.60	2.32	2.64		-11.55	9.05	-	-	-
Neoadjuvant chemo cycles (number)	0.60	-0.45	0.42		-3.32	1.69	-	-	-
Adjuvant Chemotherapy	0.60	1.26	1.76		1.58	7.29	-	-	-
Adjuvant chemo cycles (number)	0.60	-0.15	0.26		-0.50	0.76	-	-	-
Radiotherapy	0.60	-2.13	2.11		-0.94	2.52	-	-	-
Treatment finish - randomi (months)	0.60	-0.04	0.16		-0.15	0.16	-	-	-
Endocrine treatment	0.60	0.71	1.77		12.91	11.32	-	-	-
Herceptin	0.60	2.81	5.25		3.12	5.20	-	-	-
Haven Programme hours before Q1	0.60	0.02	0.06	0.63	0.04	0.06	-	-	-
Haven Programme hours from Q1 to Q2	0.60	-0.51	0.44		-1.01	0.56	-	-	-
Haven Programme hours from Q2 to Q3	0.60	0.08	0.61		0.57	0.76	-	-	-
Time from randomisation to Q1 (months)	0.60	0.48	0.65	0.63	0.56	0.63	-	-	-
MBSR cycle allocation	0.60	0.09	0.49	-	-	-	-	-	-
Study dropout	0.60	4.95	4.45		6.56	4.41	-	-	-
Difficulty or stress of illness	0.61	-1.22	0.55*	0.65	-1.34	0.54*		-1.40	0.52**
Stressful life events	0.61	0.67	0.31**		0.68	0.29*	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 43. Individual variable, multivariate and stepwise regression predictors of T3 FACT-B

