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The Development and Evaluation of a Mindfulness-Based Stress Reduction Self-Help Intervention for Patients with Medically Unexplained Symptoms

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Abstract

Background: Alongside experiencing physical symptoms with no identifiable organic cause, patients with MUS commonly experience comorbid anxiety and depression. They also have high health utilisation costs, which has implications for the health service. Interventions which target these symptoms in a cost effective way need to be developed and evaluated.

Objective: To develop and evaluate a self-help mindfulness-based stress reduction (MBSR) intervention for patients with medically unexplained symptoms (MUS).

Methods: A systematic review of the literature was carried out to evaluate the effectiveness of MBSR for reducing psychological distress in people with MUS. Study 1 developed and evaluated a self-help MBSR intervention in a clinical setting. Fifteen participants were recruited from eight practice, however only five completed post-intervention measures. A combination of t-tests and descriptive statistics were used to compare changes in levels of psychological distress, quality of life, symptoms and mindfulness at post-intervention. Pearson's correlations were used to identify relationships between improvements in mindfulness and improvements in outcomes. Study 2, exploring the reasons for the difficulties recruiting participants to Study 1, was then carried out through questionnaires to GPs.

Results: Though more evidence is needed, the systematic review found MBSR to have moderate effects on psychological distress, which are largely maintained or improved at follow-up. Study 1 found symptom frequency and levels of acceptance to have improved at post-intervention. Study 2 found that the main reasons for GPs not recruiting participants was that they were busy and found it difficult to prioritise given other demands.

Conclusions: Evidence to date suggests that MBSR is an effective intervention for patients with MUS. Future studies may benefit from recruiting participants from relevant organisations or using alternative methods such as database searches. No firm conclusions can be made about the self-help MBSR intervention's efficacy due to the study's limitations, however changes seen in the completer group suggest that further research would be warranted.

Study 1

The Development and Evaluation of a Self-Help Mindfulness-Based Stress Reduction Intervention for Patients with Medically Unexplained Symptoms

1. Systematic Review

The Efficacy of Mindfulness-Based Stress Reduction in Reducing Psychological Distress in People with Medically Unexplained Symptoms: A Systematic Review.

Running title: A systematic review of MBSR for MUS

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Abstract

Background: Physical symptoms which have no known medical cause are common, frequently debilitating, often do not respond to medical treatment and are commonly accompanied by psychological distress. Several psychological interventions have been trialled to reduce this distress, including Mindfulness-Based Stress Reduction (MBSR). These studies have produced differing outcomes and have not yet been reviewed systematically.

Methods: A literature search for studies of mindfulness-based stress reduction interventions for patients with medically unexplained symptoms, which included outcomes of psychological distress, was carried out. A number of electronic databases were searched; key journals were hand searched; first authors were contacted and reference lists of included articles were scanned.

Results: Nine studies met the inclusion criteria. Effect sizes of the more methodologically rigorous studies showed moderate reductions in psychological distress in MBSR groups which were largely maintained at follow-up. Many of the studies lacked methodological rigour, limiting the conclusions that could be drawn.

Conclusions: While the current findings suggest that MBSR is moderately effective in reducing psychological distress in patients with MUS, there is insufficient evidence to conclude that it is more effective than a control. Further methodologically-rigorous controlled studies are needed, based on clinical populations and with longer follow-up periods.

Key words: mindfulness meditation, mindfulness based stress reduction, irritable bowel, fibromyalgia, chronic fatigue, somatic.

MUS = medically unexplained symptoms; **NHS** = National Health Service; **CBT** = cognitive behaviour therapy; **MBSR** = Mindfulness-based stress-reduction; **CRD** = Centre for Reviews and Dissemination; **CF** = chronic fatigue; **IBS** = irritable bowel syndrome; **DARE** = Cochrane database of abstracts of reviews of effects; **BSI-A**= Brief Symptom Inventory – anxiety subscale; **BSI-D**= Brief Symptom Inventory – depression subscale; **VSI**= Visceral Sensitivity Index; **HADS-D**=The Hospital Anxiety And Depression Scale – depression subscale; **HADS-A**= The Hospital Anxiety And Depression Scale – anxiety subscale; **SCL-90-R (GSI)=**Symptom Checklist-90-Revised (Global Severity Index); **SCL-90-Ra**=Symptom Checklist-90-Revised – anxiety subscale; **SCL-90-Rd**=Symptom Checklist-90-Revised – depression subscale; **BDI**= Beck Depression Inventory; **BAI**= Beck Anxiety

Inventory; **CES-D =** Center for Epidemiologic Studies Depression Scale; **STAI**= State-Trait Anxiety Inventory.

1.1. Introduction

Physical symptoms which are appropriately investigated, but where no organic pathology can be identified, are often referred to as medically unexplained symptoms (MUS). Such symptoms often include pain, weakness or fatigue, and many areas of medical specialism have a diagnostic category for MUS including irritable bowel syndrome (IBS; gastroenterology), fibromyalgia (rheumatology) and chronic fatigue (1).

Medically unexplained symptoms have a considerable impact both on the individuals and on the healthcare system. Patients presenting with MUS can experience pain, distress, discomfort and disability (2) comparable to that caused by identifiable disease (3). They also visit their GP often, with prevalence estimates suggesting that they account for around a third of hospital outpatient referrals (4) and between 15 and 30% of patients in primary care (2, 5). As a result, resources can be wasted on ineffective attempts at treatment (6), with significant costs to the NHS and the potential to cause harm and discomfort through non-essential surgery or investigation (7).

Evidence suggests that a high proportion of patients with MUS experience psychological distress. Bleichhardt and colleagues found that 74% of their MUS participants had comorbid affective disorders and 47% had comorbid anxiety disorders (8). Another study found that 63% of patients with MUS had comorbid major depressive disorder (9). There are various possible explanations for these

associations with distress. Sharpe proposes that undiagnosed depression is one of the greatest causes of MUS, suggesting that physical symptoms such as fatigue, weight-loss and more complaints of pain are misdiagnosed, or go undiagnosed, due to the mistaken belief that depression is solely a mental health problem (10). For similar reasons, he suggests that anxiety and panic are another common cause of MUS. Continuing stigma in Western societies toward mental health may increase the likelihood of distress being manifested somatically. It is also possible that the distress caused by these symptoms leads to anxiety or depression, which in turn serves to worsen symptoms. Such self-perpetuating circles, where physical symptoms lead to poorer psychological wellbeing which in turn worsens symptoms are recognised in many chronic health conditions (11, 12).

Several psychological therapies have been introduced to this population to help manage distress. However, one difficulty faced in the assessment and treatment of MUS is that people often believe that problems are either purely physical or purely psychological (1). So while there is evidence that cognitive behavioural therapy (CBT) can be beneficial for some patients with MUS (13-15), many patients interpret a referral to a psychologist, or for the thought-challenging exercises typical of CBT, as a rejection or denial of their problems as being real, or feel that they are being told that it is 'all in their head'. Stone and colleagues found that psychological-sounding diagnostic labels often appear offensive to patients who preferred terms such as 'stress-related' (16).

Mindfulness provides an alternative, less challenging, stress reduction approach to such symptoms which works from a more acceptance-based stance. As a result the

focus of MBSR is not upon changing unhelpful thinking, but on changing the process by which symptoms are experienced. Mindfulness has been described as "the awareness that emerges by way of paying attention on purpose, in the present moment, and non-judgementally to the unfolding of experience moment by moment" (17; p732). In this way, emotions thoughts and bodily sensations, including negative those that are distressing or negative, are considered to be objects of attention in the practice of mindfulness.

Mindfulness-based stress-reduction (MBSR) is traditionally a standardised group-based therapy which evolved from the integration of Buddhist meditation into western psychological and clinical practice and was developed by Jon Kabat-Zinn (18). MBSR has been utilised for many physical problems, such as cancer (19) and chronic pain (20), as well as for mental health problems such as anxiety and depression (21, 22). As mindfulness does not make judgements about the cause of the symptoms, the potential for it to be beneficial for, and acceptable to, patients with MUS is promising.

There is evidence that MBSR has been useful in reducing anxiety and depression in people with fibromyalgia (23) and IBS (24), however other studies, such as that by Schmidt and colleagues (25), have had more mixed results. There have been no systematic reviews in this area to date, though a review of mindfulness for chronic pain (involving both explained and unexplained symptoms) identified that there was insufficient evidence for mindfulness-based intervention for this population due to the limitations of the studies reviewed (26).

While most studies in this area focus on one type of MUS such as CF, fibromyalgia or IBS, this study looks to review the evidence for MBSR for MUS as a whole. Irrespective of the type of symptom, CBT models of MUS propose an autopoietic system in which symptoms are self-producing or self-perpetuating. The models assume that symptoms are not the result of a physical pathology, but are generated or maintained by the interaction of physiological, cognitive and behavioural factors.

In this way, rather than attach their explanation to a particular bodily system the model proposed by Rief and Barsky (2005) suggests that symptoms arise through a two stage process of generation and selection. In the first stage chronic stress and over-arousal generate bodily symptoms, and in the second stage these symptoms are selected for conscious attention through a number of contributing factors including depression, health anxiety and uncertainty regarding symptom origins. The model suggests that these factors lead to 'faulty filtering' and an increase in the perception of, and attention to, symptoms.

This fits with theories of conscious awareness, including that by Gallagher (2005), which propose that while it plays little part in our daily life, and that automatic bodily processes remain largely outside our sphere of awareness, at times processes and sensations which would normally go unnoticed can be brought to the surface by changes in cognition or physiology. These symptoms can then interfere with the normal functioning of what are usually unconscious processes. In CBT models of MUS such symptoms may themselves become novel aversive stimuli resulting in further arousal and the development of a cognitive bias for symptoms leading to

increased rumination, with pain and illness leading to more pain and illness (Ursin, 2005).

Sometimes difficulties arise amongst healthcare workers around the meaningfulness and relatedness of different MUS diagnoses. This model helps to resolve these, to some extent, by providing a unified understanding of the nature of symptoms regardless of their type. Furthermore, this universal understanding of the maintenance of such symptoms provides potential treatment options, the lack of which can lead to concern about giving diagnoses.

While there have been some positive findings using CBT for this population the wider project is interested in the potential development of a self-help intervention and as such had to take this into account when considering the intervention. As people with MUS often experience being told that what they are experiencing is ‘all in their head’ some of the aspects of CBT, such as thought challenging, might be particularly off-putting, particularly with no therapist to engage and validate the patient's experience.

The use of MBSR as a treatment option for patients with MUS fits well with this model as it looks to build up the non-judgemental awareness of present moment experience, including symptoms, and stepping away from the attributions and thoughts that have become caught up in and maintain these experiences. Mindfulness looks to break the cycle of rumination through this process, with evidence that higher levels of acceptance, which are developed through mindfulness practice, are associated with lower rumination, thought suppression and depression (44). Alongside the research supporting the use of MBSR in managing symptoms in

patients with medically explained symptom, and the evidence that people with MUS prefer the term 'stress-related' to more psychological terminology, this model fits well with the idea that MBSR may be a useful treatment for this population. As a result, the aim of this review is to systematically evaluate the clinical effectiveness of MBSR for psychological distress in patients with MUS.

1.2. Method

This systematic review was informed by the internationally accepted guidance on carrying out systematic reviews provided by the Centre for Reviews and Dissemination (CRD) (27).

1.2.1. Inclusion and exclusion criteria

Studies were eligible for inclusion if they reported quantitative outcomes of psychological distress in people with MUS who had undertaken MBSR. Outcomes of psychological distress were defined as those which measured anxiety, depression or general psychological wellbeing. People were defined as having MUS if there was no identifiable organic pathology to their symptoms which is often identified through diagnoses such as CF, IBS and fibromyalgia. Studies were limited to those involving adult participants, regardless of race, gender or nationality.

Published conference abstracts were excluded as insufficient information about these studies could be found regarding methodology and results, as were studies where the intervention was not based predominantly on Kabat-Zinn's original MBSR (18). Studies using MBSR alongside another intervention were also omitted. Unpublished theses were included where they could be accessed and met criteria.

Studies assessing clinical effectiveness through self-report measures of anxiety, and/or depression, and/or a general psychological distress measure, were eligible for inclusion.

1.2.1.1. Literature search

The literature search was originally carried out in November 2011, and re-run in June 2012. The Cochrane Database of Abstracts of Reviews of Effects (DARE) was searched to check that a similar study had not been carried out recently. To ensure that this initial search was as thorough as possible, DARE was searched using the following terms: “medically unexplained”, “unexplained medical symptoms”, “chronic fatigue”, “irritable bowel”, and “mindful*” or “MBSR” or “MBCT”. The search revealed that no other similar review had been conducted.

The following electronic databases were then searched: Embase (1990 to 2011); Ovid MEDLINE (1990-2011); PsycINFO (1990-2011); and PsycARTICLES (1990 to 2011). Searches of these databases (in the domains of: title, abstract, heading word, table of contents, key concepts, original title, and tests & measures) were carried out using the following search string: ('medically unexplained symptom$' or 'unexplained medical symptom$' or ' somatic symptom$' or 'somatic disorder' or 'somatoform disorder' or 'functional symptoms' or 'functional syndromes' or 'functional disorders' or 'somati#ation' OR 'chronic fatigue' OR 'CFS' OR 'myalgic encephalomyelitis' OR 'chronic fatigue disorder' OR 'postviral fatigue' OR 'unexplained fatigue' OR 'post-concuss$' OR 'post concuss$' OR 'irritable bowel' OR 'IBS' OR 'irritable colon' OR 'spastic colon' OR 'functional adj5 bowel' OR 'fibromyalgia' OR 'fibromyalgia syndrome' OR 'fibromyalg$' OR 'tension headache'

OR 'tension-type headache' OR 'stress headache' OR 'muscle contraction headache') AND ('mindfulness-based stress reduction' OR 'mindful$' OR 'MBSR' OR 'meditation').

First authors of included papers, and of relevant published abstracts identified in the search, were contacted to request details of any unpublished studies that would meet the inclusion criteria. Eleven authors were approached, of these two could not be contacted and three did not respond. Seven articles (published and unpublished) were suggested by the authors who responded, but these either did not meet inclusion criteria or were already included in the review.

The reference lists for each of the included studies were manually searched in addition to a manual search of relevant journals which had published papers in this area (Journal of Psychosomatic Research, Psychosomatics and Psychotherapy, Psychosomatics and Psychosomatic Medicine) between 2009 and 2012. The original search yielded 398 potentially relevant papers, of which nine were finally determined to meet the review's criteria (see Figure 1.2.1).

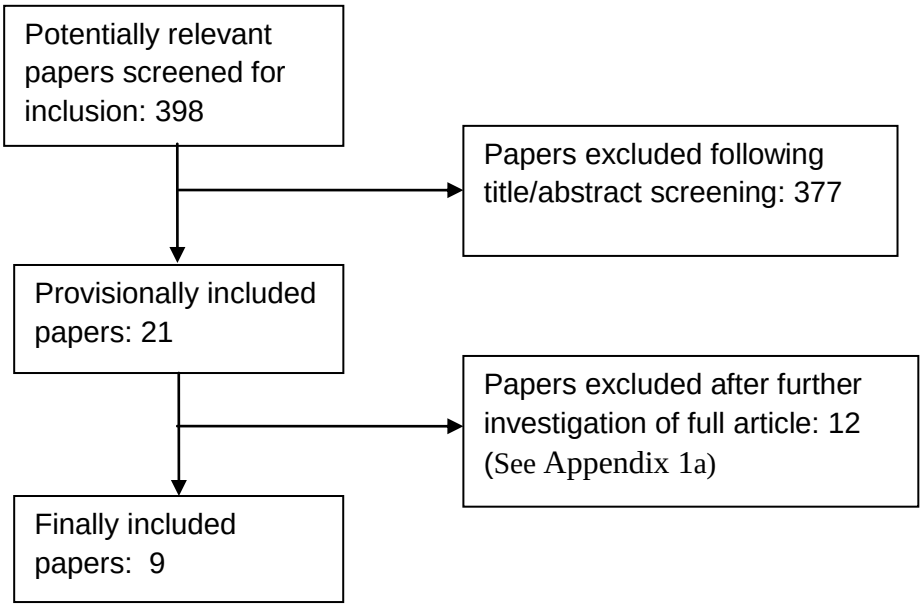

Figure 1.2.1 Flow chart of original literature search process

The search was re-run in June 2012 returning a further 27 papers, none of which met the inclusion criteria.

1.2.2. Assessing included studies

The included studies were evaluated using the 12 quality criteria outlined in Table 1.3 (full details of the criteria available in Appendix 1b). These criteria were based on recommendations by the CRD that quality criteria should cover the assessment of: chance of bias, outcome measures used, statistical issues, quality of reporting, quality of the intervention, and external validity (27). S.M. scored each study on the 12 quality criteria using the Scottish Intercollegiate Guidance Network (SIGN) outcome ratings ('Well covered': 2 points; 'Adequately addressed': 1 point; and 'Poorly addressed', 'Not reported' and 'Not applicable': 0 points) (28). Six of the nine studies, randomly selected through an online programme at www.random.org, were

independently reviewed by P.G.M. Initial review found exact agreement on 92% of quality ratings; differing by one point on 7%, and by two points on 1% of items. Where differences in scores were identified for criteria, these were reviewed and, where appropriate, amended. Studies were given an overall methodological strength related to their total score on the criteria ranging from Low to Very Good. Outcome ratings for individual quality criteria and methodological strength ratings can be seen in Table 1.2.

1.3. Results

1.3.1. Characteristics of included studies

Of the 398 articles retrieved in the original search, 377 were excluded following the initial title and abstract screening as they clearly did not meet the review's criteria. Full articles were screened for the remaining 21 articles, which resulted in the exclusion of a further 12 studies for reasons outlined in Appendix 1a.

The nine remaining studies comprised three randomised-controlled trials, two controlled trials and four uncontrolled trials. Five of these studies evaluated the effects of MBSR on both anxiety and depression; one evaluated its effect on anxiety; two on depression; and one on general psychological distress. Study characteristics and key findings are outlined in Table 1.1.

Table 1.1 Characteristics and main findings of included studies

Study	**Participants**	**Intervention arm(s)** (baseline n/ *post-intervention n*)	**% female**	**Follow-up period** post-intervention (months)	**Method used to recruit**	**Method-ological Strength**	**Outcome measures**	**Effect sizes for MBSR** (p value where available)		**Summary of main results**
								Post-intervention	**Follow-up**	
Gaylord *et al.* (2011) (24)	Females with IBS	MBSR (36/*34*) Support group (39/ *32*)	100	3	IBS patients interested in research & media	Very Good	BSI-A BSI-D VSI	d=0.41 (0.008) d=0.15 (0.266) d=0.41 (0.005)	d=0.39 (<0.001) d=0.21 (0.040) d=0.65 (<0.001)	*Psychological distress*: MBSR group not significantly different post-intervention but significant improvement in anxiety compared to support group at follow-up. MBSR group also showed significantly greater improvements in GI-specific anxiety at follow-up. Significant change in depression in MBSR group at follow-up. *Other:* IBS symptom severity reduced in MBSR group post-intervention. Improvement in QoL compared to control at follow-up.
Grossman *et al.* (2007) (23)	Females with fibromyalgia	MBSR (39/*35*) Social support (13/*11*)	100	36	Clinical & self-help groups	Good	HADS - D HADS - A	d=0.55 (<0.0001) d=0.68 (≤0.0001)	d=0.47 (<0.002) d=0.54 (<0.001)	*Psychological distress*: MBSR group significantly improved compared to the control group. Gains largely maintained at 3-year follow-up. *Other*: Pain, coping and QoL all significantly improved in MBSR group compared to control at post-intervention and largely maintained at follow-up.
Kaplan *et al.* (1993) (29)	Fibromyalgia patients	MBSR (77/*59*)	90	-	Random invite to fibromyalgia patients	Low	SCL-90-R (GSI)	-	-	*Psychological distress*: Improvement in psychological distress post-intervention. *Other*: Mean improvements on all scales post-intervention. Fifty-one % 'responders' (25% improvement on 50% of 10 measures.
Kearney *et al.* (2011) (30)	Veterans with IBS	MBSR (93/*76*)	25	4	Clinical	Good	VSI	d=0.16 (NS)	d=0.40 (0.014)	*Psychological distress*: Non-significant change in GI-specific anxiety at post-intervention, significant change at follow-up. Significant correlation between change in anxiety and mindfulness over the three time periods. *Other*: Participants experienced significant improvements in IBS-related QoL at follow-up.

Study	**Participants**	**Intervention arm(s)** (baseline n/ *post-intervention n*)	**% female**	**Follow-up period** post-intervention (months)	**Method used to recruit**	**Method-ological Strength**	**Outcome measures**	**Effect sizes for MBSR** (p value where available)		**Summary of main results**
								Post-intervention	**Follow-up**	
Lush *et al.* (2009) (31)	Females with fibromyalgia	MBSR (43/*24*)	100	-	Media	Low	BAI BDI	d=0.33 (0.123) d=0.42 (0.059)	-	*Psychological distress*: Non-significant reduction in psychological distress post-intervention. *Other*: Significant reduction in physiological response associated with anxiety.
Quintana & Fernandez (2011) (32)	Females with fibromyalgia	MBSR (14/*14*)	100	1	Media	Medium	BDI	d=0.64 (0.007)	d=0.12 (<0.05)	*Psychological distress*: Significant improvement in depressive symptoms post-intervention. Gains reduced at follow-up. *Other*: Improvements in QoL, pain and coping post-intervention were lost at post-intervention. Participant who continued practice post intervention maintained gains.
Sampalli *et al.* (2009) (33)	Females with MCS, CFS, and FM	MBSR (50/*36*) Wait list (50/*26*)	100	3	Clinical	Good	SCL-90-Ra SCL-90-Rd	d=0.37 (0.05) d=0.78 (0.001)	d=0.82 (0.05) d=1.01 (0.01)	*Psychological distress*: Significantly greater improvement for MBSR group in depression and anxiety post-intervention and at follow-up. *Other*: Five of nine subscales at post-intervention, and eight out of nine at follow-up, showed significant improvement for MBSR group.
Schmidt *et al.* (2011) (25)	Females with fibromyalgia	MBSR (53/*45*) Relaxation group (56/*51*) Wait list (59/*52*)	100	2	Mixed	Very Good	CES-D STAI	d=0.21 - d=0.44 -	d=0.36 (0.012) d=0.41 (0.003)	*Psychological distress*: The active treatment groups (MBSR and relaxation group) showed significantly greater reduction in anxiety than the waiting list group post-intervention. Trend towards greater effect size in MBSR for depression but not significant. *Other*: MBSR was no better than wait list or active control in terms of HRQoL at post-intervention. At follow-up MBSR group showed significant change in HRQoL.
Sephton *et al.* (2007) (34)	Females with fibromyalgia	MBSR (51/*41*) Waiting list (40/*27*)	100	2	Media	Good	BDI	d=0.45 -	d=0.33 -	*Psychological distress*: Significant improvement in depressive symptoms in MBSR compared to control group post-intervention. Gains maintained at follow-up.

Table 1.2 Quality ratings of methodology for included studies

	Quality criteria												
Study	i. Eligibility	ii. Recruitment	iii. Control	iv. Therapist experience	v. Outcome measure/s	vi. Baseline similarities	ii. Fidelity	viii. Randomisa-tion	ix. Sample size	x. Attrition	xi. Evaluation	ii. Analysis	**Methodo-logical strength score**
Gaylord *et al.* (2011) (24)	Well covered	Adequately addressed	Well covered	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Well covered	Very Good
Grossman *et al.* (2007) (23)	Well covered	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Well covered	Poorly addressed	Well covered	Well covered	Well covered	Poorly addressed	Good
Kaplan *et al.* (1993) (29)	Well covered	Adequately addressed	Poorly addressed	Not reported	Well covered	Not applicable	Adequately addressed	Not applicable	Well covered	Adequately addressed	Poorly addressed	Poorly addressed	Low
Kearney *et al.* (2011) (30)	Well covered	Well covered	Poorly addressed	Well covered	Well covered	Not applicable	Well covered	Not applicable	Well covered	Well covered	Well covered	Adequately addressed	Good
Lush *et al.* (2009) (31)	Well covered	Poorly addressed	Poorly addressed	Adequately addressed	Adequately addressed	Not applicable	Adequately addressed	Not applicable	Poorly addressed	Poorly addressed	Poorly addressed	Poorly addressed	Low
Quintana & Fernandez (2011) (32)	Well covered	Poorly addressed	Poorly addressed	Well covered	Adequately addressed	Not applicable	Well covered	Not applicable	Poorly addressed	Well covered	Adequately addressed	Adequately addressed	Medium
Sampalli *et al.* (2009) (33)	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Well covered	Well covered	Not addressed	Well covered	Poorly addressed	Well covered	Poorly addressed	Good
Schmidt *et al.* (2011) (25)	Well covered	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Adequately addressed	Adequately addressed	Well covered	Very Good
Sephton *et al.* (2007) (34)	Well covered	Poorly addressed	Well covered	Well covered	Adequately addressed	Well covered	Well covered	Adequately addressed	Well covered	Adequately addressed	Adequately addressed	Well covered	Good

Table 1.3 Brief description of quality criteria

(i)	Eligibility criteria are specified
(ii)	Patients are recruited in a clinical setting
(iii)	A control group is used
(iv)	At least one of the therapists was experienced or trained in teaching mindfulness
(v)	Measures of psychological distress are robust
(vi)	Similar levels of psychological distress at baseline
(vii)	The intervention is both sufficiently defined and delivered as planned (i.e. demonstrates good fidelity)
(viii)	The assignment of subjects to treatment and control groups is randomised
(ix)	Sample size is adequate for analyses
(x)	Levels of attrition are reported, acceptable, and equivalent for treatment versus control
(xi)	The intervention is evaluated for an appropriate duration
(xii)	Appropriate analysis used

A more detailed operationalisation of quality criteria scoring guidelines can be found in Appendix 1b.

1.3.2. Quality of included studies

The ratings for the quality criteria of each of the included studies are shown in Table 1.2 alongside a brief description of the related quality criteria in Table 1.3. While the ratings do not provide a comparative measure across studies they give a guide to their relative methodological strengths and weaknesses.

As none of the included studies were explicit about the validity or reliability of their measures, the psychometric properties were examined for all of the measures of

psychological distress. In addition, effect sizes for measures of psychological distress at post-intervention and follow-up were calculated, where possible, if not included in the studies. As only half of the studies were controlled, and fewer still included group-by-time interaction information, the focus of this review is largely on the effect of the MBSR group on psychological distress.

The study by Schmidt and colleagues (25), and that by Gaylord and colleagues (24) received the highest methodological rating score, and were the only studies to be rated as well covered or adequately addressed for all criteria, suggesting that they are the strongest studies methodologically.

1.3.2.1. Chance of bias

Gaylord and colleagues (24), and Kearney and colleagues (30) followed closely by Schmidt and colleagues (25) and Grossman and colleagues (23), scored more than other studies on quality criteria items that were interested in reducing chance of bias (i. Eligibility, ii. Recruitment, viii. Randomisation, x. Attrition, and xi. Evaluation). Only three studies suitably randomised their sample to MBSR and control groups (24, 25, 34), with only Gaylord's study describing the method of randomisation. Other studies either did not use random allocation or they had no control group. In three of the studies (23, 30, 32) levels of attrition were clearly detailed for treatment and control groups, acceptable, and sufficiently alike between conditions. With the exception of two studies (31, 33), where levels of attrition were below acceptable levels, other studies met the attrition criterion adequately.

Recruitment and evaluation criteria are considered separately under the *External validity* section (1.3.2.5).

1.3.2.2. Outcome measures

Outcome measures used in all studies were found to be reasonably robust, however three studies (31, 32, 34) used measures that are not ideal for this population (such as the BDI, BAI and SCL-90-R GSI) as they include somatic items which could artificially inflate distress scores in samples with medically unexplained symptoms.

1.3.2.3. Statistical issues

Statistical issues (iii. Control; iv. Baseline similarities; ix. Sample size; xii. Analysis) were well managed by some of the studies, but poorly by others. Only five of the nine studies had controls, however those that did provided clear details of differences in psychological distress at baseline between groups and were sufficiently alike or differences were controlled for. Most of the studies had sample sizes which were sufficient to be considered suitably powered to allow simple main effects (in uncontrolled trials) and interaction effects (in studies with control groups) analyses at post-intervention. Only two, uncontrolled, studies did not have a sufficient number of participants completing pre- and post-intervention measures to enable a power of at least 0.7 for simple main effects (31, 32). Analyses were described sufficiently to determine that they were conducted appropriately at post-intervention by three studies (24, 25, 34). A number of studies did not use intention to treat (ITT) principles to incorporate results for participants who did not complete post-intervention measures in their analyses (23, 29, 31, 33). One study, which stated that

ITT was used, did not provide clear details of this (30), while another did not explain why non-parametric analyses were being used over parametric alternatives (32).

Generally, the analyses carried out by uncontrolled studies were not carried out or described as well as those carried out in by the controlled studies. Alongside the lack of a control, and their inability to compare baseline scores, this lack of clear and suitable analyses impacted on the statistical quality, and general methodological shortcomings of the uncontrolled studies.

Overall, the studies by Gaylord (24), Schmidt (25), and Sephton (34) were the strongest of the studies in terms of statistical issues, closely followed by those by Grossman and Sampalli (23, 33). One study failed to meet any of the criteria for statistical issues (31) and another only scored one point (32).

1.3.2.4. Quality of the intervention

The quality of the intervention (iv. Therapist experience; iv. Fidelity) was covered relatively well by studies. Most provided evidence to show that at least one of the trainers was experienced or trained in teaching mindfulness, with only one study not providing sufficient information to meet the criterion adequately (29). Most of the studies defined the intervention well, and appeared to deliver it as planned. Two studies (29, 31), however, did not provide sufficient information to replicate the intervention.

1.3.2.5. External validity

Ratings of external validity (ii. Recruitment; xi. Evaluation) varied between studies. Recruitment of participants, for example, was carried out in very different ways ranging from a pure clinical setting, where no potential bias could be identified (30, 33), to recruitment through advertising (31, 32, 34) and registries of patients who identified themselves as being interested in taking part in research (24).

Other than two studies (29, 31), most studies included a follow-up period in their evaluation. However, only four studies included a follow-up that was at least three months post-intervention (23, 24, 30, 33), and Grossman and colleagues' study, with a three year follow-up, was the only one to include an evaluation over four months post-intervention.

1.3.3. Effectiveness of MBSR

1.3.3.1. Anxiety

Post-intervention effect sizes for reductions in anxiety, in MBSR groups, ranged from $d = 0.16$ to 0.68 (see Table 1.1). Studies rated as methodologically Good or Very Good showed a trend towards a medium effect size for anxiety post intervention, with all studies except one ranging from $d = 0.37$ to $d = 0.68$ (23-25, 30, 33). The exception to this was Kearney and colleagues' study which found a non-significant effect for gastro-intestinal specific anxiety with an effect size of $d = 0.16$, though this did increase to a significant effect of $d = 0.40$ at follow-up (30). Only one of the studies rated as Medium or Low, methodologically, evaluated and included

effect sizes for anxiety (31). This study showed an effect size of $d = 0.33$ which was slightly lower than the more methodologically rigorous studies.

1.3.3.2. Depression

A clearer difference between stronger and weaker studies is apparent in relation to post-intervention depression effect sizes. Studies rated as having Medium or Low methodological strength identified a medium to large range of effect sizes from $d = 0.42$ to $d = 0.64$. Stronger studies showed post-intervention effect sizes for depression in the small to medium range ($d = 0.15$ to 0.55) with the two studies rated as Very Good reporting effect sizes of $d = 0.15$ and $d = 0.21$ (24, 25). The effect sizes in these Very Good studies increased to $d = 0.29$ and $d = 0.36$, however, at follow-up.

1.3.3.3. Group comparisons

The study by Schmidt and colleagues, which had the largest total sample size of 148, carried out a post-hoc analysis of the group by time interaction (25). While there was no significant difference at post-intervention, MBSR performed significantly better than group relaxation and waiting list arms at follow-up. This finding was supported by the moderately sized study by Gaylord and colleagues (66 participants) (24): no significant interaction was identified for anxiety or depression at post-intervention, but at follow-up the MBSR arm performed significantly better than the control in both anxiety and GI-specific anxiety, but not depression. Grossman and colleagues' study (23), with a smaller total sample size of 48 participants, only reported group by time interactions for post-intervention data. When comparing the MBSR group with

the social support group they found that the MBSR group performed significantly better, reporting a small-medium post-intervention interaction effect size (d=0.39) for reduction in depression, and a medium-large effect size (d=0.67) in anxiety reduction, at post-intervention.

1.4. Discussion

The aim of the current article was to review studies which evaluated the impact of MBSR in reducing psychological distress in people with MUS. Methodologically, the quality of the studies reviewed varied greatly. Few studies incorporated a randomised controlled design, and baseline differences were not always measured or controlled for where necessary. Even the most methodologically rigorous studies showed limitations, with recruitment taking place through media advertisements rather than in a clinical setting in both studies (24, 25), and Schmidt and colleagues including a relatively short evaluation period of two months.

Overall these studies suggest that MBSR has a moderate beneficial effect on anxiety. In terms of depression, the stronger studies suggest a small to medium beneficial effect at post-intervention, compared to larger effects seen in the weaker studies. It is notable that effect sizes tended to improve or remain similar to post-intervention sizes at follow-up. One of the methodologically strongest, and largest of the studies (25), identified a significant group by time interaction suggesting that at follow-up MBSR had a greater impact on psychological distress than a relaxation group or waiting list control. Unlike other interventions, mindfulness-based interventions might show greater effects at follow-up compared to post-intervention because

efficacy grows as skills improve with practice, which may explain the findings identified here.

Follow-up periods in the studies reviewed were generally quite short, with most studies limited to 2-3 months. The one study with a considerably longer follow-up period (23), of three years, identified that gains from post-intervention were largely maintained at three-year follow-up.

Few studies included an active control, designed to be equivalent in structure, expectancy and support provided by a group, but excluding the 'active ingredient' of mindfulness meditation. As such, while the current evidence suggests beneficial effects of MBSR at follow-up -- which exceed those of waiting list or support groups -- the small number of randomised controlled studies available at present does not allow firm conclusions to be drawn as to whether these are specific effects of MBSR or non-specific effects of a psychological intervention.

1.4.1. Strengths of the review

The first authors of included papers, and those who had published abstracts which appeared relevant, were contacted to identify any unpublished studies with a view to limiting the potential for publication bias. A transparent process of methodological review was developed, with quality criteria outlined which are tailored to the nature of the reviewed studies. A high level of inter-rater reliability was established when the methodological quality of the studies was reviewed independently by two raters, in order to reduce potential for subjective bias.

1.4.2. Limitations of the review

Though there has been a growth in the number of studies evaluating MBSR for MUS in recent years the number of published, and unpublished, studies in the area remains limited at present. This means that there is not a large enough sample to compare effects across, and within, separate diagnostic groups such as irritable bowel syndrome, chronic fatigue, and fibromyalgia, which would prove informative in the future if research in this area continues to grow.

Much of the recent growth in this area of the literature has used MBSR. This, in addition to the evidence that suggests that patients with MUS prefer the term 'stress-related' to more psychological-sounding terms to describe their difficulties (16), led to the review's focus specifically on the effectiveness of MBSR for this population. There are clearly similarities between MBSR and other interventions such as MBCT and ACT, including the use of mindfulness and the concept of acceptance. They are, however, independent interventions which incorporate different elements such as traditional cognitive behavioural therapy. Limiting the review to studies evaluating MBSR meant that the review could not make comparisons between the effectiveness of MBSR and other interventions. Future studies and reviews would benefit from considering such evaluation, particularly when the literature in this area has grown to allow more meaningful comparisons between, as well as within, different interventions.