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B	0.62	0.78	0.04***	0.62	0.76	0.05***	0.71	0.73	0.06***
Intervention or control group	0.66	-7.65	1.54***		-7.64	1.71***		-8.97	1.46***
Age at randomisation	0.62	-0.04	0.09		-0.04	0.10	-	-	-
Socioeconomic status analytic classes	0.58	-0.00	0.03		-0.01	0.03	-	-	-
Breast cancer staging	0.62	0.63	0.96	0.71	2.59	1.15*	-	-	-
Breast cancer local recurrence	0.62	0.76	3.49		-5.83	3.68	-	-	-
Breast surgery	0.62	0.83	11.75	-	-	-	-	-	-
WLE/ Partial mastectomy	0.62	-1.05	1.27		-3.71	1.59*	-	-	-
Mastectomy	0.63	-2.40	1.40		-7.83	2.27		-2.65	1.25*
Breast reconstruction	0.62	-1.08	1.30		1.63	1.74	-	-	-
Chemotherapy	0.62	-0.24	1.65		1.47	6.08	-	-	-
Neoadjuvant chemotherapy	0.62	0.31	2.46		-15.99	8.21	-	-	-
Neoadjuvant chemo cycles (number)	0.62	-0.23	0.39		-3.22	1.53*	-	-	-
Adjuvant Chemotherapy	0.62	-0.70	1.64		-4.71	6.62	-	-	-
Adjuvant chemo cycles (number)	0.63	0.05	0.24		-3.22	1.53*	-	-	-
Radiotherapy	0.62	-0.75	1.96		0.69	2.29	-	-	-
T1 FACT-B									
Treatment finish - randomisation (months)	0.62	0.00	0.15		-0.06	0.15	-	-	-
Endocrine treatment	0.62	2.19	1.64		7.57	10.27	-	-	-
Herceptin	0.62	3.11	4.87		4.22	4.72	-	-	-
Haven Programme hours before Q1	0.62	0.02	0.05	0.66	0.02	0.05	-	-	-
Haven Programme hours from Q1 to Q2	0.62	0.31	0.41		0.35	0.51	-	-	-
Haven Programme hours from Q2 to Q3	0.62	0.10	0.57		-0.55	0.70	-	-	-
Time from randomisation to Q1 (months)	0.62	0.19	0.61	0.66	0.29	0.59	-	-	-
MBSR cycle allocation	0.62	0.09	0.46		-0.04	0.44	-	-	-
Study dropout	0.62	4.87	4.22		6.83	4.48	-	-	-
Difficulty or stress of illness	0.64	-1.89	0.50***	0.69	-2.05	0.48***	-	-	-
Stressful life events	0.63	0.39	0.28		0.44	0.26	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 44. Individual variable, multivariate and stepwise regression predictors of T2 FACT-B TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B TOI	0.59	0.79	0.05***	0.55	0.75	0.05***	0.65	0.55	0.09***
Intervention or control group	0.62	-4.83	1.15***		-4.94	1.26***		-5.18	1.11***
Age at randomisation	0.59	-0.08	0.07		-0.04	0.07	-	-	-
Socioeconomic status analytic classes	0.52	0.00	0.02		0.00	0.02	-	-	-
Breast cancer staging	0.59	1.13	0.70	0.65	3.02	0.85***		1.65	0.67*
Breast cancer local recurrence	0.59	2.05	2.57		-1.63	2.74	-	-	-
Breast surgery	0.59	-2.70	8.67	-	-	-	-	-	-
WLE/ Partial mastectomy	0.59	-0.51	0.92		-2.40	1.07*	-	-	-
Mastectomy	0.59	-1.78	1.02		-4.17	1.67*		-2.68	0.99**
Breast reconstruction	0.59	-1.45	0.92		0.749	1.23	-	-	-
Chemotherapy	0.59	0.97	1.20		-1.21	4.46	-	-	-
Neoadjuvant chemotherapy	0.59	0.42	1.78		-9.30	6.09	-	-	-
Neoadjuvant chemo cycles (number)	0.59	-0.12	0.29		-2.47	1.14*	-	-	-
Adjuvant Chemotherapy	0.59	1.31	1.20		2.31	4.86	-	-	-
Adjuvant chemo cycles (number)	0.59	-0.15	0.18		-0.38	0.51	-	-	-
Radiotherapy	0.59	-1.26	1.45		-0.58	1.68	-	-	-
Treatment finish - randomisation (months)	0.59	-0.02	0.11		-0.105	0.108	-	-	-
Endocrine treatment	0.59	0.66	1.20		7.91	7.63	-	-	-
Herceptin	0.59	2.48	3.34		1.82	3.34	-	-	-
Haven Programme hrs before Q1	0.59	0.02	0.04	0.62	0.03	0.04	-	-	-
Haven Programme hours from Q1 to Q2	0.59	-0.25	0.30		-0.68	0.38	-	-	-
Haven Programme hrs from Q2 to Q3	0.59	0.22	0.41		0.51	0.52	-	-	-
Time from randomisation to Q1 (months)	0.59	0.36	0.45	0.62	0.37	0.44	-	-	-
MBSR cycle allocation	0.59	0.15	0.33		0.23	0.33	-	-	-
MBSR group attended	0.59	-0.03	0.06		0.02	0.06	-	-	-
Study dropout	0.59	3.60	3.12		5.23	3.36	-	-	-
Difficulty or stress of illness	0.60	-0.71	0.35	0.64	-0.76	0.35		-0.85	0.33**
Stressful life events	0.60	0.27	0.21		0.30	0.20	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 45. Individual variable, multivariate and stepwise regression predictors of T3 FACT-B TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B TOI	0.62	0.80	0.04***	0.60	0.77	0.05***	0.72	0.77	0.06***
Intervention or control group	0.66	-5.33	1.07***		-4.95	1.17***		-6.06	0.10***
Age at randomisation	0.63	-0.09	0.06		-0.10	1.17***		-0.15	0.06**
Socioeconomic status analytic classes	0.56	-0.01	0.02		4.95	0.05***	-	-	-
Breast cancer staging	0.62	0.31	0.66	0.68	1.79	0.80*	-	-	-
Breast cancer local recurrence	0.62	-0.46	2.43		-4.51	2.56	-	-	-
Breast surgery	0.62	9.54	8.16	-	-	-	-	-	-
WLE/ Partial mastectomy	0.62	-0.65	0.87		-2.57	1.09	-	-	-
Mastectomy	0.63	-1.40	0.97		-5.15	1.56***		-1.78	0.87*
Breast reconstruction	0.63	-0.30	0.87		1.71	1.15	-	-	-
Chemotherapy	0.62	0.125	1.14		1.70	4.17	-	-	-
Neoadjuvant chemotherapy	0.62	1.07	1.68		-9.87	5.70	-	-	-
Neoadjuvant chemo cycles (number)	0.62	-0.28	0.27		-2.08	1.06	-	-	-
Adjuvant Chemotherapy	0.62	0.39	1.13		-3.15	4.55	-	-	-
Adjuvant chemo cycles (number)	0.63	0.06	0.17		-0.35	0.48	-	-	-
Radiotherapy	0.62	-0.05	1.34		0.26	1.58	-	-	-
Treatment finish - randomisation (months)	0.62	0.01	0.10		-0.05	0.10	-	-	-
Endocrine treatment	0.63	1.58	1.13		3.94	7.14	-	-	-
Herceptin	0.62	2.01	3.14		1.27	3.13	-	-	-
Haven Programme hours before Q1	0.62	0.03	0.04	0.80	-0.02	0.03	-	-	-
Haven Programme hours from Q1 to Q2	0.63	0.40	0.28		0.86	0.28**	-	-	-
MBSR cycle allocation	0.62	0.14	0.32		0.05	0.31	-	-	-
Study dropout	0.62	3.36	2.94		4.87	3.13	-	-	-
Difficulty or stress of illness	0.64	-1.16	0.33***	0.69	-1.23	0.32***		-1.50	0.30***
Stressful life events	0.63	0.19	0.20		0.25	0.18	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 46. Individual variable, multivariate and stepwise regression predictors of T2 FACT PWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT PWB	0.49	0.72	0.05***	0.45	0.67	0.05***	0.51	0.61	0.08***
Intervention or control group	0.50	-1.03	0.43*		-0.95	0.46		-1.09	0.43**
Age at randomisation	0.49	-0.02	0.02		-0.01	0.03	-	-	-
Socioeconomic status analytic classes	0.52	0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.49	0.26	0.25	0.53	0.88	00.32**	-	-	-
Breast cancer local recurrence	0.49	0.62	0.90		-0.31	0.99	-	-	-
Breast surgery	0.49	0.16	3.17	-	-	-	-	-	-
WLE/ Partial mastectomy	0.49	-0.48	0.34		-0.90	0.44*	-	-	-
Mastectomy	0.49	-0.18	0.38		-1.07	0.623	-	-	-
Breast reconstruction	0.49	-0.14	0.34		0.18	0.46	-	-	-
Chemotherapy	0.49	0.68	0.43		-1.62	1.67	-	-	-
Neoadjuvant chemotherapy	0.49	0.65	0.65		-1.65	2.29	-	-	-
Neoadjuvant chemo cycles (number)	0.49	-0.11	0.10		-0.80	0.43	-	-	-
Adjuvant Chemotherapy	0.49	0.76	0.43		1.98	1.83	-	-	-
Adjuvant chemo cycles (number)	0.50	-0.10	0.06		-0.15	0.19	-	-	-
Radiotherapy	0.49	0.57	0.51		0.58	0.62	-	-	-
Treatment finish - randomisation (months)	0.49	-0.01	0.04		-0.06	0.04	-	-	-
Endocrine treatment	0.49	-0.27	0.43		5.09	2.87	-	-	-
Herceptin	0.49	1.31	1.21		1.49	1.26	-	-	-
Haven Programme hours before Q	0.49	0.00	0.01	0.50	0.00	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.49	-0.12	0.11		-0.02	0.14	-	-	-
Haven Programme hours from Q2 to Q3	0.49	0.04	0.15		0.21	0.20	-	-	-
Time from randomisation to Q1 (months)	0.49	0.02	0.16	0.50	-0.01	0.16	-	-	-
MBSR cycle allocation	0.49	0.14	0.12		0.11	0.12	-	-	-
Study dropout	0.49	1.38	1.15		1.84	1.28	-	-	-
Difficulty or stress of illness	0.49	-0.14	0.21	0.51	-0.19	0.12	-	-	-
Stressful life events	0.49	0.11	0.07		0.12	0.07	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 47. Individual variable, multivariate and stepwise regression predictors of T3 FACT PWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT PWB	0.56	0.81	0.05***	0.54	0.76	0.05***	0.60	0.72	0.06***
Intervention or control group	0.58	-1.31	0.42**		-1.09	0.44**		-1.40	0.41***
Age at randomisation	0.56	-0.03	0.02		-0.03	0.02	-	-	-
Socioeconomic status analytic classes	0.52	0.00	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.56	-0.05	0.25	0.60	0.47	0.31	-	-	-
Breast cancer local recurrence	0.56	-0.65	0.89		-2.47	0.98*	-	-	-
Breast surgery	0.56	2.01	3.10	-	-	-	-	-	-
WLE/ Partial mastectomy	0.49	-0.40	0.33		-1.27	0.43**	-	-	-
Mastectomy	0.56	-0.51	0.37		-2.16	0.61***	-	-	-
Breast reconstruction	0.56	-0.05	0.33		0.53	0.45	-	-	-
Chemotherapy	0.56	0.36	0.43		0.23	1.64	-	-	-
Neoadjuvant chemotherapy	0.56	0.82	0.64		-2.70	2.25	-	-	-
Neoadjuvant chemo cycles (number)	0.56	-0.16	0.10		-0.69	0.42	-	-	-
Adjuvant Chemotherapy	0.56	0.09	0.43		-0.25	1.79	-	-	-
Adjuvant chemo cycles (number)	0.56	-0.01	0.06		-0.06	0.19	-	-	-
Radiotherapy	0.56	0.29	0.50		0.44	0.61	-	-	-
Treatment finish - randomi (months)	0.56	0.02	0.04		-0.01	0.04	-	-	-
Endocrine treatment	0.56	0.18	0.43		0.23	2.81	-	-	-
Herceptin	0.56	0.28	1.19		-0.17	1.24	-	-	-
Haven Programme hours before Q1	0.56	0.00	0.01	0.57	0.00	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.56	-0.01	0.11		-0.03	0.14	-	-	-
Haven Programme hours from Q2 to Q3	0.56	0.00	0.15		-0.02	0.19	-	-	-
Time from randomisation to Q1 (months)	0.56	-0.17	0.16	0.58	-0.18	0.16	-	-	-
MBSR cycle allocation	0.56	0.12	0.21		0.12	0.12	-	-	-
Study dropout	0.56	1.04	1.13		1.36	1.24	-	-	-
Difficulty or stress of illness	0.58	-0.32	0.12**	0.60	-0.38	0.12***		-0.33	0.11**
Stressful life events	0.57	0.08	0.07		0.12	0.07	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 48. Individual variable, multivariate and stepwise regression predictors of T2 FACT SWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT SWB	0.67	0.79	0.04***	0.66	0.80	0.04***	0.69	0.77	0.04***
Intervention or control group	0.68	-1.06	0.54*		-10.9	0.49*		-1.04	0.45*
Age at randomisation	0.67	-0.01	0.03		-0.01	0.03	-	-	-
Socioeconomic status analytic classes	0.62	0.00	0.01		0.01	0.01	-	-	-
Breast cancer staging	0.67	-0.20	0.27	0.66	-0.15	0.35	-	-	-
Breast cancer local recurrence	0.67	0.95	0.94		0.34	1.09	-	-	-
Breast surgery	0.68	-6.67	3.27*	-	-	-	-	-	-
WLE/ Partial mastectomy	0.67	-0.15	0.36		-0.56	0.49	-	-	-
Mastectomy	0.67	-0.32	0.39		-1.04	0.69	-	-	-
Breast reconstruction	0.67	0.11	0.37		0.38	0.53	-	-	-
Chemotherapy	0.67	0.04	0.46		0.07	1.86	-	-	-
Neoadjuvant chemotherapy	0.67	0.41	0.69		0.19	2.51	-	-	-
Neoadjuvant chemo cycles (number)	0.67	-0.07	0.11		-0.02	0.47	-	-	-
Adjuvant Chemotherapy	0.67	-0.12	0.46		-0.11	2.03	-	-	-
Adjuvant chemo cycles (number)	0.67	0.02	0.07		0.04	0.21	-	-	-
Radiotherapy	0.67	-0.12	0.55		0.12	0.69	-	-	-
Treatment finish - randomi (months)	0.68	0.03	0.04		0.02	0.04	-	-	-
Endocrine treatment	0.66	0.11	0.46		0.48	3.15	-	-	-
Herceptin	0.66	0.47	1.28		1.08	1.39	-	-	-
Haven Programme hours before Q1	0.67	-0.01	0.02	0.68	0.00	0.02	-	-	-
Haven Programme hours from Q1 to Q	0.68	-0.18	0.12		-0.18	0.15	-	-	-
Haven Programme hours from Q2 to Q3	0.67	-0.16	0.16		-0.04	0.20	-	-	-
Time from randomisation to Q1 (months)	0.67	0.08	0.17	0.68	0.10	0.17	-	-	-
MBSR cycle allocation	0.67	-0.13	0.13		-0.16	0.13	-	-	-
Study dropout	0.67	0.14	1.19		0.757	1.31	-	-	-
Difficulty or stress of illness	0.68	-0.24	0.12*	0.69	-0.30	0.12*		-0.24	0.11*
Stressful life events	0.68	0.14	0.08		0.18	0.08	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 49. Individual variable, multivariate and stepwise regression predictors of T3 FACT SWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT SWB	0.64	0.77	0.04***	0.62	0.78	0.05***	0.65	0.74	0.04***
Intervention or control group	0.64	-0.71	0.48		-0.89	0.52	-	-	-
Age at randomisation	0.64	0.04	0.03	0.62	0.04	0.03	-	-	-
Socioeconomic status analytic classes	0.62	0.00	0.01		0.00	0.00	-	-	-
Breast cancer staging	0.64	0.05	0.28	0.62	-0.01	0.37	-	-	-
Breast cancer local recurrence	0.64	0.51	1.00		-0.12	1.15	-	-	-
Breast surgery	0.65	-7.73	3.45*	-	-	-	-	-	-
WLE/ Partial mastectomy	0.64	0.02	0.375		-0.16	0.51	-	-	-
Mastectomy	0.64	-0.30	0.41		-1.24	0.73	-	-	-
Breast reconstruction	0.64	0.08	0.39		0.49	0.56	-	-	-
Chemotherapy	0.64	-0.56	0.48		-1.69	1.97	-	-	-
Neoadjuvant Chemotherapy	0.64	-0.84	0.73		-1.17	2.66	-	-	-
Neoadjuvant chemo cycles (number)	0.64	0.12	0.12		-0.17	0.50	-	-	-
Adjuvant Chemotherapy	0.64	-0.32	0.48		0.01	2.15	-	-	-
Adjuvant chemo cycles (number)	0.63	0.02	0.07		-0.15	0.22	-	-	-
Radiotherapy	0.64	-0.19	0.58		0.26	0.72	-	-	-
Treatment finish – randomisation (months)	0.64	0.01	0.04		0.04	0.05	-	-	-
Endocrine treatment	0.62	0.37	0.49		1.17	3.33	-	-	-
Herceptin	0.62	0.53	1.35		1.40	1.47	-	-	-
Haven Programme hours before Q1	0.64	0.01	0.02	0.64	0.01	0.02	-	-	-
Haven Programme hours from Q1 to Q	0.64	0.04	0.12		0.21	0.16	-	-	-
Haven Programme hours from Q2 to Q3	0.64	-0.22	0.17		-0.44	0.22*	-	-	-
Time from randomisation to Q1 (months)	0.64	0.24	0.18	0.64	0.27	0.18	-	-	-
MBSR cycle allocation	0.64	0.00	0.13		-0.02	0.14	-	-	-
Study dropout	0.64	0.03	1.26		0.08	1.26	-	-	-
Difficulty or stress of illness	0.65	-0.27	0.12*	0.65	-0.33	0.12		-0.27	0.12*
Stressful life events	0.64	0.13	0.08		0.18	0.08*	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 50. Individual variable, multivariate and stepwise regression predictors of T2 FACT EWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT EWB	0.45	0.66	0.05***	0.42	0.62	0.06***	0.52	0.59	0.06***
Intervention or control group	0.46	-0.93	0.43*		-1.12	0.48*		-1.31	0.43**
Age at randomisation	0.45	0.01	0.02		0.01	0.03	-	-	-
Socioeconomic status analytic classes	0.41	0.00	0.01		-0.00	0.01	-	-	-
Breast cancer staging	0.45	0.12	0.25	0.51	0.66	0.31*	-	-	-
Breast cancer local recurrence	0.45	-0.28	0.89		-1.63	0.97	-	-	-
Breast surgery	0.45	0.64	3.14	-	-	-	-	-	-
WLE/ Partial mastectomy	0.45	0.09	0.34		-0.79	0.43	-	-	-
Mastectomy	0.46	-0.74	0.37*		-1.66	0.61**	-	-	-
Breast reconstruction	0.45	-0.20	0.33		0.67	0.45	-	-	-
Chemotherapy	0.46	0.82	0.43		0.54	1.63	-	-	-
Neoadjuvant Chemotherapy	0.46	1.39	0.64*		2.85	2.22	-	-	-
Neoadjuvant chemo cycles (number)	0.46	-0.25	0.10*		-0.89	0.42*		-0.31	0.10**
Adjuvant Chemotherapy	0.45	0.34	0.43		-0.20	1.78	-	-	-
Adjuvant chemo cycles (number)	0.45	-0.04	0.06		-0.12	0.19	-	-	-
Radiotherapy	0.45	-0.51	0.52		-0.55	0.62	-	-	-
Treatment finish - randomisation (months)	0.45	-0.02	0.04		-0.06	0.04	-	-	-
Endocrine treatment	0.42	-0.13	0.43		4.62	2.79	-	-	-
Herceptin	0.45	0.76	1.29		0.08	1.28	-	-	-
Haven Programme hours before Q1	0.45	0.00	0.01**	0.46	0.01	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.45	-0.11	0.11		-0.18	0.14	-	-	-
Haven Programme hours from Q2 to Q3	0.45	-0.02	0.15		0.08	0.19	-	-	-
Time from randomisation to Q1 (months)	0.45	0.14	0.16	0.46	0.13	0.16	-	-	-
MBSR cycle allocation	0.45	0.12	0.12		0.09	0.12	-	-	-
Study dropout	0.45	1.48	1.12		0.18	1.24	-	-	-
Difficulty or stress of illness	0.46	-0.29	0.12*	0.48	-0.36	0.13		-0.34	0.12**
Stressful life events	0.46	0.16	0.07*		0.19	0.07*		0.21	0.07**