The current review looked to evaluate the effectiveness of MBSR in patients with MUS, however it was limited to studies which included distress measures. The majority of outcome studies evaluating MBSR in this population included a

psychological distress outcome measure. The inclusion of other types of outcome measure varies greatly across the available literature from physiological measures to problem-specific symptom measures. With such a diversity and inconsistency of outcome areas in a relatively small area of literature it was not deemed possible or appropriate to compare or synthesise them here. Consequently this review focused upon the impact of MBSR upon psychological distress, and as such could not explore the potential benefits of MBSR in other areas such as symptoms or quality of life, in the MUS population. As a result, the review can only comment on effectiveness in terms of the impact of MBSR on distress levels in patients with MUS. Again, as the literature grows the evaluation of MBSR on other non-distress parameters would be a valuable addition to our knowledge of this area.

1.4.3. Implications for clinical practice and research

As patients with MUS have high healthcare costs (6), in addition to the wider economic impact associated with sick leave and not working, finding an effective and acceptable intervention for patients is vital. The current findings suggest that MBSR could, potentially, be a useful intervention for this population that GPs often find difficult to manage. The focus on stress reduction, and on managing symptoms regardless of cause, means that MBSR may appear a less threatening, and potentially more acceptable, intervention to patients who might reject a more "thought-challenging" psychological intervention such as CBT. In addition, MBSR is delivered in groups which would be a more cost-effective intervention than individual CBT. In this way, MBSR has the potential not only to reduce the health-care costs of this population, but to do so in a cost-effective way. However, as the

numbers of patients who present at GPs with MUS is high (2, 5), and not everyone is open to attending group interventions, a substantial proportion of this population would not receive this intervention.

While the current review suggests that MBSR may be moderately effective in the reduction of psychological distress in patients with MUS, more methodologically rigorous, well-powered, randomised controlled studies, carried out on clinical populations, with longer follow-up periods, need to be carried out in order to generate more conclusive findings.

In addition, identifying what makes patients more likely to benefit from MBSR would be beneficial as it could help inform GP referrals for such an intervention, particularly considering the large potential population. Analysis of economic costs/benefits of MBSR for this population (using healthcare costs calculated on GP attendance pre- and post-intervention, for example), and an exploration of self-help based MBSR, which could potentially reach a larger proportion of the MUS population, would also be useful additions to this area of research.

1.5. Conclusions

This systematic review of the effectiveness of MBSR on psychological distress in patients with MUS found that it has a moderate effect on psychological distress. These effects were largely maintained or improved at follow-up, suggesting that, unlike some other therapies, gains made during the intervention may continue afterwards rather than diminish. While levels of depression and anxiety were lowered by MBSR, the limitations of the studies included meant that firm conclusions about

specific effects of MBSR compared to controls or alternative interventions could not be drawn. MBSR has the potential to offer patients with MUS a cost-effective intervention which is acceptable to them and successful in reducing psychological distress. However, more methodologically rigorous controlled trials based on clinical populations, with longer follow-up periods, are needed for these potential benefits to be substantiated, and for MBSR to be fully recognised as an evidence-based therapy for patients with MUS.

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1.7. Appendices

Appendix 1a. Table of studies excluded at second screening and reason for exclusion

Study	Reason for exclusion
Asare *et al.* (2011)	Journal letter
Astin *et al.* (2003)	MBSR not sole intervention (also Qigong movement therapy)
Ernst *et al.* (2007)	No English version available
Fjorback *et al.* (2011	Published conference abstract
Gaylord *et al.* (2011a)	Published conference abstract
Kearney *et al.* (2010a)	Published conference abstract
Kearney *et al.* (2010b)	Published conference abstract
Kearney *et al.* (2011)	Published conference abstract
Pauzano-Slam (2005)	Thesis - could not be sourced and author could not be reached
Surawy *et al.* (2005)	MBSR not sole intervention (combined with MBCT)
Weissbecker *et al.* (2002)	Not an outcome study
Zernicke *et al.* (2011)	Published conference abstract

Appendix 1b. Detailed breakdown of quality criteria scoring guidelines

i. Eligibility criteria are specified	
Well-covered (2)	Inclusion criteria clearly detailed
Adequately addressed (1)	Inclusion criteria are not outlined clearly, though they can be ascertained from the details given.
Poorly addressed (0)	Some information is given about eligibility for the trial, though it could not be confidently replicated.
Not addressed (0)	
Not applicable (0)	

ii. Patients are recruited in a clinical setting	
Well-covered (2)	It is clear that patients have been recruited in a clinical setting and all (or random sample of) eligible potential participants were invited.
Adequately addressed (1)	Patients recruited in a clinical setting but potential bias in those approached that wasn't part of inclusion/exclusion criteria.
Poorly addressed (0)	Patients recruited in a clinical setting but clear bias in those approached that was not part of inclusion/exclusion criteria.
Not addressed (0)	Not recruited in a clinical setting
Not applicable (0)	

iii. A control group is used	
Well-covered (2)	A suitable control group is carried out alongside the experimental intervention group. This could be a TAU, waiting list or an active control group.
Adequately addressed (1)	An alternative intervention group is included but no control group.
Poorly addressed (0)	
Not addressed (0)	
Not applicable (0)	

iv. At least 1 of the therapists was experienced or trained in teaching mindfulness	
Well-covered (2)	Evidence provided to show that at least one of the trainers was experienced or trained in teaching mindfulness (yrs experience etc)
Adequately addressed (1)	It is stated that one of the therapists is experienced or trained in mindfulness but no evidence is given to support this.
Poorly addressed (0)	Some information about the therapist's experience given but does not suggest 'experienced'.
Not addressed (0)	No description of the therapist's experience is given.
Not applicable (0)	

v. Measures of psychological distress are robust	
Well-covered (2)	Outcome measures robust for this population (valid, reliable - HADS, etc.)
Adequately addressed (1)	Outcome measures acceptable validity/psychometrics, or good robustness but not the most valid for this population. (GSI of SCL-R-90/BDI etc)
Poorly addressed (0)	Outcome measures poorly described and less robust.
Not addressed (0)	
Not applicable (0)	

vi. Similar levels of psychological distress at baseline	
Well-covered (2)	Clear details of differences in psychological distress at baseline, between groups. Sufficiently alike or controlled.
Adequately addressed (1)	Reasonable detail of psychological distress measure between groups, and somewhat alike at baseline.
Poorly addressed (0)	Measured but limited description, poorly alike at baseline.
Not addressed (0)	
Not applicable (0)	

vii. The intervention is both sufficiently defined and delivered as planned (i.e. demonstrates good fidelity).	
Well-covered (2)	The intervention is clearly outlined and shows good treatment fidelity – could be replicated.
Adequately addressed (1)	Some detail about the intervention, evidence of alteration of intervention from its original form.
Poorly addressed (0)	Unclear definition of the intervention and its fidelity.
Not addressed (0)	
Not applicable (0)	

viii. The assignment of subjects to treatment and control groups is randomised	
Well-covered (2)	Randomisation is clearly described using an appropriate method
Adequately addressed (1)	It is stated that randomisation is carried out, but no explanation of method.
Poorly addressed (0)	Randomisation is stated, but not using appropriate method.
Not addressed (0)	
Not applicable (0)	

ix. Sample size adequate for analyses	
Well-covered (2)	The number of participants who completed pre- and post-intervention measures was sufficient to enable Power of at least 0.8 for simple main effects (uncontrolled trials) and interaction effects (where 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Adequately addressed (1)	The number of participants who completed pre- and post-intervention measures was sufficient to enable Power of at least 0.7 for simple main effects (uncontrolled trials) and interaction effects (where 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Poorly addressed (0)	The number of participants who completed pre- and post-intervention measures did not enable Power of at least 0.7 for simple main effects and interaction effects (where there are 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Not addressed (0)	
Not applicable (0)	

x. Levels of attrition are reported, acceptable, and equivalent for treatment versus control	
Well-covered (2)	Levels of attrition (from allocation to group to completion of post intervention measures) are clearly detailed for both treatment and control groups (where present) and are sufficiently alike between conditions (within 10% of each other and less than 20% of total participants)
Adequately addressed (1)	Reasonable description of attrition (from allocation to group to completion of post intervention measures), somewhat alike between conditions (within 20% of each other), less than 30% of total participants.
Poorly addressed (0)	Poorly described (lacking specifics), or significantly different between conditions.
Not addressed (0)	Not described
Not applicable (0)	

xi. The intervention is evaluated for an appropriate duration	
Well-covered (2)	Follow-up carried out for a minimum of 3 months (must include psychological distress measure)
Adequately addressed (1)	Follow-up carried out for a minimum of 1 month (must include psychological distress measure)
Poorly addressed (0)	Follow-up less than one month
Not addressed (0)	No follow-up
Not applicable (0)	

xii. Appropriate analysis	
Well-covered (2)	Analysis described sufficiently to determine that analyses conducted appropriately at post-intervention - appropriate statistics used, ITT where there is attrition.
Adequately addressed (1)	Reasonably clear that appropriate analysis carried out at post-intervention - appropriate statistics used, ITT where there is attrition – maybe lacking in clarity/detail about.
Poorly addressed (0)	Inappropriate analyses or not addressing attrition, where relevant, at post-intervention.
Not addressed (0)	
Not applicable (0)	

2. Methods

2.1. Design

The original study design was a randomised controlled trial, with participants recruited to intervention and treatment as usual (TAU) conditions. Due to difficulties recruiting participants the design was altered to a within subjects, repeated measures study. Figure 2.3.1 illustrates the study design and subject recruitment and response.

2.2. Ethical considerations

Ethical approval was granted by the South of Scotland Research Ethics Committee 3 in November 2011 (see Appendix 3) and NHS Borders Research Governance Committee approved the study for their health board (December 2011; Appendix 4). In addition, methodological approval was also granted by the University of Edinburgh Clinical Psychology Review Team (October 2011; Appendix 5).

The main ethical considerations were around consent and confidentiality and potential distress caused by completing the questionnaires or carrying out the intervention. Potential participants were given an information sheet (see Appendix 6a) which gave details about the project. It explained that patient names and addresses were needed so that intervention packs and questionnaires could be sent out to them. The information sheet included contact details for the lead researcher if participants had any further questions. Confidentiality was maintained by giving participants a project ID number as soon as they responded, keeping personal data separate to the anonymised data collected. Participants were advised, through the

questionnaires and intervention booklet, that if they became distressed at any time, they should seek further help from their general practitioner (GP).

2.3. Participants

Initially, GPs in six medical practices in NHS Borders were involved in identifying patients eligible for the project during routine appointments. During the recruitment period, two additional medical practices became involved in identifying potential participants.

Project information packs were given out by GPs to patients who met the inclusion criteria and indicated an interest in the research. Patients who completed and returned the enclosed consent form and questionnaire became participants.

Sixteen patients were recruited. Of these, one was randomised to the TAU arm prior to the amendment to the design of the project. The remaining fifteen patients were recruited to the intervention (see Figure 2.3.1.) and became participants.

2.3.1. Inclusion criteria

To be eligible for inclusion in the project, patients needed to:

- Be identified by their GP as having at least one of the following conditions: irritable bowel syndrome, chronic fatigue syndrome, tension headaches or fibromyalgia.
- Have received appropriate investigation to exclude known medical explanations for symptoms (as determined by their GP).

- Have no known medical basis or partial basis for the symptoms (as determined by their GP).
- Have sufficient understanding of the English language to complete the standardised measures.
- Be aged over 18 and under 70

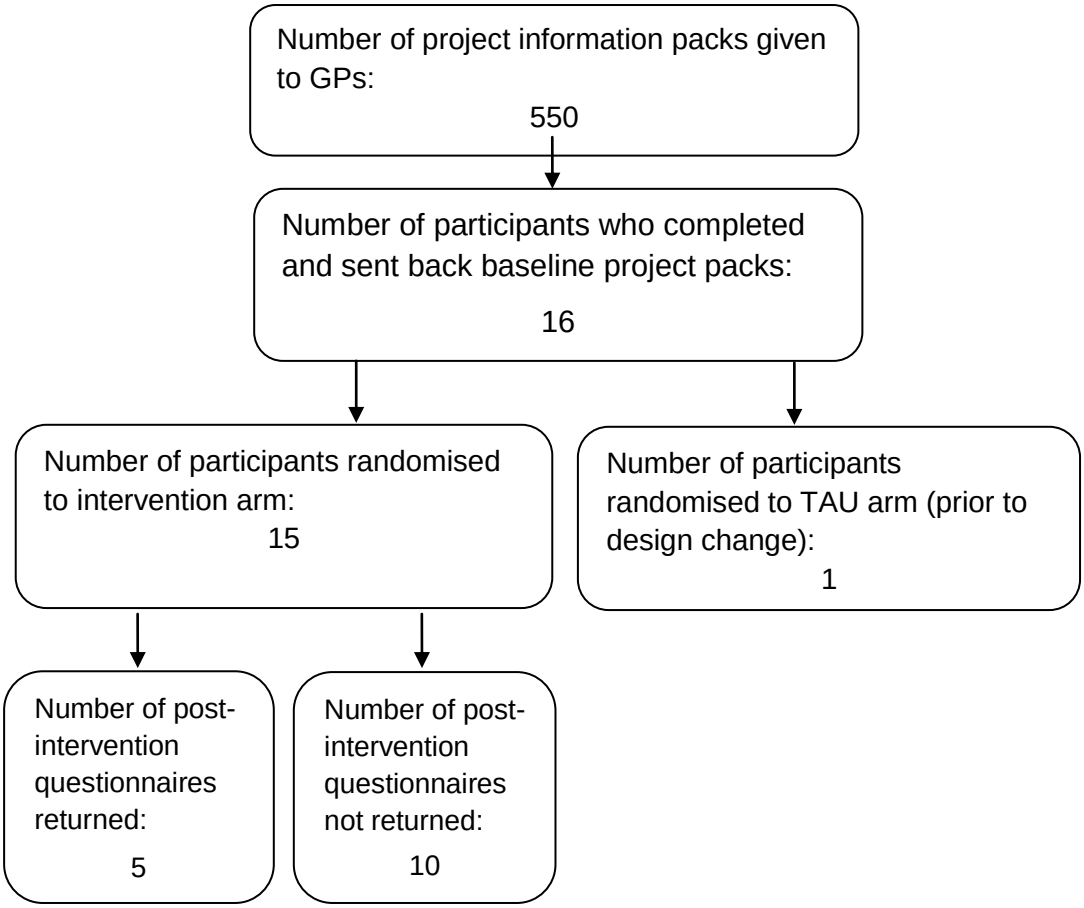

Figure 2.3.1 Participant recruitment and response numbers

2.4. Measures

Participants completed outcome and process measures upon entry to the study (baseline), at completion of the 8-week intervention period (post-intervention). Measures were collated in an A5 booklet. The baseline measures were given out by

GPs in the project information packs, the post intervention measures were sent out to participants with return envelopes.

The baseline questionnaire booklet asked participants for their age, sex, main symptom, and length of time they had experienced their symptoms for. The post-intervention measures booklet included a short additional section asking participants for feedback on the intervention and how far they had completed the intervention on a five point scale from ‘completely’ to ‘not at all’. The following outcome and process measures were included at each time point:

2.4.1. Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) was used to measure psychological distress. The HADS is a self-report measure which was initially designed for the identification of anxiety and depression in a non-psychiatric hospital population. The items on the HADS focus on cognitive and emotional symptoms of anxiety and depression rather than somatic symptoms in order to reduce the potential confound with physical problems. This makes the HADS particularly useful when assessing psychological distress in people with physical health problems. Furthermore, the brevity of the measure also makes the HADS a useful measure where a number of measures are being used.

The scale consists of 14 items: seven in the anxiety subscale (HADS-A), and seven in the depression subscale (HADS-D). Each item is scored on a scale from 0 to 3, with higher scores representing more severe symptoms. The test authors recommend that total subscale scores of 0-7 indicate sub-clinical levels of anxiety or depression;

8-10 mild cases; 11-15 moderate cases, and 16 or more indicating severe cases (Snaith & Zigmond, 1994; Zigmond & Snaith, 1983). A review by Bjelland *et al.* (2002) supports the use of 8 as a clinical cut-off.

The HADS has been used widely, with the review by Bjelland and colleagues identifying 747 studies that referred to its use prior to May 2000. This review provided support for the two factor structure, with most studies identifying relatively independent dimensions of anxiety and depression closely related to HADS-A and HADS-D. Furthermore, the review supported the HADS' reliability and validity in primary care, as well as in hospital and community settings. The HADS was found to have reliable internal consistency, and good to very good concurrent validity when compared to other measures used to assess depression or anxiety, such as the Beck Depression Inventory (BDI) and the State Trait Anxiety Inventory (STAI). Correlations between the HADS-D and the BDI were 0.62 - 0.73 while those between the STAI and the HADS-A were 0.64 - 0.81.

2.4.2. WHOQOL-BREF

The World Health Organisation Quality of Life – Brief Version (WHOQOL-BREF) (The WHOQOL Group, 1998a) was used to assess quality of life. The WHOQOL-BREF has been used to measure quality of life in a number of recent studies of patients with medically unexplained symptoms (Sampalli *et al.*, 2009), including irritable bowel syndrome (Barahmand, 2008), fibromyalgia (Haak & Scott, 2008), and chronic fatigue (Wang *et al.*, 2009).

The scale, made up of 26 items, is an abbreviated version of the WHOQOL-100 quality of life measure (The WHOQOL Group, 1998b) originally developed to produce a valid and reliable measure of quality of life. The WHOQOL-BREF, as with the WHOQOL-100, uses five-point Likert scales, and scores are produced on four domains: physical health; psychological health; social relationships, and environment. A global score, summarising two questions relating to overall quality of life and overall health satisfaction is also generated. Three questions are reverse scored. Each domain score is calculated by summing the appropriate items, then transforming it to a score between 0 and 100 to allow comparison across domains, with higher numbers indicating greater quality of life. Transformations were carried out in accordance with the WHOQOL-BREF manual (The WHOQOL Group, 1996).

It has been suggested by one study that the reduced length of the WHOQOL-BREF, compared with the WHOQOL100, has led to a loss of sensitivity in the social domain (O'Carroll *et al.*, 2000). Analysis by Skevington and colleagues (2004; Skevington & McCrate, 2012), however, found its validity and reliability to be satisfactory: internal reliability was found to be acceptable (>0.7) for physical, psychological and environment domains (0.82, 0.81, and 0.80, respectively), and marginal for the social domain (0.68); all subscales were able to discriminate between sick and well populations providing acceptable discriminant validity; and scores on the WHOQOL-BREF correlate highly (0.89 or greater) with those on the WHOQOL-100 measure, showing good construct validity.

2.4.3. The 12-item somatic subscale of the Symptom Checklist 90 (SCL-90-R)

The SCL-90-R (Derogatis *et al.*, 1976; Derogatis, 1977) is a symptom inventory measuring the intensity of self-reported somatic complaints over the past week. Each item is scored on a five-point Likert scale of distress (0-4) ranging from 'not at all' to 'extremely', and scores are produced in nine primary symptom subscales.

The 12-item somatisation subscale of the SCL-90-R was used to assess somatic symptoms experienced by participants. The subscale is made up of a list of twelve physical symptoms often reported alongside psychological problems. Mean scores are calculated resulting in scores ranging from 0-4.

2.4.4. Philadelphia mindfulness scale

The Philadelphia Mindfulness Scale (PHLMS) was used to measure mindfulness at pre- and post-intervention. Other mindfulness measures, including the Five Facet Mindfulness Questionnaire (FFMQ; Baer *et al.*, 2006) and the Mindfulness Attention Awareness Scale (Brown & Ryan, 2003), were considered as alternative measures of mindfulness. Both scales were rated relatively highly in a recent systematic review of self-report mindfulness measures (Russell, 2011). The FFMQ was developed using exploratory factor analysis of five other mindfulness measures; it measures mindfulness as a multifaceted construct with five subscales, and as such would allow the exploration of the potential roles of specific aspects of mindfulness in patient outcomes. It is, however, a long measure with 39 items and it has not been validated with a clinical sample.

The reliability and validity of the MAAS is strong and it is shorter measure with only 15 items, making it a more suitable length for this study. It is unclear, however, how far the MAAS can identify differences following a mindfulness-based intervention (Mackillop and Anderson, 2007). Furthermore, despite wide agreement in the literature that mindfulness is a multifaceted concept, mindfulness is measured as a single-factor on the MAAS. This conceptualisation of mindfulness does not fit with the definition by Bishop *et al*. (2004) as it does not assess acceptance towards that experience.

The PHLMS was rated reasonably well in the systematic review of mindfulness measures (Russell, 2011). In terms of negative factors, the extent to which the PHLMS reflects differences in meditation experience has not been investigated, and the clinical groups used for validation were relatively small. The PHLMS is a relatively short measure, however, and the subscales allow investigation of the two key components of mindfulness proposed by Bishop and colleagues (2004).

The PHLMS was considered to be the most appropriate measure for this study as it could be used to investigate the different aspects of mindfulness, and their role in patient outcomes, while not being restrictive in length. It is a 20 item measure consisting of two factors (acceptance and present moment awareness) which are scored separately (Cardaciotto *et al.*, 2008). A sample item from the awareness scale is 'Whenever my emotions change, I am conscious of them immediately', and a sample item on the acceptance scale is 'When I have a bad memory, I try to distract myself to make it go away'. Items are rated on a 5-point scale (from 'never'=1 to 'very often'=5), with items on the acceptance subscale being reverse scored. Total

scores on each subscale range from ten to fifty, with higher scores representing greater acceptance or awareness.

Internal consistency and validity of the subscales was demonstrated by Cardaciotto and colleagues. They found that the acceptance and awareness subscales were not correlated, and as such that they be considered separate constituents of mindfulness and that they be examined separately. They also found that the subscales showed different relationships with other measures. While the awareness scale is related to more general mindfulness measures, the acceptance scale is not. Despite a small psychiatric sample which limited the conclusions that could be drawn regarding the subscales' relationships to psychopathology, higher levels of acceptance were found to be associated with lower levels of thought suppression, rumination, depression, and anxiety, suggesting that acceptance may be more important in improving mood than simply awareness.

2.4.5. Additional measures

In addition to the formal measures two questions were asked about the severity and frequency of symptoms. The first asked 'How frequently have you experienced your symptoms over the last week?' Answers were on a 7-point Likert scale from 1 (never) to 7 (always). The second asked 'How severe have your symptoms been over the last week?' with answers also on a 7-point scale from 1 (None - no symptoms so no impact) to 7 (Very severe - cannot be ignored and markedly limits my daily activities).

2.5. Procedures

2.5.1. Intervention development

A focus group was carried out with a group of five GPs prior to the development of the self-help booklet. The GPs discussed the number of patients presenting with medically unexplained symptoms, the most frequent types of medically unexplained symptoms presented, and their thoughts on the benefits and difficulties of having a self-help booklet that could be offered to help patients manage such symptoms. Feedback from the GPs about having a self-help booklet to offer such patients was very positive, identifying it as an area where they would like more options to offer patients. They identified that the most frequent medically unexplained symptoms that they experienced in their clinics were irritable bowel syndrome (IBS), chronic fatigue (CF) and tension headaches.

2.5.1.1. Intervention booklet and CD

The intervention booklet was developed based on the mindfulness-based stress reduction (MBSR) programme designed by Jon Kabat-Zinn (1990). A clinical psychologist with over 15 years experience of mindfulness practice was involved in initial discussions about the booklet and in guiding its development alongside another psychologist experienced in mindfulness and in developing self-help booklets. They advised on its content, including the exercises and language used, to ensure that the booklet was consistent with an MBSR approach.

The final booklet (see Appendix 7) was a 32-page A5 booklet entitled 'Helping you control your symptoms, instead of them controlling you: A mindful way towards managing physical symptoms'. It included a front cover and contents page followed by an introductory section which consisted of short sub-sections on how to use the booklet; what mindfulness is; why it may be of use; tips for practice; and common frustrations. As participants were being given this as a pure self-help intervention, with no therapist involvement, the aim of this section was to try to provide information to participants about, and to engage them in, the intervention.

The remainder of the booklet was based on Jon Kabat-Zinn's eight week Mindfulness-Based Stress Reduction (MBSR) group programme. The booklet was tailored towards MUS by making particular reference to how unpleasant or distressing symptoms or sensations might be incorporated into exercises, as seen in the 'Staying with things that are difficult' section for example. Like the original programme, the self-help intervention followed an eight-week programme which was broken down into five steps. Each of the first three steps was to be carried out over two weeks each, and the final two steps one week each (see Table 2.1). Each step outlined the mindfulness practice to be carried out every day/week, and was followed by explanations of, or scripts for, the exercises. Prompts were also given to remind participants when tracks on the CD could be used.

MBSR weekly sessions vary between groups but are generally made up of four core different types of mindfulness exercises: the body scan; focusing attention on the breath; practicing full awareness in everyday activities; and physical yoga exercises with a focus on awareness of the body. The first three elements were built into the

self-help intervention, however the physical exercises were not included following guidance from an experienced MBSR practitioner who advised that correct performance and participant safety could be jeopardised without an experienced member of staff present, as there would be in a group setting.

Table 2.1 Outline of the MBSR intervention structure

	Exercises
Step 1 Weeks 1-2	Heading: *Starting to become mindful* - Carry out the One minute breathing exercise (page 9) at least once a day (but more often if you can). - Do the 10 minute Seated mindfulness exercise (page 10-11) with the attached CD or script every other day. - Choose one routine mindful activity in your daily life and make a deliberate effort to bring moment-to-moment awareness to that activity each time you do it. This could be brushing your teeth, having a shower or washing the dishes. Simply focus in on knowing what you are doing as you are actually doing it.
Step 2 Weeks 3-4	Heading: *Becoming aware of the pleasant* - Continue doing the Seated mindfulness with the CD or script (page 10-11) every other day. - On the days that you don't do the Seated mindfulness, carry out the Body scan with the attached CD or script (page 14-16). The idea is to "fall awake" rather than asleep. If you have trouble with sleepiness do it with your eyes open. - Practice the Three minute breathing space (page 17) once a day. - Pay attention to your experience of pleasant events over the next week and try to become aware of body sensations, thoughts and emotions occurring with the pleasant event. Simply focus in on

	knowing what you are doing as you are actually doing it. - Choose another everyday activity to be your routine mindful activity, bringing moment-to-moment awareness to it each time you do it.
Step 3 Weeks 5-6	Heading: *Increasing your mindful awareness* - Continue to do the Seated mindfulness (pages 10-11) and Body scan exercise (page 14-16) on alternate days. If you have been doing these for about 10 minutes each until now, try to extend the length of time you spend practicing these to 20 minutes each day. - Introduce the Mindful eating exercise (page 20-21) and carry out one meal or snack mindfully each day. - Carry out the Turning towards the unpleasant exercise (page 22) three times per week. - Introduce mindfulness "dots" into your life by placing stickers on objects in your immediate environment (e.g. on your computer, telephone, bathroom mirror, the key hole at your office door) and use them to act as triggers to remind you to take a breath and become more aware again. - Continue to apply the three minute breathing space when you are struggling with something. Apply the practice as a coping space for these difficult moments as they arise.
Step 4 Weeks 7	Heading: *Staying with things that are difficult* - Continue to do the Seated mindfulness exercise (page 10-11) and Body scan (pages 14-16) and on alternate days. If you have been using the CD for the Body scan, try doing it without the CD this week if possible. Try to increase the time that you spend doing these exercises. - Continue to eat one meal or snack a day mindfully (page 20-21). - Introduce a period of Mindful walking (page 25) everyday – this is best done when you are not in a rush to be somewhere! - Bring particular awareness to any experiences of difficulty arising

	this week, and use periods of your formal practice to work with this. Notice when you find yourself getting caught up in thoughts about unpleasant sensations or symptoms and use the techniques practiced in the Turning towards the unpleasant exercise (page 22). - Continue to use the mindfulness "dots" placed throughout your house/life to act as triggers to remind you to take a breath and come back to full awareness.
Step 5 Weeks 8	Heading: *Your own mindful practice* - Continue your mindful practice each day. During this week you can decide each day what is right for you to do from your experience of the exercises practiced over the past seven weeks. - Try the Loving kindness meditation (page 28). While some people can be put off by its name, many people find the exercise very helpful – calming the mind and body through cultivating compassion for yourself and others. - Read through the Mindfulness in everyday life section (page 29) and try to become more aware of what is happening and what you are doing throughout the day. - Consider ways that you will continue using the mindfulness practices you have been developing over the past eight weeks in day to day life.

Each step included a page titled 'My notes on step 1', for example, where participants were encouraged to note down when exercises were carried out and any comments following it (see Appendix 7).

Seated mindfulness and Body scan exercise scripts were supplemented by audio tracks on an accompanying CD to help guide practice. The tracks were recorded by one of the psychologist guiding the intervention's development and he gave

permission for them to be used for the purposes of this research. Both tracks were approximately 30 minutes long, with a gong sounding every 10 minutes during the seated mindfulness track, signalling that participants could stop, to allow participants to build up their skill and experience gradually, particularly in early weeks.

An overall Flesch readability score of 65 for the booklet was a calculated using Word 2007, with sample sections ranging from 55.1 to 78.3, suggesting that the content should be easily understood by 13-15 year olds. Additionally, the booklet was assessed and passed by BISSY (Borders public Information Support Site for You), in NHS Borders, who ensure that materials produced by the health board are at an appropriate level of accessibility and readability for patients.

Once the booklet was in final draft form, piloting was carried out with a focus group of staff -- including a nurse, occupational therapist, psychologist and support worker -- and non-staff. They gave feedback on usability, readability and size of the booklet. Feedback from the focus groups was incorporated into the final version of the booklet.

2.5.2. Intervention evaluation

Eight general practices from across NHS Borders were involved in the identification of potential participants for this project. The practices varied in location and socio-economic area, as well as by size, ranging from a list size of around 3000, to around 11,500. GPs in each of the participating practices were given packs which included: a reminder sheet with the inclusion criteria on it; packs to offer patients who met the

criteria; an information sheet giving details of what to do if they had any questions or if they ran out of project information packs to give to patients.

In most practices patients were identified by GPs as meeting the research criteria during routine appointments. GPs were given a guide script to introduce the research to patients who met the inclusion criteria: ‘One of our colleagues has developed a self-help intervention to help people manage symptoms such as yours, and is in the process of evaluating it. Would you be interested in being involved in the study?’ GPs were, however, able to introduce the intervention as they felt appropriate, depending on the individual patient and their circumstances. Patients who were interested were given a pack to take away and look at in their own time. The pack included: an introduction letter (Appendix 6a); a participant information sheet (Appendix 6b); a consent form (Appendix 6c); a questionnaire booklet and a pre-paid addressed return envelope. Following an amendment to the project (for ethical approval and R&D approval see Appendix 8 and Appendix 9), one practice decided to identify patients who met the inclusion criteria through a database search of relevant diagnoses, and offered them inclusion in the project by sending them information packs by post.

In the initial letter patients were invited to read through the information sheet and, if they were still interested in participating, to complete the consent form and questionnaire booklet and return them in the envelope provided. When packs were received each participant was given a project ID number. Identifiable patient information was stored separately in a locked filing cabinet and other data was given the appropriate ID number.

Participants were then sent the intervention booklet and CD alongside a covering letter asking them to follow the eight week programme outlined in the booklet. They were also told that they would be asked to complete questionnaires again after the eight week intervention.

Post-intervention questionnaires were sent to all participants after eight weeks. Participants who did not return questionnaires within ten days were sent another questionnaire and return envelope, with a covering letter asking them to complete and return it if they had not already done so. Throughout the study, all participants continued with their usual medical care. A diagrammatic representation of participant recruitment and response can be seen in Figure 2.3.1.

2.6. Power calculation

A power analysis was carried out to calculate how many participants would be required to detect effects in the data. There is no available research in the area of mindfulness-based self-help with this population. A meta-analysis of a wide range of self-help interventions (Gould & Clum, 1993), in a mix of clinical and non-clinical populations, found an overall treatment effect size (*d*) of 0.76 at post-treatment. However, effect sizes varied widely depending on the presenting problem and population, and not all were psychological interventions. A recent meta-analysis of CBT-based guided self-help found effect sizes in clinical populations of 0.31 compared to a mean effect size of 1.02 in media-recruited studies (Coull & Morris, 2011). Due to the lack of research into the application of mindfulness, through self-help, to this clinical population, a presumption was made that the effect size would

fall at the lower end of the spectrum shown in these meta-analyses. For this reason, a small-medium effect size was assumed.

A power analysis using the G-Power 3.1.2 computer program (Faul *et al.*, 2010) indicated that a total sample of 42 people would be needed to detect this small-medium effect size (f =0.2) with 80% power using a repeated-measures ANOVA, with alpha at .05.

An estimated attrition rate was based upon existing literature. Attrition rates of 33% and 35% have been found in an studies evaluating CBT for chronic fatigue of self-help for patients with chronic fatigue (Friedberg & Sohl, 2009; Leone *et al.*, 2006), while a rate of 16.6% was found in an RCT of generic self-help for patients with chronic fatigue (Chalder *et al.*, 1997). Palmer and colleagues (2002) found an attrition rate of 25% in an RCT of self-help for bulimia, with 29% in the control group. To allow for an attrition rate at the higher end of this range an additional thirty-five percent was added to the indicated size giving a total planned baseline sample size of 57.

2.7. Statistical analysis

Analysis of the data was carried out using the statistical package SPSS (version 19 for Windows). Primary analysis used the intention to treat principle, assuming return to baseline values for non-completers. Due to the high rate of attrition, additional analyses were carried out with the data from the sample that completed the post-intervention measures, for exploratory purposes. Descriptive statistics were used to

investigate demographic information, looking at the sex, age, and type and duration of medically unexplained symptom reported.

Exploratory data analysis was carried out to determine if the data met the assumptions of parametric statistical testing. Checks of skewness and kurtosis were carried out, and visual inspection of box-plots and histograms were used to assess normality. Discerning the shape of the histogram can be difficult with a small sample size, with the histogram changing significantly with changes in the interval width of the bars. For this reason, normal probability plots were inspected and the Shapiro-Wilk test was also used to assess whether data was normally distributed.

Parametric tests are more powerful than non-parametric tests (Dancey & Reidy, 2007) and are robust to violations of their assumptions (Clark-Carter, 2004; Howell, 2009), making them less likely to commit type II errors as a result (Clark-Carter, 2004). Parametric tests are recommended if the data shows no clear contraindications, such as outliers, marked skewdness or great disparity of variances (Kinnear & Gray, 2009). Using such analyses was therefore considered appropriate, and the primary research questions were analysed using a series of repeated measures t-tests. For the secondary hypotheses, Pearson's correlations were used to evaluate the relationship between improvements in levels of mindfulness and improvements in outcome measures. Baseline comparisons of those who did and those who did not return post-intervention questionnaires (referred to as completers and non-completers respectively from here on) were carried out using independent t-test alongside Levene's test for homogeneity of variance.

Raw scores from the assessments, or transformed scores where this was outlined in administration and scoring guidelines for individual tests, were used to identify change in responses over the course of the intervention.

3. Journal Article

Self-Help Mindfulness-Based Stress Reduction: An Evaluation of its Impact on Psychological Distress, Symptoms, and Quality of Life in Patients with Medically Unexplained Symptoms

Running title: Self-help MBSR for medically unexplained symptoms

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This journal article has been written in accordance with the author guidelines for the journal of Psychosomatic Medicine (for author guidelines see Appendix 2)

Abstract

Background: Medically unexplained symptoms (MUS) can be as debilitating as those with a clear organic cause and are often associated with increased psychological distress and lower quality of life. Previous studies have found Mindfulness-Based Stress Reduction (MBSR) to be useful in improving anxiety, depression, symptom and quality of life in people with MUS. This study sought to evaluate a self-help MBSR intervention for this population.

Methods: Participants with MUS (N=15) were introduced to the project by their GP during routine consultations. Psychological distress, symptoms, quality of life (QoL) and mindfulness were assessed prior to and following the eight week self-help MBSR intervention, and changes were evaluated using a within subjects design. In addition to the intention to treat group (ITT, N=15) analysis, those who completed post-intervention questionnaires (N=5) were evaluated separately for exploratory purposes.

Results: Reductions in symptom frequency were significant in the completer and ITT groups. Mean clinical improvements in anxiety and general and physical QoL were also observed in the completer sample, though changes were not statistically significant. Levels of mindful acceptance were found to improve significantly at post-intervention.