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 51. Individual variable, multivariate and stepwise regression predictors of T3 FACT EWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT EWB	0.42	0.65	0.05***	0.44	0.60	0.06***	0.52	0.61	0.07***
Intervention or control group	0.46	-1.72	0.43***		-1.9	0.48***		-2.06	0.42***
Age at randomisation	0.42	0.03	0.03		0.03	0.03	-	-	-
Socioeconomic status analytic classes	0.40	0.01	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.42	0.01	0.26	0.51	0.74	0.31*	-	-	-
Breast cancer local recurrence	0.42	0.83	0.93		-1.07	0.99	-	-	-
Breast surgery	0.42	-0.38	3.27	-	-	-	-	-	-
WLE/ Partial mastectomy	0.42	-0.28	0.35		-1.26	0.44**		-0.94	0.39*
Mastectomy	0.43	-0.89	0.39		-1.96	0.62**		-1.34	0.43**
Breast reconstruction	0.43	-0.56	0.34		0.20	0.62**	-	-	-
Chemotherapy	0.42	0.56	0.45		0.27	1.66	-	-	-
Neoadjuvant Chemotherapy	0.42	0.63	0.67		-4.36	2.26	-	-	-
Neoadjuvant chemo cycles (number)	0.42	-0.15	0.11		-0.84	0.42*		-0.21	0.10*
Adjuvant Chemotherapy	0.42	0.12	0.45		-2.44	1.81	-	-	-
Adjuvant chemo cycles (number)	0.42	-0.04	0.07		-0.18	0.19	-	-	-
Radiotherapy	0.42	-0.61	0.54		-0.36	0.63	-	-	-
Treatment finish - randomi (months)	0.42	0.00	0.04		-0.04	0.04	-	-	-
Endocrine treatment	0.42	0.02	0.45		2.18	2.84	-	-	-
Herceptin	0.43	0.97	1.34		0.78	1.30	-	-	-
Haven Programme hours before Q1	0.42	0.00	0.02	0.46	0.01	0.02*	-	-	-
Haven Programme hrs from Q1 to Q2	0.42	-0.14	0.11		-0.10	0.14	-	-	-
Haven Programme hours from Q2 to Q3	0.42	-0.20	0.15		-0.19	0.20	-	-	-
Time from randomisation to Q1 (months)	0.42	0.02	0.17	0.46	0.03	0.17	-	-	-
MBSR cycle allocation	0.42	0.02	0.13		-0.02	0.12	-	-	-
Study dropout	0.42	1.55	1.17		2.332	1.27	-	-	-
Difficulty or stress of illness	0.43	-0.24	0.13	0.47	-0.31	0.13*	-	-	-
Stressful life events	0.42	0.03	0.08		0.04	0.08	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 52. Individual variable, multivariate and stepwise regression predictors of T2 FACT FWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT FWB	0.54	0.78	0.05***	0.50	0.75	0.06***	0.59	0.70	0.06***
Intervention or control group	0.56	-1.91	0.53***		-1.96	0.58**		-2.06	0.51***
Age at randomisation	0.54	-0.06	0.03*		-0.04	0.03		-0.08	0.03**
Socioeconomic status analytic classes	0.46	-0.01	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.54	0.31	0.32	0.58	0.10	0.39	-	-	-
Breast cancer local recurrence	0.53	-0.62	1.13		-2.42	1.24		-2.26	1.15*
Breast surgery	0.53	-0.61	3.95	-	-	-	-	-	-
WLE/ Partial mastectomy	0.53	0.13	0.42		-0.82	0.55	-	-	-
Mastectomy	0.54	-0.80	0.47		-1.92	0.78		-1.39	0.48**
Breast reconstruction	0.54	-0.57	0.42		0.42	0.57	-	-	-
Chemotherapy	0.53	0.04	0.55		-0.35	2.08	-	-	-
Neoadjuvant chemotherapy	0.53	0.24	0.81		7.28	2.84**	-	-	-
Neoadjuvant chemo cycles (number)	0.54	-0.11	0.13		-1.49	0.53**	-	-	-
Adjuvant Chemotherapy	0.53	-0.05	0.54		-0.19	2.27	-	-	-
Adjuvant chemo cycles (number)	0.54	0.01	0.08		-0.20	0.24	-	-	-
Radiotherapy	0.54	-0.81	0.65		-0.60	0.79	-	-	-
Treatment finish - randomisation (months)	0.53	0.00	0.05		-0.01	0.05	-	-	-
Endocrine treatment	0.53	0.56	0.55		-0.59	3.57	-	-	-
Herceptin	0.53	0.52	1.52		0.01	1.56	-	-	-
Haven Programme hours before Q1	0.54	0.01	0.02	0.57	0.02	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.53	-0.09	0.14		0.02	0.02	-	-	-
Haven Programme hours from Q2 to Q3	0.54	0.33	0.19		-0.33	0.17	-	-	-
Time from randomisation to Q1 (months)	0.54	0.29	0.20	0.56	0.30	0.20	-	-	-
MBSR cycle allocation	0.53	-0.02	0.15		-0.07	0.15	-	-	-
Study dropout	0.53	0.83	1.42		1.43	1.55	-	-	-
Difficulty or stress of illness	0.54	-0.29	0.16	0.57	-0.28	0.15		-0.36	0.15*
Stressful life events	0.54	0.02	0.09				-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 53. Individual variable, multivariate and stepwise regression predictors of T3 FACT FWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT FWB	0.48	0.69	0.05***	0.49	0.74	0.06***	0.53	0.59	0.06***
Intervention or control group	0.51	-1.80	0.52***		-1.99	0.57***		-1.96	0.51***
Age at randomisation	0.48	-0.04	0.03		-0.04	0.03	-	-	-
Socioeconomic status analytic classes	0.46	-0.01	0.01		-0.01	0.01	-	-	-
Breast cancer staging	0.48	-0.15	0.31	0.52	0.29	0.39	-	-	-
Breast cancer local recurrence	0.48	-0.85	1.12		-2.59	1.23*	-	-	-
Breast surgery	0.49	7.40	3.88	-	-	-	-	-	-
WLE/ Partial mastectomy	0.48	0.03	0.42		-0.94	0.54	-	-	-
Mastectomy	0.49	-0.82	0.46		-1.82	0.76*	-	-	-
Breast reconstruction	0.48	-0.45	0.41		0.43	0.57	-	-	-
Chemotherapy	0.48	-0.04	0.54		-1.22	2.07	-	-	-
Neoadjuvant Chemotherapy	0.48	0.54	0.81*		-5.18	2.83	-	-	-
Neoadjuvant chemo cycles (number)	0.48	-0.15	0.13		-1.16	0.53*	-	-	-
Adjuvant Chemotherapy	0.48	-0.20	0.54		-1.60	2.26	-	-	-
Adjuvant chemo cycles (number)	0.49	0.00	0.08		-0.42	0.24	-	-	-
Radiotherapy	0.48	-0.77	0.64		-0.88	0.78	-	-	-
Treatment finish - randomisation (months)	0.48	-0.00	0.05		-0.00	0.05	-	-	-
Endocrine treatment	0.48	0.96	0.54		0.26	3.55	-	-	-
Herceptin	0.48	0.40	1.51		0.48	1.55	-	-	-
Haven Programme hours before Q1	0.48	0.01	0.02	0.51	0.01	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.49	0.17	0.14		0.02	0.17	-	-	-
Haven Programme hours from Q2 to Q3	0.49	0.19	0.19		0.23	0.24	-	-	-
Time from randomisation to Q1 (months)	0.49	0.32	0.20	0.51	0.35	0.20		0.41	0.19*
MBSR cycle allocation	0.48	-0.04	0.15		-0.08	0.15	-	-	-
Study dropout	0.48	0.94	1.41		1.34	1.53	-	-	-
Difficulty or stress of illness	0.49	-0.38	0.15*	0.52	-0.37	0.15*	-	-	-
Stressful life events	0.49	-0.01	0.09		0.01	0.09	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 54. Individual variable, multivariate and stepwise regression predictors of T2 WHO-5 item wellbeing questionnaire

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 WHO-5	0.35	0.61	0.06***	0.35	0.59	0.06***	0.45	0.62	0.05***
Intervention or control group	0.39	-2.01	0.51***		-2.04	0.57***		-2.28	0.50***
Age at randomisation	0.35	-0.02	0.03		-0.01	0.03	-	-	-
Socioeconomic status analytic classes	0.31	0.00	0.01*		0.00	0.01	-	-	-
Breast cancer staging	0.36	0.67	0.31*	0.46	1.38	0.37***		1.14	0.31***
Breast cancer local recurrence	0.35	0.71	1.14		-1.32	1.19	-	-	-
Breast surgery	0.35	3.17	3.84	-	-	-	-	-	-
WLE/ Partial mastectomy	0.35	-0.18	0.41		-0.94	0.51	-	-	-
Mastectomy	0.36	-0.92	0.45*		-2.44	0.72***		-1.07	0.44*
Breast reconstruction	0.26	-3.99	2.09		0.77	0.53	-	-	-
Chemotherapy	0.35	-0.28	0.53		-0.67	2.11	-	-	-
Neoadjuvant chemotherapy	0.35	0.77	0.80		-4.15	2.64	-	-	-
Neoadjuvant chemo cycles (number)	0.35	-0.16	0.13		-1.12	0.52*		-0.34	0.13**
Adjuvant Chemotherapy	0.35	-0.42	0.53		0.88	2.15	-	-	-
Adjuvant chemo cycles (number)	0.36	0.09	0.08		-0.01	0.23	-	-	-
Radiotherapy	0.35	-0.42	0.62		0.04	0.71	-	-	-
Treatment finish - randomisation (months)	0.35	0.00	0.05		-0.03	0.05	-	-	-
Endocrine treatment	0.36	0.06	0.52		2.47	3.29	-	-	-
Herceptin	0.36	0.27	1.45		0.08	1.44	-	-	-
Haven Programme hours before Q1	0.35	0.01	0.02	0.39	0.00	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.25	-0.89	0.66		-0.15	0.17	-	-	-
Haven Programme hours from Q2 to Q3	0.35	0.18	0.18		0.23	0.23	-	-	-
Time from randomisation to Q1 (months)	0.35	0.06	0.20	0.38	0.09	0.19	-	-	-
MBSR cycle allocation	0.35	0.02	0.15		0.01	0.15	-	-	-
Study dropout	0.35	0.59	1.47		1.03	1.43	-	-	-
Difficulty or stress of illness	0.36	-0.13	0.14	0.41	-0.15	0.14	-	-	-
Stressful life events	0.37	0.08	0.09				-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 55. Individual variable, multivariate and stepwise regression predictors of T3 WHO-5 item wellbeing questionnaire

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 WHO-5	0.32	0.57	0.06***	0.35	0.54	0.06***	0.40	0.55	0.05***
Intervention or control group	0.37	-2.15	0.50***		-2.3	0.56***		-2.41	0.50***
Age at randomisation	0.31	0.02	0.03		0.02	0.03	-	-	-
Socioeconomic status analytic classes	0.29	0.01	0.01		0.00	0.01	-	-	-
Breast cancer staging	0.31	0.09	0.31	0.39	0.47	0.39	-	-	-
Breast cancer local recurrence	0.31	-0.10	1.14		-1.65	1.25	-	-	-
Breast surgery	0.31	2.07	3.83	-	-	-	-	-	-
WLE/ Partial mastectomy	0.31	-0.21	0.41		-0.98	0.53	-	-	-
Mastectomy	0.32	-0.62	0.45		-2.02	0.76**	-	-	-
Breast reconstruction	0.32	-0.23	0.41		0.60	0.56	-	-	-
Chemotherapy	0.31	-0.24	0.53		-0.75	2.22	-	-	-
Neoadjuvant chemotherapy	0.32	0.56	0.80		-6.47	2.77*		-5.51	2.56*
Neoadjuvant chemo cycles (number)	0.32	-0.17	0.13		-1.35	0.55*		-1.12	0.41**
Adjuvant Chemotherapy	0.32	-0.54	0.53		0.225	2.26	-	-	-
Adjuvant chemo cycles (number)	0.32	0.09	0.08		-0.04	0.24	-	-	-
Radiotherapy	0.32	-0.44	0.62		-0.31	0.75	-	-	-
Treatment finish - randomisation (months)	0.31	0.02	0.05		-0.005	0.05	-	-	-
Endocrine treatment	0.32	-0.08	0.53		-0.04	3.46	-	-	-
Herceptin	0.32	1.54	1.47		1.95	1.51	-	-	-
Haven Programme hours before Q1	0.35	0.01	0.02	0.36	0.01	0.02	-	-	-
Haven Programme hours from Q1 to Q2	0.31	0.07	0.13		0.04	0.17	-	-	-
Haven Programme hours from Q2 to Q3	0.31	0.06	0.18		-0.08	0.23	-	-	-
Time from randomisation to Q1 (months)	0.31	0.04	0.20	0.36	0.11	0.19	-	-	-
MBSR cycle allocation	0.31	-0.08	0.15		0.09	0.14	-	-	-
Study dropout	0.31	0.66	1.47		0.796	1.59	-	-	-
Difficulty or stress of illness	0.33	-0.24	0.14	0.39	-0.29	0.14	-	-	-
Stressful life events	0.25	0.10	0.44		0.06	0.09	-	-	-

*p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 56. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Total Mood Disturbance

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 POMS TMD	0.26	0.51	0.06***	0.13	0.24	0.10**	0.14	0.27	0.09**
Time from randomisation to Q1 (months)	0.14	-1.22	2.18		1.38	2.39	-	-	-
MBSR cycle allocation	0.15	0.40	1.72		0.97	1.76	-	-	-
MBSR group attended	0.14	0.37	0.34		-0.26	0.51	-	-	-
Number of hours of MBSR	0.15	0.57	0.45		3.27	4.78	-	-	-
Number of weekly sessions attended	0.15	-1.77	1.36		-6.19	10.52	-	-	-
Attended MBSR Saturday	0.15	8.18	6.82		18.51	27.75	-	-	-
Dropped out of MBSR classes	0.14	-4.55	8.47		216.07	389.78	-	-	-
Reasons for dropping out of MBSR classes	0.13	-0.07	0.11		-2.27	4.71	-	-0.44	0.18*
Study dropout	0.17	-24.27	12.21*		138.66	372.40	-	-	-
Reasons for dropping out	0.18	-0.41	0.16*		-2.49	4.63	-	-	-
Hours of formal home practice	0.13	-0.49	0.26		-0.72	0.36*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 57. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Total Mood Disturbance