Discussion: No firm conclusions can be drawn from this study, though improvements in the completer group suggest that further research would be warranted. The low levels of participation indicate that a greater understanding regarding the reasons for recruitment difficulties in this type of research would be beneficial.

Key words: MBSR, self-help, chronic fatigue, fibromyalgia, irritable bowel syndrome.

MUS = medically unexplained symptoms; **GP** = general practitioner; **CBT** = cognitive behaviour therapy; **MBSR** = mindfulness-based stress reduction; **WHOQOL-BREF** = World Health Organisation Quality of Life – Brief Version; **QoL** = quality of life; **HADS** = The Hospital Anxiety and Depression Scale; **HADS-a** = HADS-anxiety subscale; **HADS-d** = HADS depression subscale; **SCL-90-R** = The Symptom Checklist 90; **PHMLS** = The Philadelphia Mindfulness Scale; **CD** = compact disc; **SD** = standard deviation; **ITT** = intention to treat;

3.1. Introduction

Medically unexplained symptoms (MUS), physical symptoms where no organic pathology can be identified following investigation, have a considerable impact on individuals and the healthcare system. Symptoms can include pain, weakness or fatigue, and many medical specialisms have developed diagnostic categories for MUS such as irritable bowel syndrome (gastroenterology), fibromyalgia (rheumatology) and chronic fatigue (1). Patients presenting with MUS can experience pain, distress, discomfort and disability comparable to that caused by identifiable disease (2-4). They also visit their GP often, with prevalence estimates suggesting that they account for around a third of hospital outpatient referrals (5) and between 15 and 30% of patients in primary care (2, 6). In addition, resources are often wasted on ineffective attempts at treatment (7, 8) resulting in significant costs to the NHS and the potential to cause harm and discomfort to the patient through non-essential surgery or investigation (9).

Evidence suggests that a high proportion of patients with MUS experience psychological distress. In their study of cognitive behavioural therapy (CBT) for MUS, Bleichhardt and colleagues (10) found that 74% of their subjects had comorbid affective disorders and 47% had comorbid anxiety disorders. Another study (11) found that 63% of patients with MUS had comorbid major depressive disorder. Sharpe (12) proposes that undiagnosed depression is one of the greatest causes of MUS, suggesting that physical symptoms such as fatigue, weight-loss and complaints of pain are misdiagnosed, or go undiagnosed, due to the erroneous belief that depression is solely a mental health problem. For similar reasons he suggests

that anxiety and panic are also common causes of MUS. Continuing stigma in Western societies toward mental health may increase the likelihood of psychological distress being manifested somatically. It has also been identified that the distress caused by these symptoms can lead to anxiety or depression, which in turn serves to worsen symptoms (13). Such self-perpetuating circles - where physical symptoms lead to poorer psychological wellbeing, which in turn worsens symptoms - are recognised in many chronic health conditions (14, 15).

Several psychological therapies have been introduced to this population to help manage distress. However, a difficulty for the psychological treatment of MUS is that people often believe that their problems are either purely physical or purely psychological (1). So while there is evidence that cognitive behavioural therapy can be beneficial for some patients with MUS (16-18), many patients interpret a referral to a psychologist, or for the thought-challenging exercises typical of CBT, as a rejection or denial of their problems as being real, or feel that they are being told that it is "all in their head". Stone and colleagues found that psychological-sounding diagnostic labels often appear offensive to patients who preferred terms such as 'stress-related' (19).

Mindfulness-Based Stress Reduction (MBSR) is traditionally a standardised group therapy which evolved from the integration of Buddhist meditation into western psychological and clinical practice, and was developed by Jon Kabat-Zinn (20). Growing evidence indicates that MBSR can improve coping and quality of life (QoL) in many chronic conditions, including cancer (21, 22) and chronic pain (23, 24), and in mental health problems it has been shown to reduce anxiety, depression

and stress (25-27). Methodologically rigorous studies investigating the effectiveness of MBSR for MUS such as IBS and fibromyalgia, have shown positive changes in psychological distress, symptoms and QoL (28, 29). MBSR therefore provides an alternative, and potentially less threatening, stress reduction approach to dealing with unexplained symptoms.

Unlike traditional CBT, mindfulness therapies sit within the "third wave" of cognitive behaviour therapies which work from a more acceptance-based stance. As a result the focus of MBSR is not upon changing unhelpful thinking, but on changing the process by which symptoms are experienced. A two-component model of mindfulness has been defined by Bishop *et al*. (30).

> *The first component involves the self-regulation of attention so that it is maintained on immediate experience, thereby allowing for increased recognition of mental events in the present moment. The second component involves adopting a particular orientation toward one's experiences in the present moment, an orientation that is characterized by curiosity, openness, and acceptance.'* (p232).

In this way, mindfulness includes attending to negative physical sensations or distressing thoughts or images when these occur, in contrast with the avoidance or distraction that is often used as means of coping with these distressing experiences.

It has been proposed that while avoidance and distraction can be useful in response to temporary stresses, they become maladaptive when used for long term pain, discomfort or distress (31), and evidence suggests that thought suppression and

avoidant coping generally predict poorer long-term outcome (32). This reduction in avoidance and reactivity to symptoms and cognitions allow for exposure to, and acceptance of, the experiences (33, 34), reducing negative affect and potentially improving psychological health (35).

Given the large numbers of people presenting to their GP with MUS, small improvements in physical or psychological wellbeing, or quality of life, in this population have the potential not only to improve people's lives, but also to have a beneficial economic impact on health services. As a result of the difficulties experienced by patients with MUS, and the frustration that GPs experience due to a perceived lack of effective treatment options (36), an MBSR-based self-help intervention has been developed as a means of reaching patients who may otherwise not have access to, or the inclination to accept, direct psychological input. There have been no evaluations of self-help MBSR for such symptoms to date.

This study evaluates a pilot of the self-help MBSR intervention, investigating its impact on psychological distress, symptoms, mindfulness and QoL, with the hypothesis that these outcomes would improve following the intervention.

3.2. Method

3.2.1. Participants

Eight Scottish NHS medical practices were involved in the recruitment of participants. GPs were responsible for identifying and introducing the project to potential participants. Inclusion criteria for the project were adult patients with a

diagnosis of IBS, chronic fatigue, tension headaches or fibromyalgia; their GP determined that they had undergone appropriate investigation of their symptoms, and that there was no known medical basis or partial basis for the symptoms. Participants also needed to have sufficient understanding of the English language to complete standardised forms.

Patients who met these inclusion criteria were introduced to the project by their GP who gave them a project information pack to read, complete and return to the investigator if they decided to participate. Those who completed and returned the enclosed consent form and questionnaire were considered participants. This resulted in 15 patients, between the ages of 22 and 65, being recruited as project participants.

3.2.2. Procedure

Participants completed the questionnaire booklet at baseline. Once this had been returned they were sent the intervention booklet and CD, and eight weeks later they were sent a post-intervention questionnaire. The baseline questionnaire booklet asked participants for their age, sex, main symptom, and length of time they had experienced their symptoms. Participants who did not return the post-intervention questionnaire within ten days were sent a reminder letter asking them to complete and return the enclosed questionnaire. The following outcome and process measures were included in the questionnaire booklet:

3.2.2.1. Psychological distress

The Hospital Anxiety and Depression Scale (HADS) was used to measure psychological distress (37). The HADS is a self-report measure which was initially

designed for use with physically ill patients, and as a result somatic symptoms were excluded to avoid potential confounding by physical problems. The scale consists of 14 items: seven for anxiety (HADS-a) and seven for depression (HADS-d); each scored 0-3 with higher scores representing more severe symptoms. Subscale scores of 0-7 are considered "normal", while scores of eight or above are considered cases of anxiety or depression (38, 39). A review by Bjelland and colleagues provides support for its reliability and validity in primary care, as well as in hospital and community settings (39).

3.2.2.2. Quality of life (QoL)

The World Health Organisation Quality of Life – Brief Version (WHOQOL-BREF) (40) was used to assess quality of life. This 26 item scale is an abbreviated version of the WHOQOL-100. Five point Likert scales are used, and scores are produced on four domains: Physical health; Psychological health; Social relationships, and Environment. These scores are transformed to a scale of 0-100 making them comparable across domains. Two questions, relating to overall QoL and overall health satisfaction, are summed to produce a 'General' score between 2 and 10. Scores on the WHOQOL-BREF correlate highly (0.89 or greater) with those on the WHOQOL-100 measure. The WHOQOL-BREF has good to excellent reliability and performs well in tests of validity (41).

3.2.2.3. Symptoms

The Symptom Checklist 90 (SCL-90-R) (42, 43) is a symptom inventory. Somatic symptoms experienced by participants were assessed using the 12-item somatisation

subscale of the SCL-90-R, consisting of a list of physical symptoms often reported alongside psychological problems. Participants were asked how much each problem has bothered or distressed them, scoring each on a five-point Likert scale (from "not all all" = 0, to "extremely" = 4). Two additional questions, scored on a seven-point Likert scale, relating to symptom severity and symptom frequency were also included.

3.2.2.4. Philadelphia mindfulness scale

The Philadelphia Mindfulness Scale (PHMLS) (44) is a 20 item measure of two factors: acceptance, and present moment awareness. These factors are scored separately. Items are rated on a 5-point scale (from "Never"=1 to "Very often"=5). Total scores on each subscale range from ten to fifty, with higher scores representing greater acceptance or awareness. Internal consistency and validity of the subscales was demonstrated by Cardaciotto and colleagues (44).

3.2.3. Intervention

Participants were each given a 32-page, A5, self-help intervention booklet and accompanying audio CD, entitled "*Helping you control your symptoms, instead of them controlling you: A mindful way towards managing physical symptoms".* The booklet and CD were based on the mindfulness-based stress reduction (MBSR) programme designed by Jon Kabat-Zinn (20) (for the development of this booklet see Methods section 2.5.1). The booklet included short sub-sections on: how to use the booklet; what mindfulness is; why it may be of use; tips for practice; and common frustrations. These sections included an explanation of why MBSR was

considered beneficial for people with symptoms without a clear medical cause, as well as for those with symptoms which do. As participants were being given this as a pure self-help intervention with no therapist involvement, the aim of these sections was to provide a rational and to engage them in the intervention.

The remainder of the booklet was based on Jon Kabat-Zinn's eight week Mindfulness-Based Stress Reduction (MBSR) group programme. The booklet was tailored towards MUS, for example by making reference to how exercises might relate to symptoms or sensations in the 'Staying with things that are difficult' section. Like the original MBSR programme, the current self-help intervention followed an eight-week programme which was broken down into five steps. The first three steps were carried out for two weeks each, and the final two steps one week each. Each step outlined the mindfulness practice to be carried out every day/week, and was followed by details for the mindfulness exercises. Prompts were also given to remind participants when tracks on the CD could be used.

Physical yoga exercises usually included in MBSR group interventions were not included following guidance from an experienced MBSR practitioner who advised that correct performance, and participant safety, could be jeopardised without an experienced member of staff present (a staff member would be present in a group setting).

3.2.4. Statistical analysis

Exploratory data analysis was carried out to check that the data met the assumptions required for parametric statistics. Baseline comparisons of those who did and those

who did not return post-intervention questionnaires (referred to as completers and non-completers respectively from here on) were carried out using independent t-test alongside Levene's test for equality of variance. Following the exploratory analysis of the data and consideration of the design of the study and hypotheses being tested, the primary research questions were analysed by a series of repeated measures t-tests. As data for non-completers was limited to that gained at baseline, intention to treat (ITT) principals were followed for primary analyses, using the last observation carried forward method, imputing data from baseline at post-intervention. Due to the small sample size and relatively high attrition rate, analysis of data solely from the completer sample was also carried out. There are limitations to what can be inferred from the results of such a small sample, however the analyses were carried out for exploratory purposes with a view to guiding further investigations in this area rather than producing conclusive evidence.

3.3. Results

Five of the fifteen participants who were sent the self-help intervention booklet completed and returned the post-intervention questionnaires, while ten did not, giving an attrition rate of 67%.

3.3.1. Demographic Information

The clinical population considered in this study was a mixed sample of individuals with different types of medically unexplained symptoms. The 15 participants involved in this study came from five of the eight practices that agreed to take part in recruitment. Participants were aged between 22 and 65 years, with a mean age of

38.9 (*SD* = 11.9). Of these, four-fifths were female, and all of those who completed the intervention were female. In terms of primary diagnosis, nine participants had IBS (60%); four had chronic fatigue (27%); one had fibromyalgia (7%) and one tension headaches (7%). Of those who completed and returned post-intervention questionnaires, two had IBS, two had chronic fatigue and one had fibromyalgia.

The length of time that participants had experienced their symptoms ranged from one month to thirty years (*M* = 8.1 years , *SD* = 8.77). Three of the participants who returned post-intervention questionnaires reported that they followed the eight week intervention completely and one completed it "somewhat". One participant did not complete this section.

3.3.2. Baseline comparisons of completer and non-completer groups

Baseline data for non-completers was compared with that of the completer group (see Table 3.1). The only area in which scores differed significantly at baseline was on the social subscale of the WHOQOL-BREF, with the completer sample showing significantly better social QoL than the non-completers (p =.016). Differences in duration of symptoms appear marked, with the completer sample showing a mean duration of over 16 years compared with over five years in the non-completers. However, as variances were significantly different (F = 7.73, p = .017), the mean difference between the groups was non-significant (p =.105).

Though differences in anxiety and depression were not statistically significant, clinically relevant differences were also considered. When comparing mean scores against clinical cut-off scores for caseness of anxiety and depression on the HADS

(39) the completer group fell below the cut-off of 8 for anxiety, while the non-completer sample fell within the mild to moderate range. The completer sample also showed sub-clinical levels of depression, while the non-completer group scored above the clinical cut-off again. None of the completers fell in the moderate or severe range of HADS scores for either anxiety or depression at baseline, compared with the non-completer group where six participants (60%) fell into this range for anxiety, and four (40%) for depression.

In addition, though differences were not significant, the completer sample showed lower mean symptom scores and higher quality of life scores than the non-completer sample on all sub-scales. The only area where non-completers performed better then completers at baseline was on the awareness subscale of the PHLMS mindfulness measure.

Table 3.1 Baseline comparisons of completer and non-completer samples.

	Mean *(SD)*		Comparison of completer and non-completers	
	Completers (N=5)	**Non-completers (N=10)**	***t***	***p***
Age in years	41.6 (8.5)	38.1 (13.2)	0.529	.607
Duration of symptoms in months	200.2 (146.7)	62.9 (64.0)	1.990	.105
Outcome measures				
HADS-d	6.00 (3.00)	9.00 (4.19)	-1.418	.180
HADS-a	7.40 (1.95)	10.90 (4.23)	-1.736	.106
SCL-90-R	1.62 (0.56)	1.71 (0.75)	-0.251	.806
Symptom frequency	5.60 (0.55)	6.20 (0.79)	-1.515	.154
Symptom severity	4.60 (1.14)	5.60 (1.17)	-1.569	.141
WHOQOL-BREF General	5.60 (0.55)	5.00 (1.70)	1.016	.330
WHOQOL-BREF Physical	43.80 (19.31)	36.40 (13.18)	0.881	.394
WHOQOL-BREF Psych	58.80 (10.52)	47.60 (18.25)	1.257	.231
WHOQOL-BREF Social	82.00 (14.08)	55.00 (19.28)	2.767	.016
WHOQOL-BREF Environmental	76.40 (13.80)	56.80 (18.94)	2.043	.062
Awareness subscale of PHLMS	35.00 (4.69)	36.15 (6.80)	-0.337	.741
Acceptance subscale of PHLMS	27.20 (10.26)	26.00 (7.29)	0.263	.796

3.3.3. Primary analyses

Analyses of change in outcome measures between pre- and post-intervention were carried out using paired t-tests. Means and standard deviations, in addition to p-values and effect sizes (*Cohen's d*), are reported for the ITT sample (Table 3.2) and for the completer sample (Table 3.3). Effects on psychological distress, symptoms and QoL are considered in the following sections.

3.3.3.1. Effects on psychological distress

Reductions in mean depression scores were observed in the ITT and completer groups, however the changes were not statistically significant (see Table 3.2 and Table 3.3). Mean anxiety scores were found to reduce and, while the changes were also non-significant, the reduction took mean HADS-a scores for the completer sample clearly below the clinical cut-off.

Table 3.2 Changes in psychological distress, symptoms and QoL between pre- and post-intervention in the ITT group (N=15)

	Pre-intervention		Post-intervention				
	Mean	***SD***	**Mean**	***SD***	***t***	***p***	***Cohen's d***
Psychological distress							
HADS-d	8.00	4.00	7.80	4.00	0.676	.510	0.07
HADS-a	9.73	3.94	9.27	4.37	1.705	.110	0.11
Symptoms							
SCL-90-R	1.68	0.68	1.53	0.72	2.442	.281	0.07
Symptom frequency	6.00	0.76	5.27	1.28	1.710	.028	0.33
Symptom severity	5.27	1.22	5.07	1.39	1.146	.271	0.04
Quality of Life (QoL)							
WHOQOL-BREF General †	5.20	1.42	5.60	1.19	-1.468	.164	0.20
WHOQOL-BREF Physical †	38.87	15.20	43.87	17.63	-1.714	.109	0.21
WHOQOL-BREF Psych †	51.33	16.60	52.13	16.51	-0.652	.525	0.05
WHOQOL-BREF Social †	64.00	21.65	61.67	20.18	1.372	.192	0.11
WHOQOL-BREF Environmental †	63.33	19.40	62.40	18.70	1.080	.299	0.05

† Indicates measures where an increase in mean score represents a better outcome

HADS: Hospital Anxiety and Distress Scale; SCL-90-R: Symptom Checklist 90 Revised; WHOQOL-BREF: World Health Organisation Quality of Life – Brief Version

Table 3.3 Changes in psychological distress, symptoms and QoL between pre- and post-intervention in the completer sample (N=5)

	Pre-intervention		Post-intervention				
	Mean	***SD***	**Mean**	***SD***	***t***	***p***	***Cohen's d***
Psychological distress							
HADS-d	6.00	3.00	5.40	2.40	0.647	.553	0.19
HADS-a	7.40	1.95	6.00	2.55	2.064	.108	0.54
Symptoms							
SCL-90-R	1.62	0.56	1.18	0.56	1.146	.316	0.68
Symptom frequency	5.60	0.55	3.40	0.55	5.880	.004	3.49
Symptom severity	4.75	1.26	4.33	1.53	1.177	.305	0.26
Quality of Life (QoL)							
WHOQOL-BREF General †	5.60	0.55	6.80	2.08	-1.633	.178	0.68
WHOQOL-BREF Physical †	43.80	19.31	58.80	16.69	-2.082	.106	0.72
WHOQOL-BREF Psych †	58.80	10.52	61.20	7.12	-0.623	.567	0.23
WHOQOL-BREF Social †	82.00	14.08	75.00	15.98	1.486	.212	0.40
WHOQOL-BREF Environmental †	76.40	13.80	73.60	13.45	1.095	.335	0.18

† Indicates measures where an increase in mean score represents a better outcome

HADS: Hospital Anxiety and Distress Scale; SCL-90-R: Symptom Checklist 90 Revised; WHOQOL-BREF: World Health Organisation Quality of Life – Brief Version

3.3.3.2. Effects on symptoms

Improvements observed on the SCL-90-R somatic subscale and symptoms severity were not significant in either the ITT or completer groups.