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 POMS TMD	0.27	0.50	0.07***	0.24	0.31	0.10**	0.22	0.43	0.09***
Time from randomisation to Q1 (months)	0.16	0.93	2.35		3.98	2.46			
MBSR cycle allocation	0.15	0.31	0.17		2.34	1.82	-	-	-
-MBSR group attended	0.16	0.41	0.37		-0.34	0.52	-	-	-
Number of hours of MBSR	0.16	-0.67	0.48		3.22	4.92	-	-	-
Number of weekly sessions attended	0.29	-2.42	0.93**		-5.24	10.83	-	-	-
Attended MBSR Saturday	0.15	4.73	7.36		-1.93	28.57	-	-	-
Dropped out of MBSR classes	0.17	-13.34	9.01		330.63	401.28	-	-	-
Reasons for dropping out of MBSR classes	0.61	-0.18	0.12		-3.90	4.85	-	-	-
Study dropout	0.17	-23.81	13.15		70.77	383.39	-	-	-
Reasons for dropping out	0.18	-0.39	0.18*		-1.63	4.76	-	-	-
Hours of formal home practice	0.22	-0.81	0.27*		-1.34	0.38***	-	-0.85	0.28**

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 58. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Tension-Anxiety subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Tension-Anxiety	0.18	0.43	0.06***	0.10	0.31	0.10**	0.16	0.28	0.09**
Time from randomisation to Q1 (months)	0.14	-0.43	0.48		0.04	0.53	-	-	-
MBSR cycle allocation	0.14	-0.31	0.35		0.09	0.40	-	-	-
MBSR group attended	0.13	0.06	0.08		-0.06	0.11	-	-	-
Number of hours of MBSR	0.16	-0.19	0.10		0.09	1.07	-	-	-
Number of weekly sessions attended	0.16	-0.54	0.30		-0.26	2.36	-	-	-
Attended MBSR Saturday	0.16	2.81	1.47		2.36	6.23	-	-	-
Dropped out of MBSR classes	0.14	-2.09	1.87		12.11	87.78	-	-	-
Reasons for dropping out of MBSR classes	0.13	-0.02	0.02		-0.09	1.06	-	-	-
Study dropout	0.16	-5.44	2.72*		12.16	83.45	-	-8.68	3.32**
Reasons for dropping out	0.17	-0.09	0.04*		-0.29	1.04	-	-	-
Hours of formal home practice	0.14	-0.10	0.06		-0.07	0.08	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 59. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Tension-Anxiety subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Tension-Anxiety	0.18	0.41	0.06***	0.20	0.30	0.10**	0.17	0.39	0.09***
Time from randomisation to Q1 (months)	0.19	0.22	0.49		0.86	0.52	-	-	-
MBSR cycle allocation	0.12	-0.03	0.36		0.45	0.38	-	-	-
MBSR group attended	0.12	0.07	0.08		-0.08	0.11	-	-	-
Number of hours of MBSR	0.13	-0.14	0.10		0.03	1.04	-	-	-
Number of weekly sessions attended	0.14	-0.53	0.30		-0.09	2.29	-	-	-
Attended MBSR Saturday	0.12	0.58	1.52		-4.21	6.05	-	-	
Dropped out of MBSR classes	1.31	-2.49	1.88		37.25	85.26	-	-	-
Reasons for dropping out of MBSR classes	0.13	-0.03	0.02		-00.41	1.03	-	-	-
Study dropout	0.15	-5.48	2.74*		-4.43	81.05	-	-	-
Reasons for dropping out	0.16	-0.09	0.04*		-0.13	1.01	-	-	-
Hours of formal home practice	0.17	-0.15	0.06*		-0.20	0.08**	-	-0.15	0.06*

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 60. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Depression-Dejection subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Depression-Dejection	0.31	0.56	0.06***	0.10	0.22	0.10*	0.12	0.24	0.09*
Time from randomisation to Q1 (months)	0.14	-0.42	0.69		0.43	0.74	-	-	-
MBSR cycle allocation	0.14	-0.28	0.50		0.25	0.55	-	-	-
MBSR group attended	0.15	0.09	0.11		-0.12	0.16	-	-	-
Number of hours of MBSR	0.14	-0.06	0.14		0.88	1.49	-	-	-
Number of weekly sessions attended	0.14	-0.11	0.43		-0.08	3.28	-	-	-
Attended MBSR Saturday	0.14	1.59	2.12		5.79	8.66	-	-	-
Dropped out of MBSR classes	0.14	-1.48	2.66		66.50	121.44	-	-	-
Reasons for dropping out of MBSR classes	0.14	-0.03	0.03		-0.79	1.47	-	-	-
Study dropout	0.16	-6.34	3.86		79.74	116.52	-	-	-
Reasons for dropping out	0.17	-0.11	0.05*		-1.24	1.45	-	-0.13	0.06*
Hours of formal home practice	0.09	-0.13	0.18		-0.23	0.11*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 61. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Depression-Dejection subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Depression-Dejection	0.29	0.51	0.05***	0.16	0.63	0.11**	0.14	0.37	0.10***
Time from randomisation to Q1 (months)	0.13	-0.21	0.71		0.58	0.77	-	-	-
MBSR cycle allocation	0.13	-0.51	0.52		0.33	0.57	-	-	-
MBSR group attended	0.14	0.09	0.11		-0.12	0.17	-	-	-
Number of hours of MBSR	0.13	-0.02	0.15		2.66	1.55	-	-	-
Number of weekly sessions attended	0.13	-0.18	0.45		-4.47	3.42	-		-
Attended MBSR Saturday	0.13	0.01	2.22		10.92	9.01	-	-	-
Dropped out of MBSR classes	0.14	-1.17	2.77		27.27	126.37	-	-	-
Reasons for dropping out of MBSR classes	0.13	-0.02	0.04		-0.31	1.53	-	-	-
Study dropout	0.29	-2.90	3.39		70.49	121.26	-	-	-
Reasons for dropping out	0.16	-0.10	0.05		-1.12	1.51	-	-	-
Hours of formal home practice	0.14	-0.17	0.09		-0.34	0.12**	-	-0.18	0.09*

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 62. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Anger-Hostility subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Anger-Hostility	0.20	0.45	0.06***	0.15	0.16	0.10	0.13	0.27	0.09**
Time from randomisation to Q1 (months)	0.07	-0.42	0.54		0.34	0.48	-	-	-
MBSR cycle allocation	0.08	-0.47	0.39		-0.17	0.43	-	-	-
MBSR group attended	0.10	0.16	0.09		0.00.	0.12	-	-	-
Number of hours of MBSR	0.10	-0.20	0.11		0.83	1.16	-	-	-
Number of weekly sessions attended	0.10	-0.60	0.33		-1.68	2.56	-	-	-
Attended MBSR Saturday	0.10	3.03	1.61		5.85	6.75		-	-
Dropped out of MBSR classes	0.07	-1.51	2.10		15.47	94.67	-	-	-
Reasons for dropping out of MBSR classes	0.07	-0.01	0.03		-0.10	1.14	-	-	-
Study dropout	0.10	-5.88	3.05		164.20	92.57	-	-	-
Reasons for dropping out	0.10	-0.08	0.04*		-2.13	1.15	-	-	-
Hours of formal home practice	0.14	-0.18	0.16**		-0.20	0.09*	-	-0.18	0.07**

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 63. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Anger-Hostility subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Anger-Hostility	0.34	0.56	0.05***	0.36	0.32	0.08***	0.30	0.37	0.07***
Time from randomisation to Q1 (months)	0.20	0.45	0.08		0.73	0.43	-	-	-
MBSR cycle allocation	0.22	0.62	0.32		0.90	0.32**	-	-	-
MBSR group attended	0.26	0.20	0.07**		0.01	0.09	-	0.20	0.07**
Number of hours of MBSR	0.24	-0.24	0.09**		-0.24	0.87	-	-	-
Number of weekly sessions attended	0.25	-0.80	0.27**		0.21	1.92	-	-	-
Attended MBSR Saturday	0.12	2.22	1.37		-3.92	5.07	-	-	-
Dropped out of MBSR classes	0.23	-4.03	1.69*		19.64	71.12	-	-	-
Reasons for dropping out of MBSR classes	0.22	-0.05	0.02		-0.20	0.86	-	-	-
Study dropout	0.34	-2.74	2.38		114.96	69.54	- -	-	-
Reasons for dropping out	0.24	-0.09	0.03**		-1.54	0.87	-	-	-
Hours of formal home practice	0.28	-0.12	0.05*		-0.17	0.07*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 64. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Vigour-Activity subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Vigour-Activity	0.26	0.52	0.06***	0.27	0.43	0.09***	0.26	0.47	0.08***
Time from randomisation to Q1 (months)	0.28	0.21	0.38		0.43	0.42	-	-	-
MBSR cycle allocation	0.28	0.05	0.28		0.50	0.31	-	-	-
MBSR group attended	0.78	0.00	0.06		-0.04	0.09	-	-	-
Number of hours of MBSR	0.28	0.04	0.08		0.07	0.83	-	-	-
Number of weekly sessions attended	0.79	0.00	0.24		-1.01	1.83	-	-	-
Attended MBSR Saturday	0.29	-1.61	1.81		-2.80	4.82	-	-	-
Dropped out of MBSR classes	0.29	1.70	1.47		22.72	68.02	-	-	-
Reasons for dropping out of MBSR classes	0.27	0.02	0.02		-0.19	0.82	--	-	-
Study dropout	0.28	-0.71	2.15		-24.70	64.58	-	-	-
Reasons for dropping out	0.26	-0.02	0.03		0.22	0.80	-	-	-
Hours of formal home practice	0.28	0.03	0.05		-0.03	0.06	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 65. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Vigour-Activity subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Vigour-Activity	0.25	0.52	0.06***	0.27	0.41	0.09***	0.28	0.44	0.09***
Time from randomisation to Q1 (months)	0.23	0.32	0.44		0.89	0.45	-	-	-
MBSR cycle allocation	0.23	-0.10	0.32		0.22	0.34	-	-	-
MBSR group attended	0.22	-0.00	0.07		-0.08	0.10	-	-	-
Number of hours of MBSR	0.23	0.03	0.09		0.51	0.91	-	-	-
Number of weekly sessions attended	0.23	-0.16	0.26		-0.52	2.00	-	-	-
Attended MBSR Saturday	0.22	-0.14	1.37		-0.43	5.27	-	-3.26	1.63*
Dropped out of MBSR classes	0.23	-1.05	1.69		112.11	74.36	-	-	-
Reasons for dropping out of MBSR classes	0.21	-0.02	0.02		-1.36	0.90	-	-	-
Study dropout	0.23	-1.05	2.46		-33.00	70.60	-	-	-
Reasons for dropping out	0.21	-0.03	0.03		0.33	0.88	-	-	-
Hours of formal home practice	0.27	-0.11	0.05*		-0.22	0.07**	-	-0.19	0.06**

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 66. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Fatigue-Inertia subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 Fatigue-Inertia	0.18	0.42	0.06***	0.06	0.20	0.10	0.05	0.23	0.09**
Time from randomisation to Q1 (months)	0.07	-0.24	0.44		0.02	0.49	-	-	-
MBSR cycle allocation	0.07	0.16	0.32		0.11	0.36	-	-	-
MBSR group attended	0.07	0.07	0.07		0.03	0.10	-	-	-
Number of hours of MBSR	0.19	-0.12	0.07		1.37	0.97	-	-	-
Number of weekly sessions attended	0.07	-0.20	0.27		-1.04	2.14	-	-	-
Attended MBSR Saturday	0.06	0.25	1.36		0.44	5.67	-	-	-
Dropped out of MBSR classes	0.06	0.11	1.70		3.20	79.96	-	-	-
Reasons for dropping out of MBSR classes	0.05	0.00	0.02		-2.95	0.97	-	-	-
Study dropout	0.08	-3.01	2.47		-2.08	76.11	-	-	-
Reasons for dropping out	0.08	-0.06	0.03		1.79	0.94	-	-	-
Hours of formal home practice	0.06	-0.05	0.05		-0.18	0.08	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 67. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Fatigue-Inertia subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Fatigue-Inertia	0.23	0.48	0.06***	0.15	0.34	0.11**	0.18	0.41	0.10***
Time from randomisation to Q1 (months)	0.14	0.33	0.48		0.70	0.53	-	-	-
MBSR cycle allocation	0.14	-0.04	0.35		0.08	0.39	-	-	-
MBSR group attended	0.14	0.05	0.07		-0.02	0.11	-	-	-
Number of hours of MBSR	0.16	-0.14	0.10		0.18	1.04	-	-	-
Number of weekly sessions attended	0.16	-0.46	0.29		0.05	2.30	-	-	-
Attended MBSR Saturday	0.15	1.43	1.47		-1.18	6.11	-	-	-
Dropped out of MBSR classes	0.17	-3.43	1.81		146.26	86.10	-	-	-
Reasons for dropping out of MBSR classes	0.17	-0.05	0.02		-1.81	1.04	-	-	-
Study dropout	0.15	-2.32	2.68		-54.58	81.96	-	-	-
Reasons for dropping out	0.14	-0.05	0.04		0.64	1.02	-	-	-
Hours of formal home practice	0.19	-0.12	0.06*		-0.15	0.08	-	0.14	0.06*

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 68. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 POMS Confusion-Bewilderment subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Confusion-Bewilderment	0.34	0.54	0.05***	0.27	0.46	0.08***	0.29	0.46	0.07***
Time from randomisation to Q1 (months)	0.76	0.01	0.30		0.24	0.33	-	-	-
MBSR cycle allocation	0.28	-0.07	0.22		0.19	0.24	-	-	-
MBSR group attended	0.28	0.02	0.05		-0.05	0.07	-	-	-
Number of hours of MBSR	0.32	-0.15	0.06*		0.42	0.67	-	-0.16	0.07*
Number of weekly sessions attended	0.31	-0.39	0.18*		0.85	1.46	-	-	-
Attended MBSR Saturday	0.38	2.23	0.90**		-0.47	3.85	-	-	-
Dropped out of MBSR classes	0.29	1.50	1.14		43.87	53.96	-	-	-
Reasons for dropping out of MBSR classes	0.29	0.82	0.57		-49	0.65	-	-	-
Study dropout	0.30	-3.34	1.66*		-10.72	51.26	-	-	-
Reasons for dropping out	0.31	-0.05	0.02*		0.06	0.64	-	-	-
Hours of formal home practice	0.29	-0.08	0.04*		-0.07	0.05	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 69. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 POMS Confusion-Bewilderment subscale

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 Confusion-Bewilderment	0.35	0.55	0.05***	0.36	0.55	0.09***	0.36	0.56	0.08***
Time from randomisation to Q1 (months)	0.27	-0.18	0.34		0.10	0.35	-	-	-
MBSR cycle allocation	0.27	0.09	0.25		0.41	0.26	-	-	-
MBSR group attended	0.28	0.02	0.05		-0.04	0.08	-	-	-
Number of hours of MBSR	0.29	-0.12	0.07		-0.36	0.72	-	-	-
Number of weekly sessions attended	0.30	-0.41	0.21*		0.28	1.57	-	-	-
Attended MBSR Saturday	0.27	0.88	1.05		-4.38	4.14	-	-	-
Dropped out of MBSR classes	0.27	-1.36	1.30		-19.15	58.03	-	-	-
Reasons for dropping out of MBSR classes	0.27	-0.02	0.02		0.28	0.70	-	-	-
Study dropout	0.29	-3.11	1.90		-13.18	55.13	-	-	-
Reasons for dropping out	0.29	-0.05	0.03		0.09	0.68	-	-	-
Hours of formal home practice	0.36	-0.13	0.04***		-0.19	0.04***	-	-0.14	0.04***

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 70. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT-ES

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT ES	0.59	0.73	0.05***	0.49	0.62	0.09***	0.49	0.66	0.08***
Time from randomisation to Q1 (months)	0.49	0.80	1.01		0.67	1.13	-	-	-
MBSR cycle allocation	0.48	-0.16	0.77		-0.95	0.83	-	-	-
MBSR group attended	0.48	-0.14	0.16		0.18	0.24	-	-	-
Number of hours of MBSR	0.50	0.42	0.21*		-1.90	2.23	-	-	-
Number of weekly sessions attended	0.51	1.54	0.64*		5.46	4.91	-	-	-
Attended MBSR Saturday	0.59	-2.02	2.16		-4.47	12.99	-	-	-
Dropped out of MBSR classes	0.59	4.07	2.77		-70.22	209.88	-	-	-
Reasons for dropping out of MBSR classes	0.49	0.08	0.05		0.70	2.55	--	-	-
Study dropout	0.51	13.74	5.81*		-33.16	174.19	-	-	-
Reasons for dropping out	0.51	0.21	0.08**		0.72	2.17	-	0.20	0.09*
Hours of formal home practice	0.49	0.25	0.12*		0.31	0.17	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 71. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT-ES

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES	0.58	0.75	0.04***	0.55	0.70	0.08***	0.56	0.75	0.07***
Time from randomisation to Q1 (months)	0.52	0.80	1.01		0.11	1.08	-	-	-
MBSR cycle allocation	0.51	-0.24	0.75		0.97	0.80	-	-	-
MBSR group attended	0.52	-0.14	0.16		0.16	0.23	-	-	-
Number of hours of MBSR	0.55	0.55	0.20**		-0.02	2.13	-	-	-
Number of weekly sessions attended	0.56	1.85	0.62**		1.53	4.70	-	-	-
Attended MBSR Saturday	0.59	-3.67	2.06		3.70	12.43	-	-	-
Dropped out of MBSR classes	0.54	7.71	3.96*		-92.72	200.73	-	-	-
Reasons for dropping out of MBSR classes	0.53	0.10	0.05		1.01	2.44	-	-	-
Study dropout	0.54	13.50	5.68*		-18.70	166.60	-	-	-
Reasons for dropping out	0.54	0.20	0.08**		0.45	2.07	-	-	-
Hours of formal home practice	0.57	0.34	0.12**		0.34	0.17*	-	0.34	0.12**