Changes observed in symptom frequency were, however, significantly improved at post-intervention both in the completer sample and the ITT group (p =.004 and p =.028, respectively). A large effect was identified for the completer sample and a small effect for the ITT group (d = 3.49 and d = 0.33, respectively). In terms of clinical meaning, the changes in scores in the completer sample related to participants experiencing symptoms 'most of the time' at baseline and 'occasionally' at post-intervention.

3.3.3.3. Effects on quality of life (QoL)

The completer sample showed two standard deviations of mean change, in the anticipated direction, on the WHOQOL-BREF 'General' subscale. However, these changes were not statistically significant.

Mean changes in score on the physical QoL subscale were in the anticipated direction at post-intervention, with almost one standard deviation difference, however these changes were also not statistically significant.

3.3.4. Secondary analysis

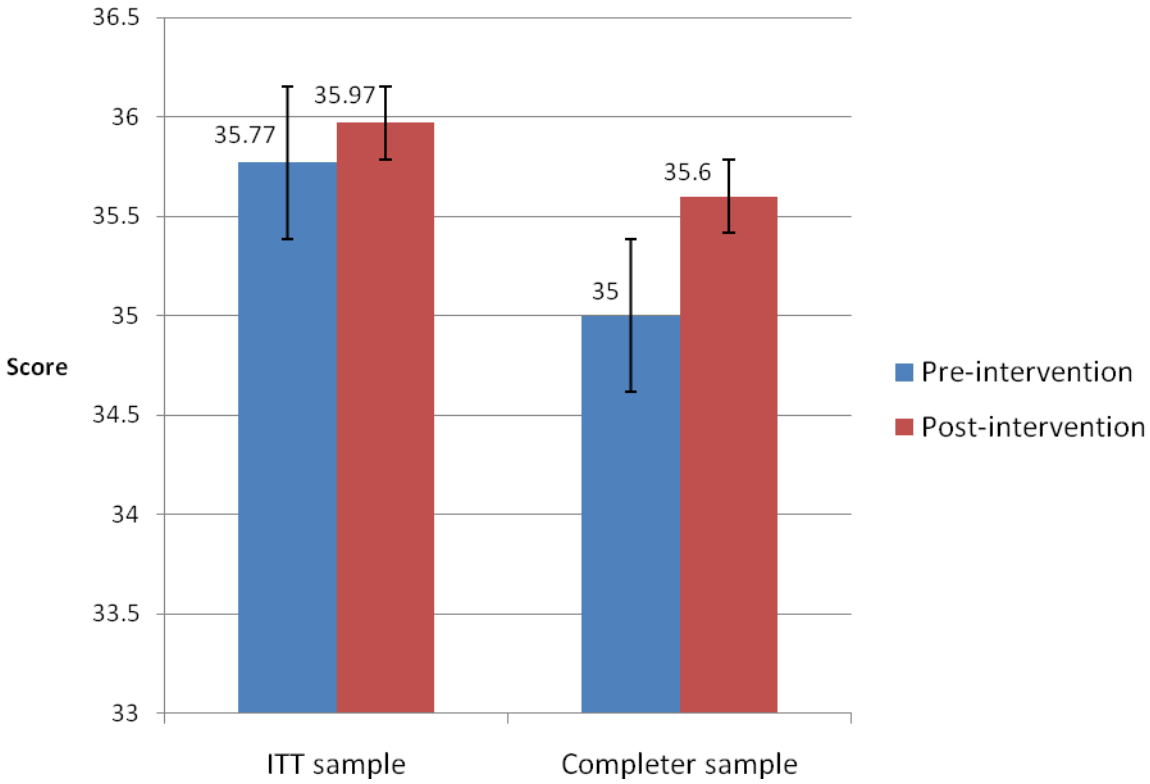
Mindfulness was hypothesised to increase at post-intervention. Analyses of change in mindfulness between pre- and post-intervention were carried out using paired t-tests. Awareness and acceptance subscales were considered separately, and completer

sample analyses were once again carried out in addition to the ITT analyses for exploratory purposes.

3.3.4.1. Effects on awareness

Mean post-intervention scores on the awareness subscale of the PHLMS remained similar to baseline scores for both the ITT and completer samples (as seen in Figure 3.3.1.) Neither the ITT nor the completer sample showed significant changes (t =-.289, p =.777; and t =-.268, p =.801, respectively.)

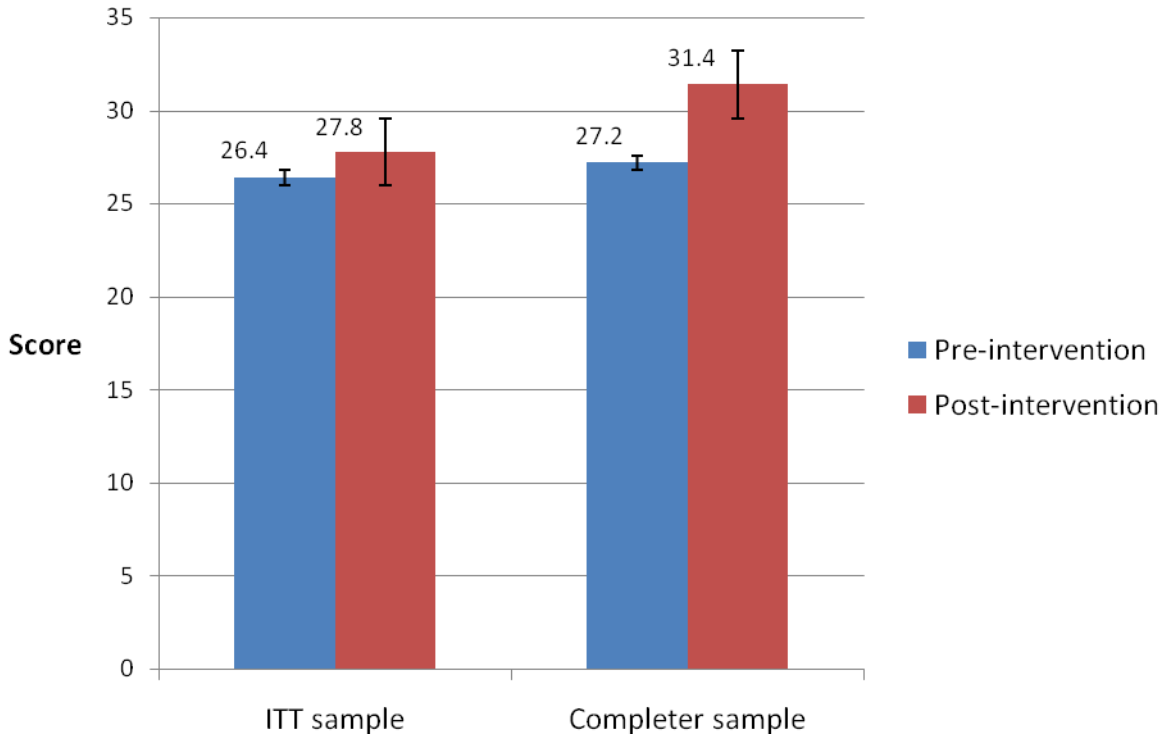
Figure 3.3.1 Mean awareness scores at pre- and post-intervention for ITT and completer samples



3.3.4.2. Effects on acceptance

Mean levels of acceptance were found to improve at post-intervention in both the ITT and completer samples, as seen in Figure 3.3.2. These changes in acceptance were found to be significant both for the ITT sample (t =-2.143, p =.05) and the completer sample (t =-3.384, p =.028). Effect sizes were small in the ITT sample and small-medium in the completer sample (d = 0.16 and d = 0.36, respectively.)

Figure 3.3.2 Mean acceptance scores at pre- and post-intervention for ITT and completer samples



3.4. Discussion

As this was a within-subjects study of a small sample, no firm conclusions can be drawn from the findings. The value of the findings is largely in their utility in future research, guiding hypotheses and informing study design and recruitment planning.

3.4.1. General outcomes

Symptom frequency reduced following the intervention, not only for the completer sample, but also for the more conservative ITT group. Though the results are restricted by the small sample size, limiting their generalisability, they suggest that self-help MBSR may reduce reported symptom frequency in patients with MUS.

None of the other outcome improvements observed were significant in either the completer sample or ITT group, meaning that the hypotheses that participants who carried out the MBSR intervention would show improvements in psychological distress and QoL are not supported. Given the small number of subjects this is unsurprising. However, while these changes were non-significant, eight out of the ten measures changed in the anticipated direction at post-intervention, showing enough promise to warrant future research.

Only social and environmental QoL showed a change in the opposite direction to what was expected at post-intervention, and these were also not significant. Though QoL was expected to increase following completion of the intervention, social and environmental areas of QoL were not targeted in this intervention so it is unsurprising that no improvement was observed in this area.

Without a control group or long-term follow-up it is impossible to determine if the changes observed were due to the intervention, rather than involvement in the study, natural improvement over time, or other issues such as chance or measurement limitations. Participants' symptoms had existed for a mean duration of around eight years prior to the intervention. So, while it may be considered unlikely that

spontaneous improvement in symptoms occurred during the course of the intervention, the lack of follow-up assessment means that the possibility that changes could be due to natural fluctuations in symptoms cannot be ruled out.

The attrition rate was high for this study, which was not entirely unanticipated. A combination of issues are likely to have contributed to this, including that the intervention was self-help based and as such required a reasonable level of motivation and self-efficacy, which are commonly impaired in people with depression. As the non-completer group showed more clinically relevant levels of depression than the completers it is possible that this impacted upon attrition rates. Secondly, the focus of the intervention was on patients managing symptoms rather than eradicating or curing them, which some participants may have found difficult. Thirdly, the intervention uses techniques that people may find hard to put into practice, particularly on their own. These factors may have contributed towards the high attrition rates observed in addition to the fact that high attrition rates are not uncommon in participants with MUS (45, 46).

Whilst levels of awareness did not improve following the intervention, levels of acceptance improved significantly. Levels of awareness amongst participants appeared to be relatively high at baseline. Mean scores were comparable with non-clinical samples found in previous research, whilst levels of acceptance were lower than other clinical samples (44). It is possible that the non-judgemental, experiential nature of MBSR in relation to negative experiences may have led to an increase in levels of acceptance. Again these findings are limited by the sample size, however as it is acceptance rather than awareness that is thought to impact most on psychological

wellbeing (44), these finding provide optimism for the possibility of MBSR being carried out by some patients in this self-help format.

3.4.2. Limitations of the study

Recruitment to the project was considerably lower than anticipated, and in spite of repeated efforts to adapt the project to improve this (see Chapter 5.3), numbers remained small. In addition to difficulties recruiting, a high level of attrition led to particularly small number of completers, making conclusions about the effectiveness of the intervention very difficult.

The majority of potential participants did not engage in the study, and there appear to be notable differences between those who completed the intervention and those who did not. As a result the representativeness of the sample is limited, adding to the difficulty generalising findings.

The lack of a control group also limits this study as it meant that changes could not be compared to a non-active or alternative therapy group, preventing such changes from being definitively attributed to the intervention.

3.4.3. Strengths of the study

The study attempted to evaluate a newly developed intervention, targeting an area in which both GPs and patients identify there to be a lack of effective treatment options (47). It attempted to implement and evaluate the intervention in a context as close to clinical reality as possible, in a bid to provide ecologically valid findings which could be easily transferred to practice. While this appears to have made recruitment

difficult, the study did recruit a clinical sample in a clinical setting. As other studies have identified, evaluating clinical samples can produce different, often less impressive, results to a non-clinical, or self-selecting sample (48).

In addition, unlike some studies where those who dropped out after receiving a detailed description of the intervention are not included as participants (49), this study considered everyone who completed baseline measures as participants. So while it experienced greater attrition rates than other studies, it demonstrated greater ecological validity.

3.4.4. Implications

The findings presented here do not provide generalisable evidence of the effectiveness of this self-help MBSR intervention for patients presenting to their GP with MUS. However, the improvements in symptom frequency and levels of acceptance suggest that more research is warranted in this area. Larger, suitably powered studies are needed in order for conclusions to be drawn about the effectiveness of the intervention for people with MUS. Future studies would also benefit from both treatment-as-usual and active controls. The controls would help to determine whether changes were attributable to the MBSR intervention, rather than involvement in study or natural improvement over time. In addition, as gains made over the course of MBSR have been found to continue to improve following completion of the intervention (28), sometimes with non-significant changes becoming significant at follow-up (50), the inclusion of a follow-up stage of assessment would also improve future studies. This would help to identify if a

similar pattern of continued improvement is observed following the use of a self-help MBSR intervention.

A better understanding of the difficulties recruiting patients to this type of study would be beneficial. One option would be to carry out interviews with a sample of GPs, exploring themes that arise with regard to recruitment issues. Another option would be to identify factors which could explain some of the difficulty experienced recruiting participants through the use of a questionnaire survey to participating GPs.

3.5. Conclusions

Due to the small sample, the findings of this study are unable to determine whether the self-help MBSR intervention is effective in improving psychological distress, symptoms or QoL, however the positive changes observed suggest that further investigation in this area is merited. Such research would benefit from a much larger sample size, as well as control groups and a follow-up stage. Further exploration of some of the difficulties experienced recruiting participants to this type of study could help to avoid similar difficulties being experienced, allowing larger samples to be recruited.

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4. Additional Results

This study investigated the effectiveness of a self-help MBSR intervention in improving participants' symptoms, mood, and quality of life. Each participant was assessed prior to and following the eight week intervention.

Demographic information, and information about baseline differences between completer and ITT groups were considered in the journal article results section (see Chapter 3.3) and will not be repeated here. The following sections outline the testing of each of the study's hypotheses. The next section outlines the changes that each individual participant who completed the intervention made between pre- to post-intervention. This is followed by a summary of participant feedback on the intervention.

4.1. Hypothesis testing

Three main hypotheses were:

> **Hypothesis 1:** Participants with MUS who carry out the self-help based MBSR intervention will show improvements in symptoms, psychological distress and quality of life at post-intervention.

Results in relation to Hypothesis 1 are covered in the journal article, Chapter 3.3, and as such are not duplicated here.

> **Hypothesis 2:** Levels of mindfulness will be improved following completion of the MBSR intervention.

Results in relation to Hypothesis 2 are covered in the journal article, Chapter 3.3.4, and as such are not duplicated here.

> **Hypothesis 3:** There will be an association between improvements in levels of mindfulness, particularly levels of acceptance, and improvements in symptoms, psychological distress and quality of life.

Correlations were conducted to investigate if any relationship existed between improvements in participants' outcome scores and improvements in their scores on the mindfulness subscales of awareness and acceptance. Scores were calculated by subtracting outcome scores gained at baseline from those at post-intervention. This same calculation was carried out for the acceptance and awareness subscale scores. Correlations were only carried out in the completer sample as comparing change scores of zero with other change scores of zero would result in erroneously greater correlations (as would be the case in the ITT group where the last observation carried forward method was used).

As the data fulfilled the assumptions for parametric statistics Pearson's correlations were used. The level of significance was based on a two-tailed test at the 0.05 level.

4.1.1. Hypothesis 3.1: Improvements in outcome measure are associated with increased Awareness

Correlations between changes in the mindfulness subscale of Awareness and changes in outcome measures can be seen in Table 4.1.

Table 4.1 Correlations of change in outcome measures with change in Awareness in the completer sample

Change scores in	**Pearson's *r***	***p***
Psychological distress		
HADS-d*	-.247	.689
HADS-a*	.040	.949
Symptoms		
SCL-90-R *	.894	.041
Symptom frequency*	.816	.092
Symptom severity*	.696	.192
Quality of Life (QoL)		
WHOQOL-BREF General †	-.660	.226
WHOQOL-BREF Physical †	.100	.873
WHOQOL-BREF Psych †	.261	.672
WHOQOL-BREF Social †	.505	.385
WHOQOL-BREF Environmental †	-.189	.749

* Indicates measures where a negative correlation represents improvement on an outcome measure being associated with improvements in Awareness.

† Indicates measures where a positive correlation represents improvements on an outcome being associated with improvements in Awareness.

4.1.1.1. Hypothesis 3.1.1: Psychological distress

No significant correlation was found between changes in Awareness and either changes in depression or anxiety at post-intervention.

4.1.1.2. Hypothesis 3.1.2: Symptoms

A significant correlation was identified between changes on the SCL-90-R somatic symptom subscale and changes on the mindfulness subscale of Awareness (r =.894, p= .041). The correlations shows a relationship between increased awareness and increased somatic symptom score.

There was no significant correlation associating changes in symptom frequency or symptom severity with changes in Awareness.

4.1.1.3. Hypothesis 3.1.3: Quality of Life

Changes on the awareness subscale were not found to significantly correlate with changes in WHOQOL-BREF subscales.

4.1.2. Hypothesis 3.2: Improvements in outcome measure are associated with increased Acceptance

Correlations between changes in the mindfulness subscale of Acceptance and changes in outcome measures were carried out and can be seen in Table 4.2.