*****$p < 0.05$, **$p < 0.01$, *** $p < 0.001$; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 72. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT-ES TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-ES TOI	0.59	0.80	0.05***	0.29	0.61	0.61***	0.53	0.66	0.07***
Time from randomisation to Q1 (months)	0.51	0.86	0.75		0.54-	0.80	-	-	-
MBSR cycle allocation	0.50	-0.11	0.56		0.70	0.59	-	-	-
MBSR group attended	0.51	-0.10	0.12		0.13	0.13	-	-	-
Number of hours of MBSR	0.53	0.34	0.15*		-0.76	-0.76	-	-	-
Number of weekly sessions attended	0.54	1.26	0.46**		2.86	2.86	-	-	-
Attended MBSR Saturday	0.51	-2.73	2.33		1.4	1.4	-	-	-
Dropped out of MBSR classes	0.52	5.27	2.97		-54.17	-54.17	-	-	-
Reasons for dropping out of MBSR classes	0.51	0.07	0.04		0.54	0.54	-	-	-
Study dropout	0.53	10.05	4.23*		-4.37	-4.37	-	12.12	5.16*
Reasons for dropping out	0.53	0.15	0.06**		0.28	0.28	-	-	-
Hours of formal home practice	0.53	0.20	0.09*		0.26	0.26*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 73. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT-ES TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT-ES TOI	0.59	0.78	0.05***	0.56	0.66	0.08***	0.57	0.71	0.07***
Time from randomisation to Q1 (months)	0.53	0.82	0.75		0.32	0.79	-		
MBSR cycle allocation	0.52	0.13	0.56		-0.38	0.59	-	-	-
MBSR group attended	0.53	-0.09	0.12		0.13	0.17	-	-	-
Number of hours of MBSR	0.56	0.45	0.15**		1.30	1.58	-	-	-
Number of weekly sessions attended	0.57	1.44	0.46**		-1.73	3.48	-	-	-
Attended MBSR Saturday	0.52	-4.69	2.29*		9.67	9.19	-	-	-
Dropped out of MBSR classes	0.55	6.53	2.93*		-93.35	149.47	-	-	-
Reasons for dropping out of MBSR classes	0.45	0.09	0.04*		1.07	1.82	-	-	-
Study dropout	0.55	9.95	4.21*		-9.38	123.10	-	-	-
Reasons for dropping out	0.55	0.51	0.06**		0.25	1.53	-	-	-
Hours of formal home practice	0.58	0.26	0.09**		0.23	0.12	-	0.27	0.09**

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 74. Intervention group only individual, multivariate and stepwise regression predictors of T2 FACT-B

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B	0.60	0.80	0.05***	0.50	0.67	0.09***	0.49	0.74	0.08***
Time from randomisation to Q1 (months)	0.52	1.24	0.94		0.65	1.04	-	-	-
MBSR cycle allocation	0.51	-0.16	0.70		-0.90	0.76	-	-	-
MBSR group attended	0.51	-0.10	0.15		0.20	0.23	-	-	-
Number of hours of MBSR	0.53	0.36	0.19		-2.61	2.17	-	-	-
Number of weekly sessions attended	0.54	1.30	0.58*		7.14	4.81	-	-	-
Attended MBSR Saturday	0.52	-3.73	2.88		-10.96	12.36	-	-	-
Dropped out of MBSR classes	0.52	4.46	3.69		-30.18	190.96	-	-	-
Reasons for dropping out of MBSR classes	0.53	0.16	0.07*		0.21	2.32	-	-	-
Study dropout	0.53	10.91	5.23*		-81.30	160.30	-	-	-
Reasons for dropping out	0.53	0.16	0.07*		1.25	1.20	-	-	-
Hours of formal home practice	0.50	0.18	0.11		0.25	0.16	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 75. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT-B

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT-B	0.62	0.78	0.04***	0.59	0.74	0.08***	0.60	0.80	0.07***
Time from randomisation to Q1 (months)	0.58	0.31	0.87		-0.36	0.94	-	-	-
MBSR cycle allocation	0.58	-0.13	0.65		-0.87	0.69	-	-	-
MBSR group attended	0.58	-0.10	0.13		0.18	0.20	-	-	-
Number of hours of MBSR	0.61	0.48	0.17**		-1.38	1.96	-	-	-
Number of weekly sessions attended	0.62	1.66	0.52**		5.15	4.35	-	1.70	0.61**
Attended MBSR Saturday	0.59	-4.59	2.66		-2.46	11.18	-	-	-
Dropped out of MBSR classes	0.59	6.21	3.39		-36.18	172.82	-	-	-
Reasons for dropping out of MBSR classes	0.60	0.15	0.07*		0.32	2.10	-	-	-
Study dropout	0.60	10.61	4.84*		-52.29	145.05	-	-	-
Reasons for dropping out	0.60	0.15	0.07*		0.81	1.81	-	-	-
Hours of formal home practice	0.60	0.28	0.10**		0.30	0.14*	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 76. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT-B TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT-B TOI	0.59	0.79	0.05***	0.58	0.60	0.08***	0.51	0.67	0.07***
Time from randomisation to Q1 (months)	0.50	0.64	0.64		0.15	0.68	-	-	-
MBSR cycle allocation	0.50	-0.03	0.47		-0.61	0.50	-	-	-
MBSR group attended	0.50	-0.06	0.10		0.19	0.15	-	-	-
Number of hours of MBSR	0.52	0.28	0.13*		-1.57	1.43	-	-	-
Number of weekly sessions attended	0.53	1.02	0.39**		4.78	3.17	-	-	-
Attended MBSR Saturday	0.51	-2.65	1.95		-5.01	8.11	-	-	-
Dropped out of MBSR classes	0.51	3.44	2.50		-38.08	126.64	-	-	-
Reasons for dropping out of MBSR classes	0.50	0.04	0.03		0.34	1.54	-	-	-
Study dropout	0.52	7.70	3.53*		-70.39	105.17	-	-	-
Reasons for dropping out	0.21	0.12	0.05*		1.06	1.31	-	0.11	0.05*
Hours of formal home practice	0.51	0.14	0.08		0.18	0.10	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 77. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT-B TOI

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT-B TOI	0.62	0.80	0.04***	0.59	0.70	0.80***	0.60	0.76	0.07***
Time from randomisation to Q1 (months)	0.57	0.35	0.61		-0.10	0.66	-	-	
MBSR cycle allocation	0.57	0.27	0.45		-0.25	0.48	-	-	-
MBSR group attended	0.57	-0.05	0.10		0.16	0.14	-	-	-
Number of hours of MBSR	0.61	0.37	0.12**		0.38	1.37	-	-	-
Number of weekly sessions attended	0.62	1.24	0.36***		0.87	3.05	-	1.32	0.43**
Attended MBSR Saturday	0.59	-3.54	1.84		5.71	7.80	-	-	-
Dropped out of MBSR classes	0.59	5.00	2.34*		-43.07	121.74	-	-	-
Reasons for dropping out of MBSR classes	0.59	0.07	0.03*		0.46	1.49	-	-	-
Study dropout	0.59	7.24	3.36*		-55.64	101.10	-	-	-
Reasons for dropping out	0.60	0.11	0.05*		0.78	1.26	-	-	-
Hours of formal home practice	0.60	0.20	0.07**		0.18	0.10	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 78. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT PWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT PWB	0.49	0.72	0.05***	0.49	0.57	0.08***	0.49	0.68	0.07***
Time from randomisation to Q1 (months)	0.50	0.00	0.22		-0.17	0.24	-	-	-
MBSR cycle allocation	0.50	-0.03	0.16		-0.20	0.18	-	-	-
MBSR group attended	0.51	-0.02	0.03		0.06	0.05	-	-	-
Number of hours of MBSR	0.52	0.08	0.05		-0.28	0.48	-	-	-
Number of weekly sessions attended	0.52	0.29	0.14*		0.97	1.07	-	-	-
Attended MBSR Saturday	0.51	-0.68	0.68		-0.43	2.82	-	-	-
Dropped out of MBSR classes	0.51	1.03	0.89		-35.52	46.82	-	-	-
Reasons for dropping out of MBSR classes	0.51	0.01	0.01		0.41	0.57	-	-	-
Study dropout	0.53	2.66	1.27*		-8.81	37.83	-	-	-
Reasons for dropping out	0.53	0.04	0.02*		0.17	0.47	-	-	-
Hours of formal home practice	0.50	0.03	0.03		0.04	0.04	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 79. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT PWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT PWB	0.56	0.81	0.05***	0.56	0.67	0.08***	0.58	0.74	0.07***
Time from randomisation to Q1 (months)	0.57	-0.08	0.21		-0.26	0.24	-	-	-
MBSR cycle allocation	0.57	0.16	0.16		0.05	0.17	-	-	-
MBSR group attended	0.57	-0.01	0.03		0.06	0.05	-	-	-
Number of hours of MBSR	0.59	0.10	0.04*		0.31	0.47	-	-	-
Number of weekly sessions attended	0.59	0.31	0.03*		-0.61	1.03	-	-	-
Attended MBSR Saturday	0.59	-1.28	0.64*		1.64	2.72	-	-	-
Dropped out of MBSR classes	0.58	1.55	0.84		-48.99	45.13	-	-	-
Reasons for dropping out of MBSR classes	0.58	0.02	0.01		0.59	0.55	-	-	-
Study dropout	0.59	2.44	1.22*		-8.40	36.47	-	-	-
Reasons for dropping out	0.59	0.04	0.02*		0.14	0.45	-	-	-
Hours of formal home practice	0.58	0.05	0.03*		0.04	0.04	-	0.06	0.03*

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 80. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT SWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT SWB	0.67	0.79	0.04***	0.61	0.77	0.07***	0.60	0.77	0.06***
Time from randomisation to Q1 (months)	0.65	0.39	0.25		0.40	0.29	-	-	-
MBSR cycle allocation	0.64	-0.10	0.19		-0.17	0.21	-	-	-
MBSR group attended	0.60	-0.03	0.04		-1.33	0.06	-	-	-
Number of hours of MBSR	0.64	-0.02	0.05		2.97	0.56	-	-	-
Number of weekly sessions attended	0.67	-0.02	0.10		-6.31	1.25	-	-	-
Attended MBSR Saturday	0.64	0.50	0.78		-8.26	3.30	-	-	-
Dropped out of MBSR classes	0.64	-0.33	1.01		0.08	52.36	-	-	-
Reasons for dropping out of MBSR classes	0.63	0.00	0.01		0.15	0.63	-	-	-
Study dropout	0.64	1.16	1.43		0.03	44.09	-	-	-
Reasons for dropping out	0.63	0.02	0.02		0.02	0.55	-	-	-
Hours of formal home practice	0.61	0.00	0.03		0.77	0.04	-	-	-