Table 4.2 Correlations of change in outcome measures with change in Acceptance in the completer sample

Change scores in	**Pearson's *r***	***p***
Psychological distress		
HADS-d*	-.582	.303
HADS-a*	-.024	.970
Symptoms		
SCL-90-R *	.293	.632
Symptom frequency*	-.194	.755
Symptom severity*	-.032	.960
Quality of Life (QoL)		
WHOQOL-BREF General †	-.230	.709
WHOQOL-BREF Physical †	.134	.830
WHOQOL-BREF Psych †	.393	.513
WHOQOL-BREF Social †	.043	.946
WHOQOL-BREF Environmental †	.312	.609

*Indicates measures where a negative correlation represents improvement on an outcome measure being associated with improvements in Acceptance.

† Indicates measures where a positive correlation represents improvements on an outcome being associated with improvements in Acceptance.

4.1.2.1. Hypothesis 3.2.1: Psychological distress

No significant relationship was found between changes in levels of Acceptance and changes in levels of anxiety or depression.

4.1.2.2. Hypothesis 3.2.2: Symptoms

There was no significant relationships between change in symptom scores and changes in levels of Acceptance.

4.1.2.3. Hypothesis 3.2.3: Quality of Life

Changes on the WHOQOL-BREF subscales, and general QoL score, did not significantly correlate with changes in Acceptance.

4.2. Outcomes by participant

The following section outlines the outcomes for each individual participant who completed the intervention. Graphs show changes in outcome for the individual participants and reliable change index scores and clinically significant change index scores have been calculated where possible.

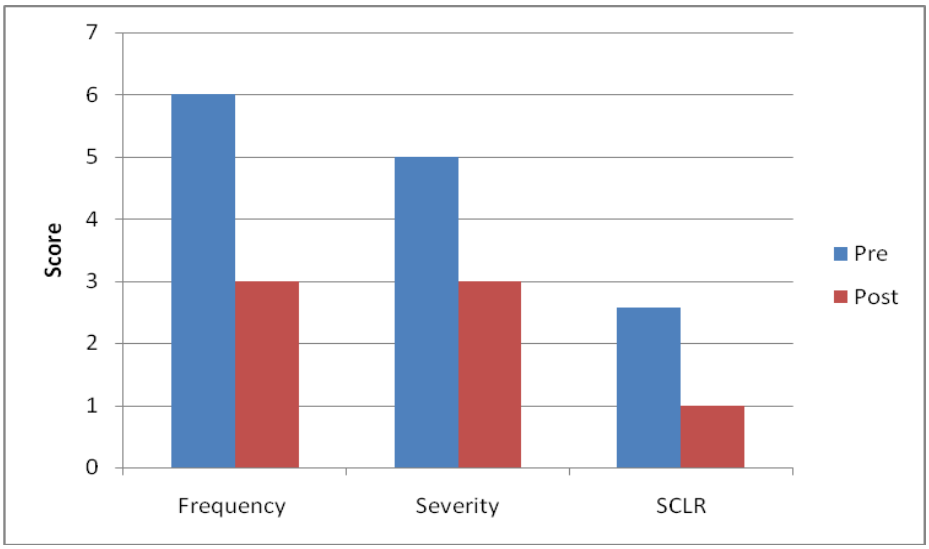
The reliable change index was a concept introduced by Jacobson and colleagues (1984) and developed further by Jacobson & Traux (1991). It provides a measure of statistical and clinical significance, taking into account scale reliability. A reliable change index score (RCI) of 1.96 or greater, in either direction, is considered statistically reliable at the 95% confidence level (Jacobson & Traux, 1991). RCI scores were calculated for each of the measures where test-retest reliability information was available. The concept of clinical significance was also introduced by Jacobsen and colleagues (1984) and relates to whether change experienced takes the person from a score typical of problem or clinical difficulties to a score typical of the "normal" population. Depending on the information that is available Jacobsen and Traux (1991) offer different methods of calculating clinical significance. Their

methods were used to calculate clinical significance and, where possible, they were calculated using both clinical and normative data.

4.2.1. Participant 1

4.2.1.1. Symptoms

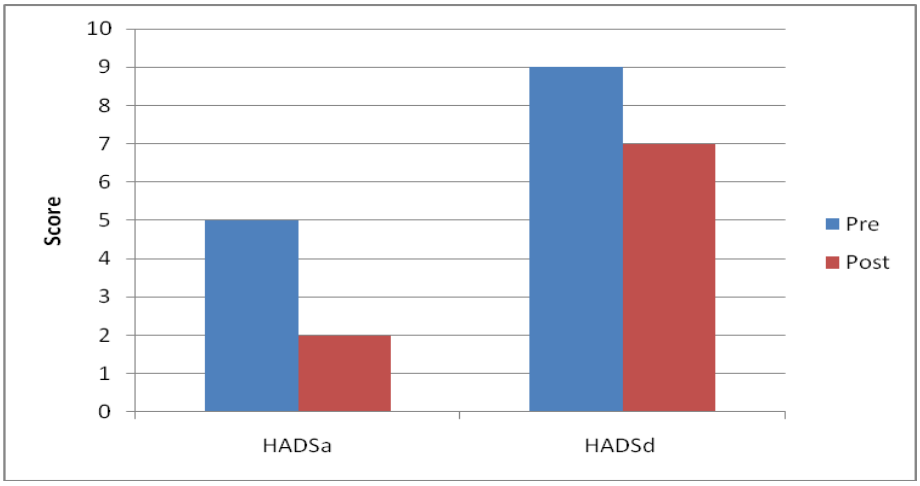
Figure 4.2.1 Participant 1: Pre- and post-intervention scores on symptom measures



Participant 1 had an RCI of 3.53 on the SCL-90-R somatic symptom subscale, suggesting that the change observed (see Figure 4.2.1) is unlikely to be due to simple measurement unreliability. In addition, the changes were clinically significant with a score typical of the non-clinical population at post-intervention. Changes in symptom frequency were clinically significant, when analysed using clinical distribution, though reliable change could not be calculated.

4.2.1.2. Psychological distress

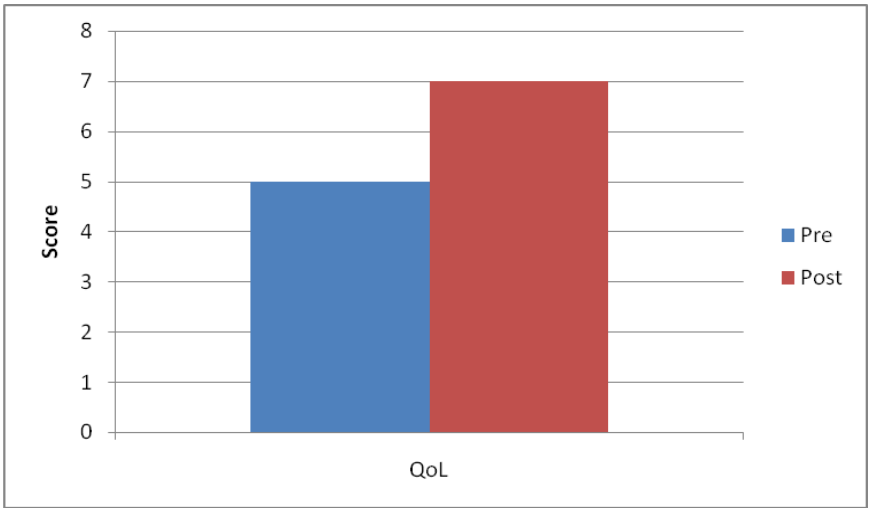
Figure 4.2.2 Participant 1: Pre- and post-intervention scores on HADS anxiety and depression scales



The change in level of anxiety from pre- to post-intervention (see Figure 4.2.2) had an RCI of 2.56, suggesting significance at the 95% confidence level. The participant's levels of anxiety were already below the cut-off for clinical significance at pre-intervention. Reliable and clinical changes were not significant when considering changes in levels of depression.

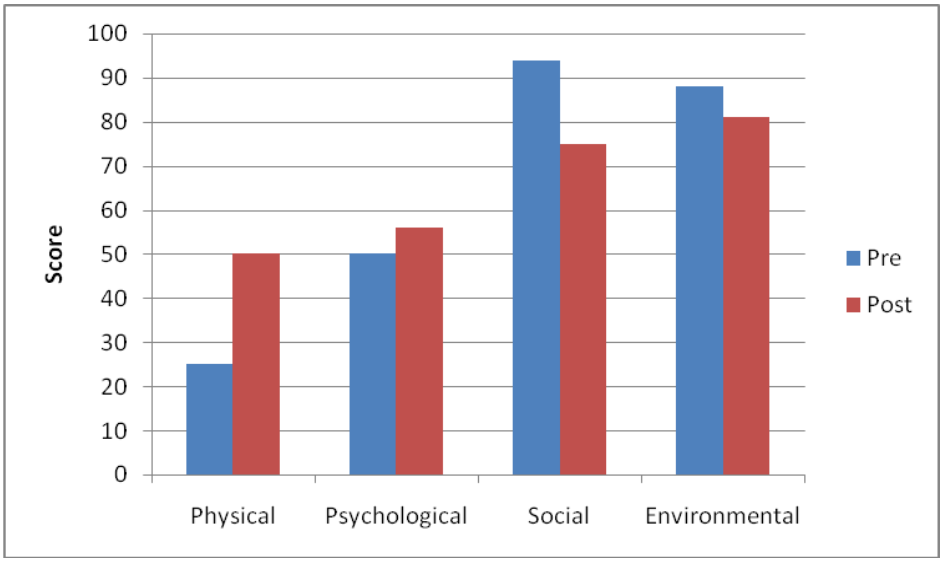
4.2.1.3. Quality of Life

Figure 4.2.3 Participant 1: General quality of life at pre- and post-intervention



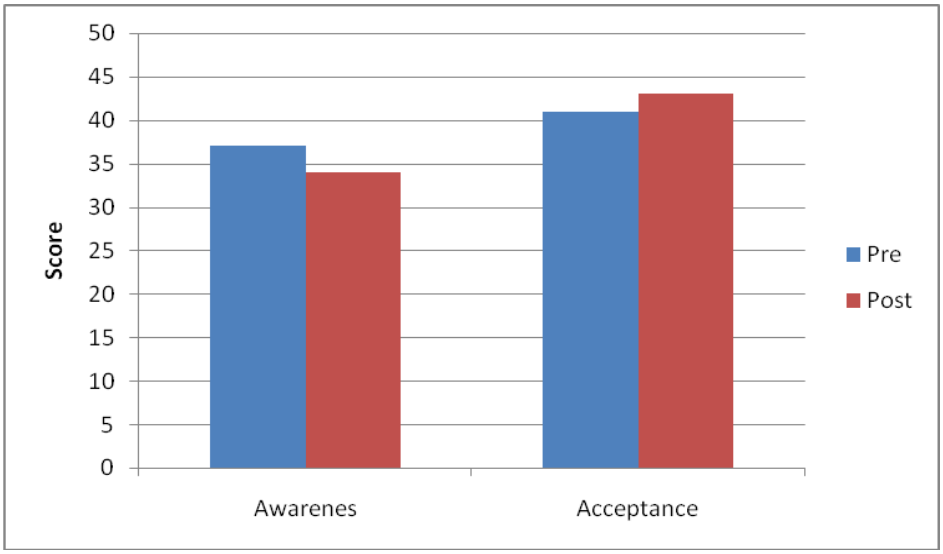
Improvement in general quality of life (see Figure 4.2.3) was clinically significant for participant 1 however an RCI cannot be calculated so there is no measure of reliable change. None of the changes on the domains of quality of life (see Figure 4.2.4) were significant using the criteria for reliable change.

Figure 4.2.4 Participant 1: Quality of life domains at pre- and post-intervention



4.2.1.4. Awareness & Acceptance

Figure 4.2.5 Participant 1: Awareness and Acceptance at pre- and post-intervention

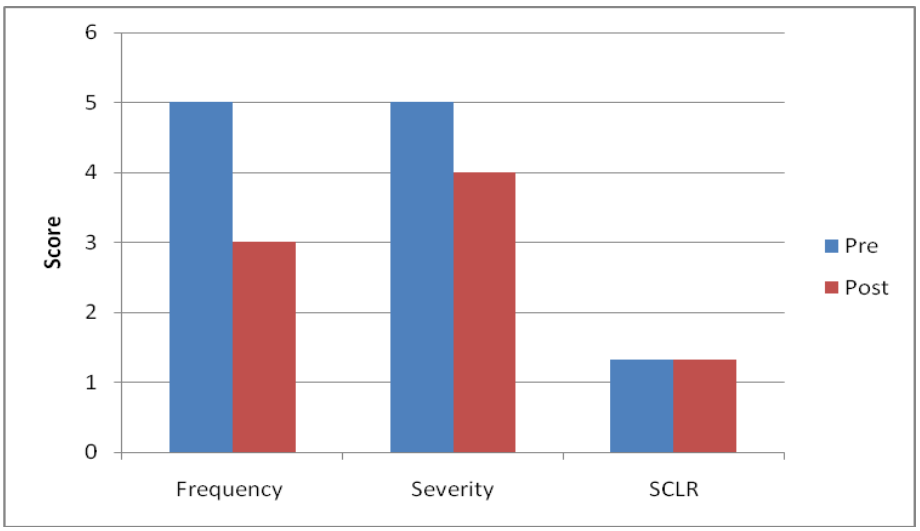


There was no significant change (see Figure 4.2.5) in Awareness or Acceptance using the reliable change index in participant 1.

4.2.2. Participant 2

4.2.2.1. Symptoms

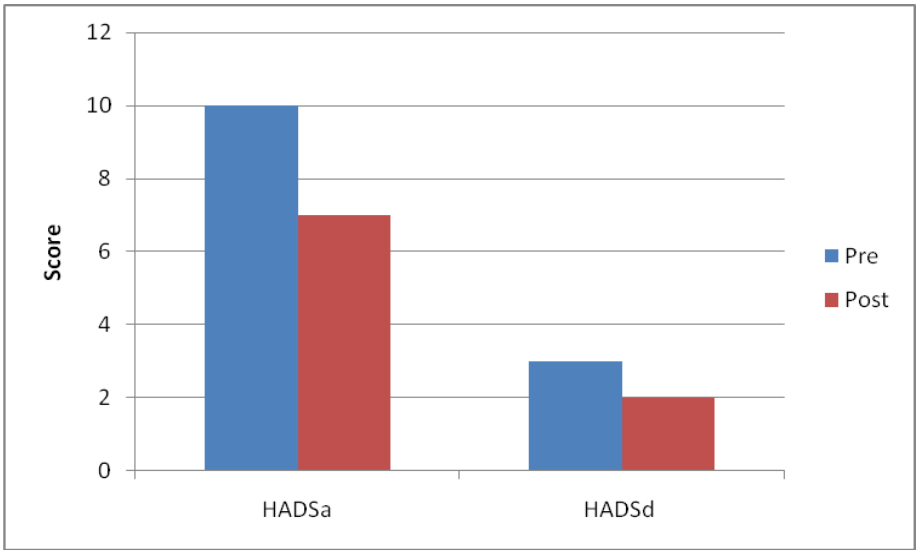
Figure 4.2.6 Participant 2: Pre- and post-intervention scores on symptom measures



Changes in frequency at post-intervention (see Figure 4.2.6) were clinically significant for participant 1 using the clinical distribution; changes in severity were not. There was no change on the somatic symptom subscale of the SCL-90-R.

4.2.2.2. Psychological distress

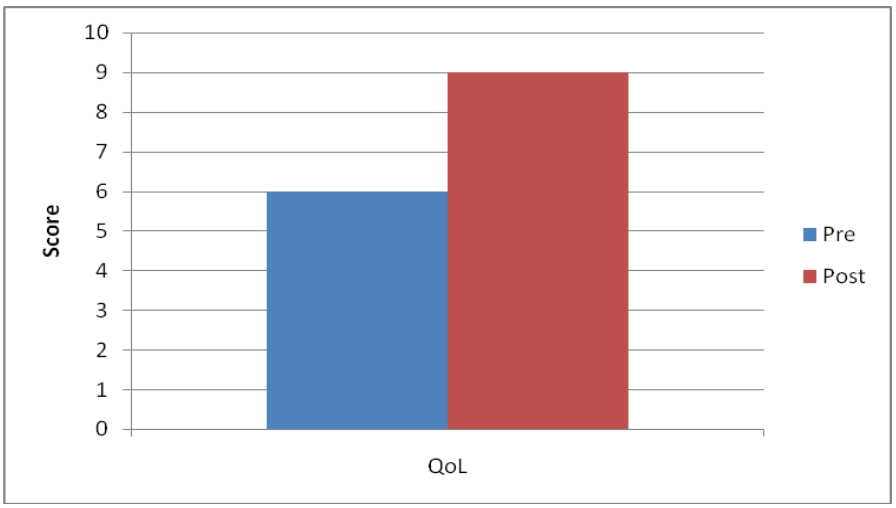
Figure 4.2.7 Participant 2: Pre- and post-intervention scores on HADS anxiety and depression scales



While change on the anxiety domain of the HADS (see Figure 4.2.7) was significant using the reliable change index (RCI = 2.56) it did not meet the criteria for clinical significance. Change on the depression subscale was not significant.