*****$p < 0.05$, **$p < 0.01$, *** $p < 0.001$; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 81. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT SWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT SWB	0.64	0.77	0.04***	0.60	0.78	0.07***	0.60	0.79	0.07***
Time from randomisation to Q1 (months)	0.63	0.03	0.27		-0.07	0.30	-	-	-
MBSR cycle allocation	0.63	-0.14	0.19		0.27	0.22	-	-	-
MBSR group attended	0.63	-0.03	0.04		0.00	0.06	-	-	-
Number of hours of MBSR	0.63	0.01	0.05		-1.29	0.59***	-	-	-
Number of weekly sessions attended	0.64	0.03	0.11		2.97	1.30***	-	-	-
Attended MBSR Saturday	0.63	0.06	0.82		-5.60	3.44	-	-	-
Dropped out of MBSR classes	0.63	-0.22	1.05		-10.19	64.63	-	-	-
Reasons for dropping out of MBSR classes	0.62	0.00	0.01		0.09	0.66	-	-	-
Study dropout	0.63	0.84	1.49		6.81	46.00	-	-	-
Reasons for dropping out	0.62	0.02	0.02		-0.04	0.57	-	-	-
Hours of formal home practice	0.61	0.04	0.03		0.08	0.05	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 82. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT EWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT EWB	0.45	0.66	0.05***	0.30	0.54	0.10***	0.33	0.60	0.09***
Time from randomisation to Q1 (months)	0.40	0.21	0.22		0.08	0.25	-	-	-
MBSR cycle allocation	0.40	0.05	0.16		-1.42	0.19	-	-	-
MBSR group attended	0.40	0.00	0.04		0.07	0.06	-	-	-
Number of hours of MBSR	0.42	0.10	0.05*		0.21	0.50	-	-	-
Number of weekly sessions attended	0.42	0.30	0.14*		-3.32	1.10	-	-	-
Attended MBSR Saturday	0.42	-1.28	0.68		0.89	2.93	-	-	-
Dropped out of MBSR classes	0.41	1.34	0.87		-22.12	46.53	-	-	-
Reasons for dropping out of MBSR classes	0.45	0.01	0.01		0.25	0.66	-	-	-
Study dropout	0.45	1.48	1.12		-35.55	39.63	-	-	-
Reasons for dropping out	0.12	0.03	0.02*		0.48	0.49	-	-	-
Hours of formal home practice	0.35	0.05	0.03		0.03	0.04	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 83. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT EWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 FACT EWB	0.42	0.65	0.05***	0.36	0.56	0.09***	0.37	0.63	0.08***
Time from randomisation to Q1 (months)	0.37	0.02	0.22		-0.13	0.24	-	-	-
MBSR cycle allocation	0.38	-0.16	0.16		-0.34	0.18	-	-	-
MBSR group attended	0.38	-0.02	0.04		0.07	0.05	-	-	-
Number of hours of MBSR	0.40	0.10	0.05*		-0.04	0.48	-	-	-
Number of weekly sessions attended	0.41	0.34	0.14*		0.33	1.05	-	-	-
Attended MBSR Saturday	0.38	-0.86	0.68		0.72	2.80	-	-	-
Dropped out of MBSR classes	0.39	1.50	0.87		-18.55	44.45	-	-	-
Reasons for dropping out of MBSR classes	0.43	0.02	0.01*		0.20	0.54	-	-	-
Study dropout	0.42	1.55	1.17		-29.56	37.86	-	-	-
Reasons for dropping out	0.40	0.04	0.02*		0.43	0.47	-	-	-
Hours of formal home practice	0.39	0.04	0.03		0.04	0.04	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 84. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 FACT FWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT FWB	0.54	0.78	0.05***	0.53	0.68	0.08***	0.51	0.72	0.08***
Time from randomisation to Q1 (months)	0.50	0.32	0.28		0.16	0.30	-	-	-
MBSR cycle allocation	0.49	0.01	0.21		-0.25	0.22	-	-	-
MBSR group attended	0.50	-0.02	0.04		0.42	0.07	-	-	-
Number of hours of MBSR	0.51	0.10	0.06		-0.91	0.59	-	-	-
Number of weekly sessions attended	0.52	0.43	0.17**		2.78	1.30	-	-	-
Attended MBSR Saturday	0.50	-0.47	0.67		-1.79	3.43	-	-	-
Dropped out of MBSR classes	0.50	1.52	1.11		46.15	55.23	-	-	-
Reasons for dropping out of MBSR classes	0.50	0.02	0.01		-0.59	0.67	-	-	-
Study dropout	0.50	2.35	1.57		-9.96	45.98	-	-	-
Reasons for dropping out	0.51	0.04	0.02		0.17	0.57	-	-	-
Hours of formal home practice	0.52	0.08	0.03**		0.11	0.05*	-	0.09	0.03*

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 85. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 FACT FWB

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 FACT FWB	0.48	0.69	0.05***	0.50	0.70	0.08***	0.50	0.75	0.08***
Time from randomisation to Q1 (months)	0.49	0.32	0.20		0.05	0.31	-	-	-
MBSR cycle allocation	0.04	-0.03	0.20		0.12	0.23	-	-	-
MBSR group attended	0.04	0.00	0.04		0.04	0.07	-	-	-
Number of hours of MBSR	0.06	0.09	0.06		0.61	0.62	-	-	-
Number of weekly sessions attended	0.52	0.34	0.18		-0.72	1.36	-	-	-
Attended MBSR Saturday	0.04	-0.30	0.85		6.29	3.59	-	-	-
Dropped out of MBSR classes	0.07	1.87	1.08		21.97	57.75	-	-	-
Reasons for dropping out of MBSR classes	0.07	0.01	0.01		-0.29	0.70	-	-	-
Study dropout	0.14	4.94	1.47***		-9.24	48.08	-	-	-
Reasons for dropping out	0.13	0.06	0.02**		0.16	0.60	-	-	-
Hours of formal home practice	0.05	0.05	0.03		0.09	0.05	-	-	-

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 86. Intervention group only individual variable, multivariate and stepwise regression predictors of T2 WHO-5 item wellbeing questionnaire

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error	*Adjusted* R^2	*B*	Std error
T1 WHO-5	0.35	0.61	0.06***	0.34	0.58	0.10***	0.38	0.59	0.08***
Time from randomisation to Q1 (months)	0.34	0.13	0.56		0.02	0.29	-	-	-
MBSR cycle allocation	0.34	-0.06	0.19		-0.23	0.21	-	-	-
MBSR group attended	0.35	-0.03	0.04		0.04	0.06	-	-	-
Number of hours of MBSR	0.38	0.14	0.06*		0.11	0.57	-	-	-
Number of weekly sessions attended	0.38	0.44	0.17**		0.10	1.25	-	-	-
Attended MBSR Saturday	0.36	-1.40	0.84		1.45	3.28	-	-	-
Dropped out of MBSR classes	0.37	2.17	1.06*		-38.72	70.10	-	-	-
Reasons for dropping out of MBSR classes	0.35	0.04	0.02		0.46	0.84	-	-	-
Study dropout	0.35	2.17	1.56		25.91	110.31	-	-	-
Reasons for dropping out	0.35	0.04	0.02		-0.27	1.34	-	-	-
Hours of formal home practice	0.39	0.08	0.03**		0.07	0.04	-	0.08	0.03**

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

Appendix 87. Intervention group only individual variable, multivariate and stepwise regression predictors of T3 WHO-5 item wellbeing questionnaire

	Individual variable			Multiple			Stepwise		
Variables	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error	*Adjusted R^2*	*B*	Std error
T1 WHO-5	0.32	0.57	0.06***	0.35	0.53	0.10***	0.36	0.60	0.09***
Time from randomisation to Q1 (months)	0.27	0.10	0.30		-0.15	0.31	-	-	-
MBSR cycle allocation	0.28	-0.17	0.22		-0.41	0.23	-	-	-
MBSR group attended	0.28	-0.04	0.05		0.04	0.07	-	-	-
Number of hours of MBSR	0.30	0.12	0.06		-0.27	0.61	-	-	-
Number of weekly sessions attended	0.30	0.42	0.20*		0.76	1.35	-	-	-
Attended MBSR Saturday	0.28	-0.81	0.91		1.12	3.55	-	-	-
Dropped out of MBSR classes	0.29	2.04	1.23		-37.01	75.98	-	-	-
Reasons for dropping out of MBSR classes	0.28	0.04	0.02		0.30	0.92	-	-	-
Study dropout	0.28	2.35	1.80		64.75	119.57	-	-	-
Reasons for dropping out	0.28	0.04	0.02		-0.70	1.45	-	-	-
Hours of formal home practice	0.67	0.11	0.03***		0.17	0.05***	-	0.12	0.04***

*****p < 0.05, **p < 0.01, *** p < 0.001; Significant variables from univariate and multivariate analyses included in stepwise

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