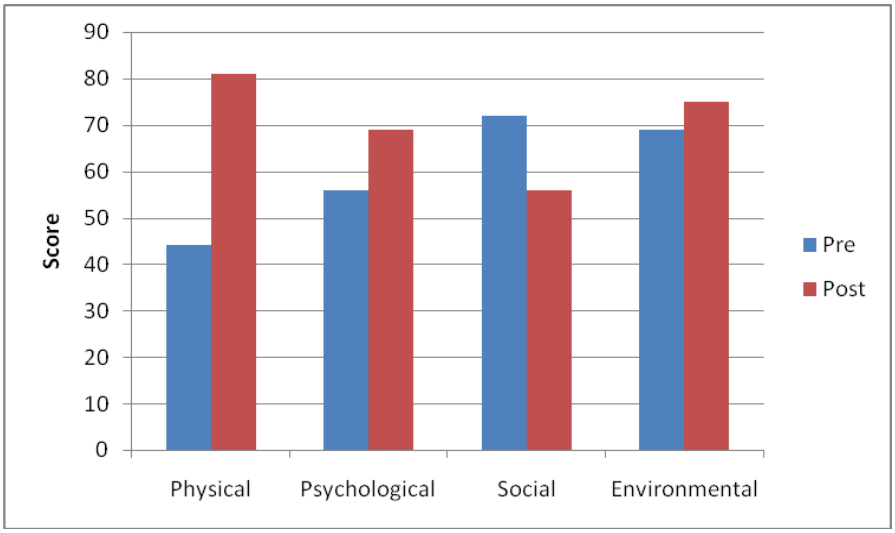
4.2.2.3. Quality of Life

Figure 4.2.8 Participant 2: General quality of life at pre- and post-intervention



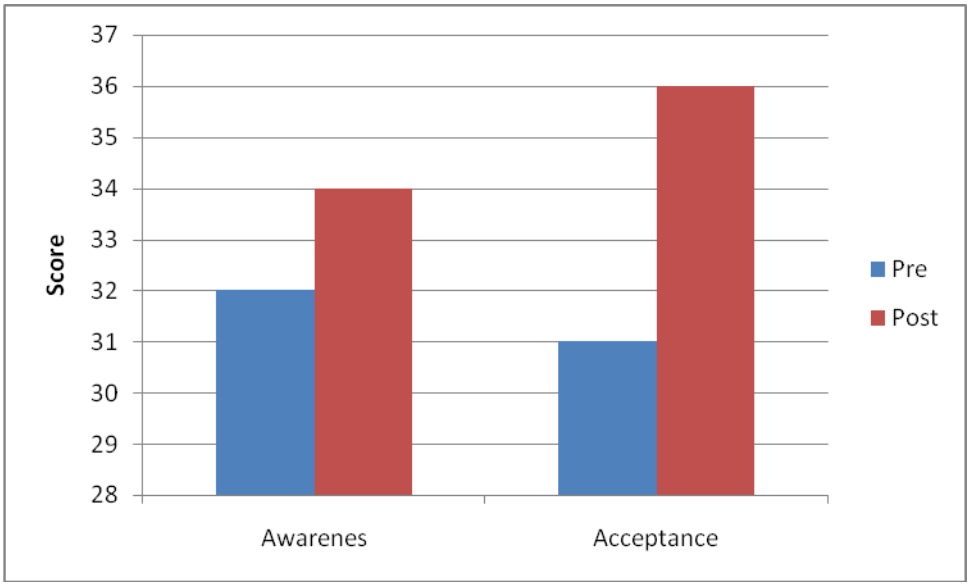
Change in general quality of life (see Figure 4.2.8) was clinically significant using the clinical distribution. Of the changes on the domains of quality of life (see Figure 4.2.9) only physical QoL was significant using the reliable change index (RCI: 3.19). The change was also clinically significant as the change gave participant 2 a score which fell within the range expected in a non-clinical population at post-intervention.

Figure 4.2.9 Participant 2: Quality of life domains at pre- and post-intervention



4.2.2.4. Awareness & Acceptance

Figure 4.2.10 Participant 2: Awareness and Acceptance at pre- and post-intervention

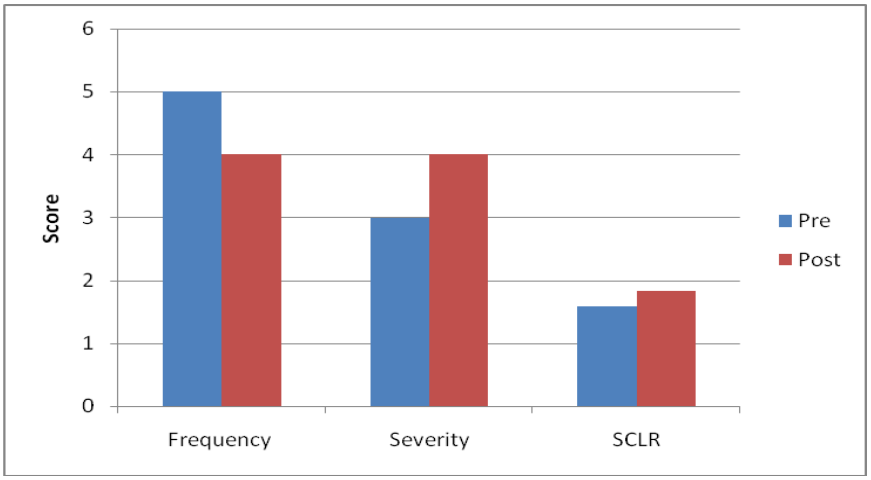


Changes in Awareness and Acceptance (see Figure 4.2.10) did not show reliable change (RCIs of 0.78 and 0.96, respectively).

4.2.3. Participant 3

4.2.3.1. Symptoms

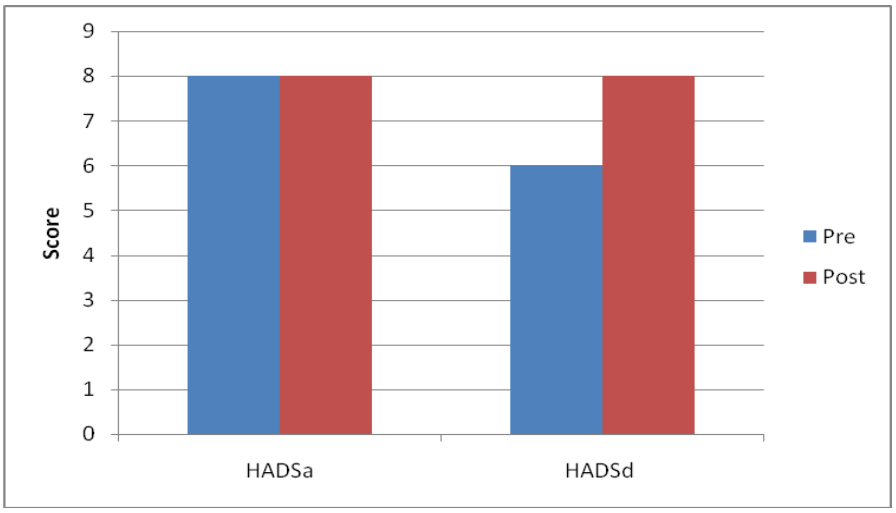
Figure 4.2.11 Participant 3: Pre- and post-intervention scores on symptom measures



Changes on symptom measures were not significant using the reliable change index and did not meet the cut-off for clinical significance.

4.2.3.2. Psychological distress

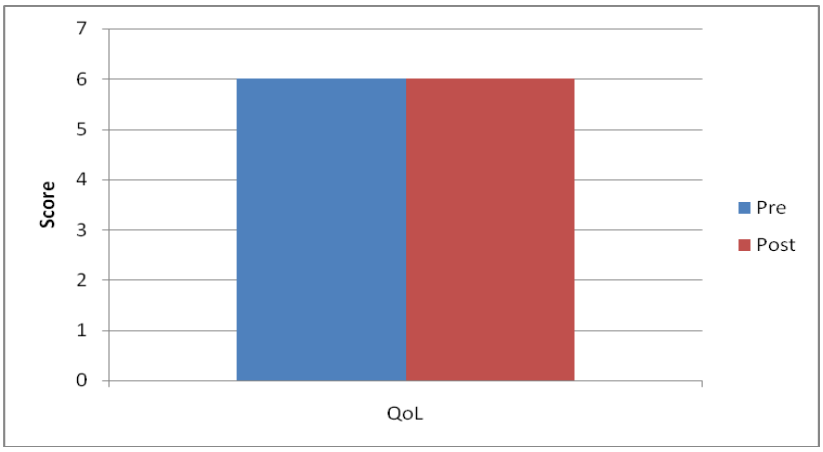
Figure 4.2.12 Participant 3: Pre- and post-intervention scores on HADS anxiety and depression scales



Participant 3 showed no change on the anxiety subscale of the HADS. Change on the depression subscale (see Figure 4.2.12) was non-significant on the reliable change index (0.98).

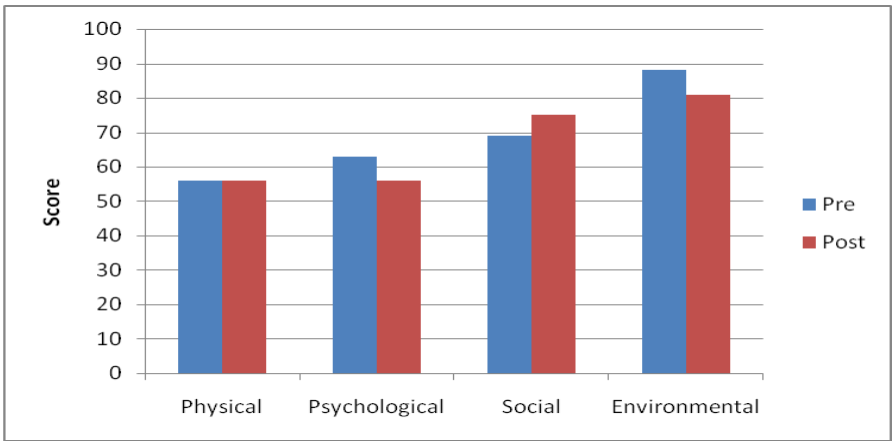
4.2.3.3. Quality of Life

Figure 4.2.13 Participant 3: General quality of life at pre- and post-intervention



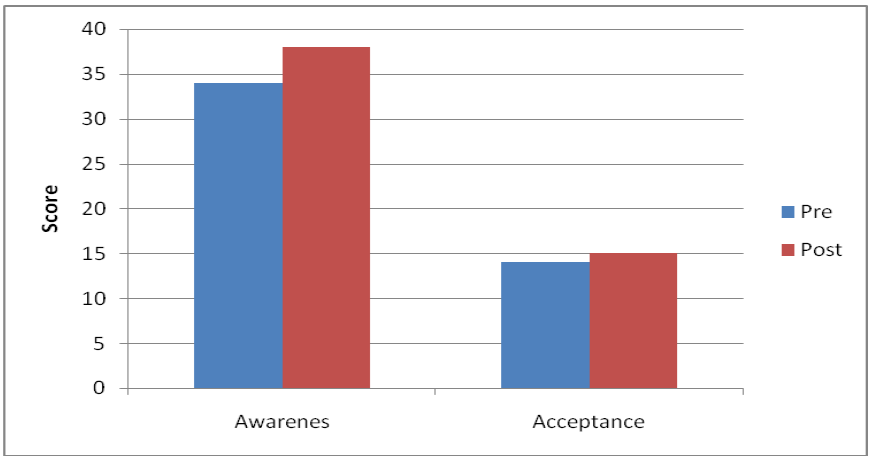
There was no change in general QoL score at post-intervention for participant 3 (see Figure 4.2.13). None of the changes in QoL domain (see Figure 4.2.14) were found to be significant using the reliable change index analyses.

Figure 4.2.14 Participant 3: Quality of life domains at pre- and post-intervention



4.2.3.4. Awareness & Acceptance

Figure 4.2.15 Participant 3: Awareness and Acceptance at pre- and post-intervention



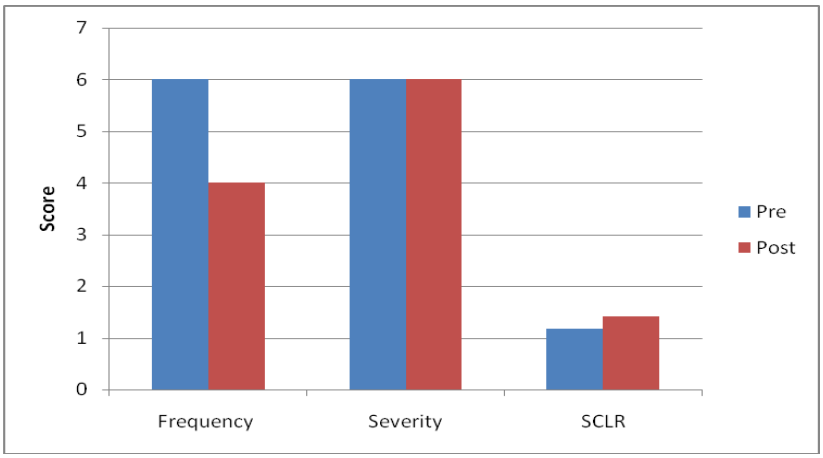
Though changes in Awareness subscale of the PHLMS (see Figure 4.2.15) put participant 3's scores in the non-clinical range, the change the RCI (1.56) fell below

the cut-off for significance. Changes in levels of Acceptance were non-significant using both reliable change and clinical significance calculations.

4.2.4. Participant 4

4.2.4.1. Symptoms

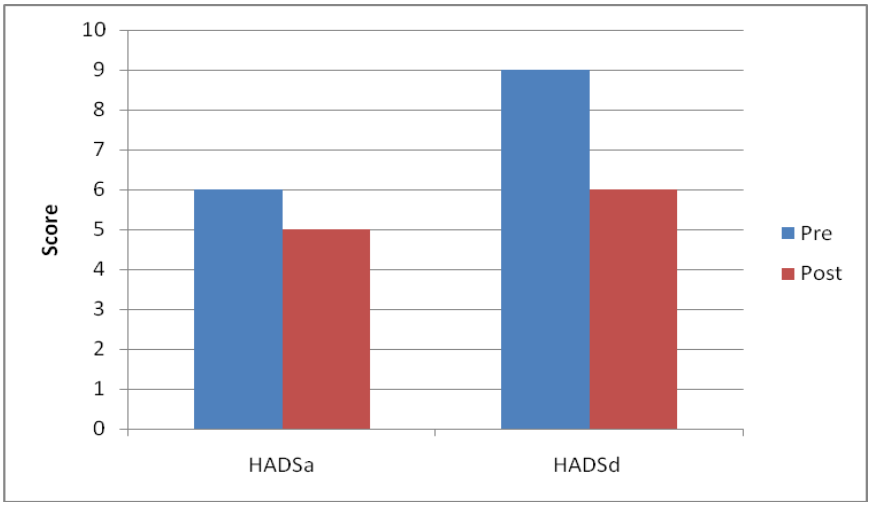
Figure 4.2.16 Participant 4: Pre- and post-intervention scores on symptom measures



Reduction in symptom frequency (see Figure 4.2.16) was clinically significant for participant 4. Symptom severity did not change however, and change on the somatic subscale of the SCL-90-R was not significant using reliable change analyses.

4.2.4.2. Psychological distress

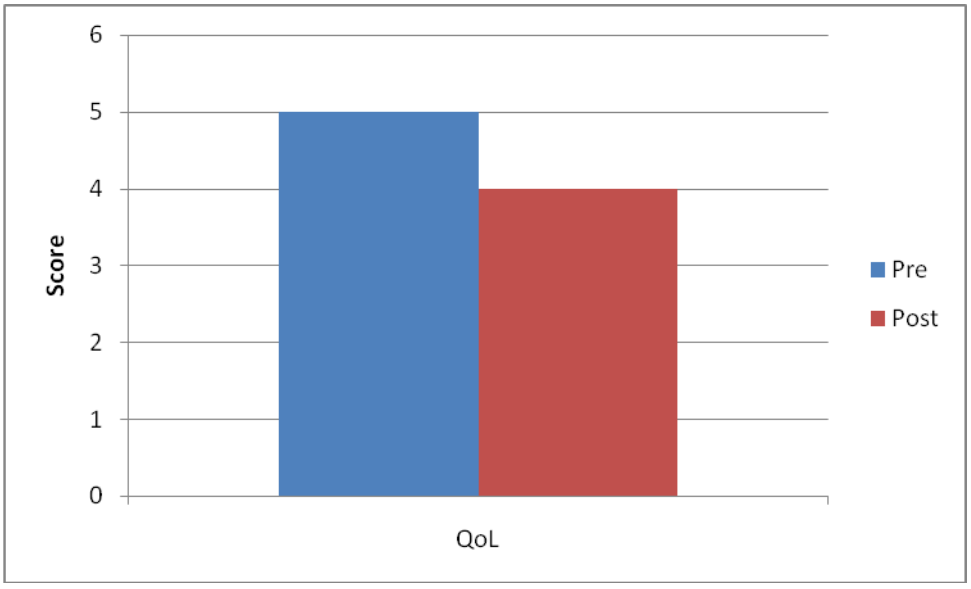
Figure 4.2.17 Participant 4: Pre- and post-intervention scores on HADS anxiety and depression scales



Changes in anxiety and depression (see Figure 4.2.17) at post-intervention were not significant using the RCI (0.85 and 1.47, respectively).

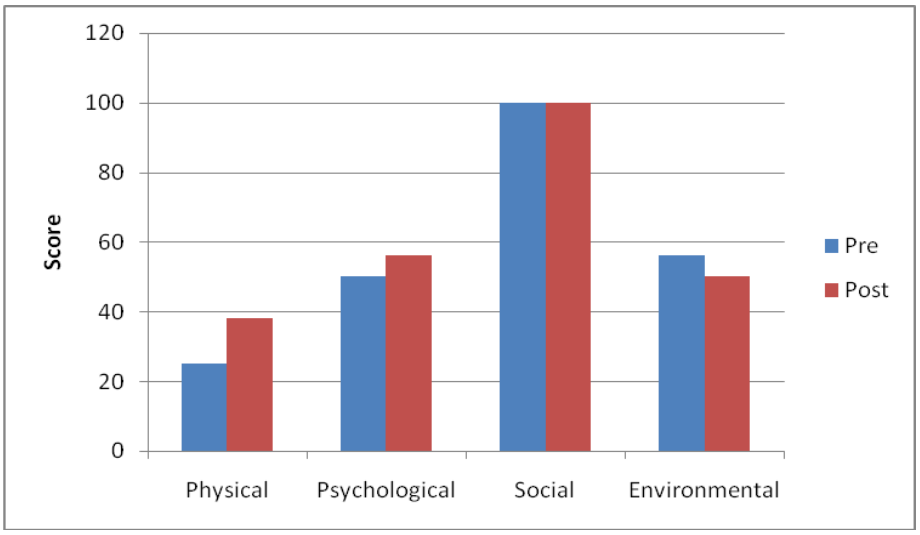
4.2.4.3. Quality of Life

Figure 4.2.18 Participant 4: General quality of life at pre- and post-intervention



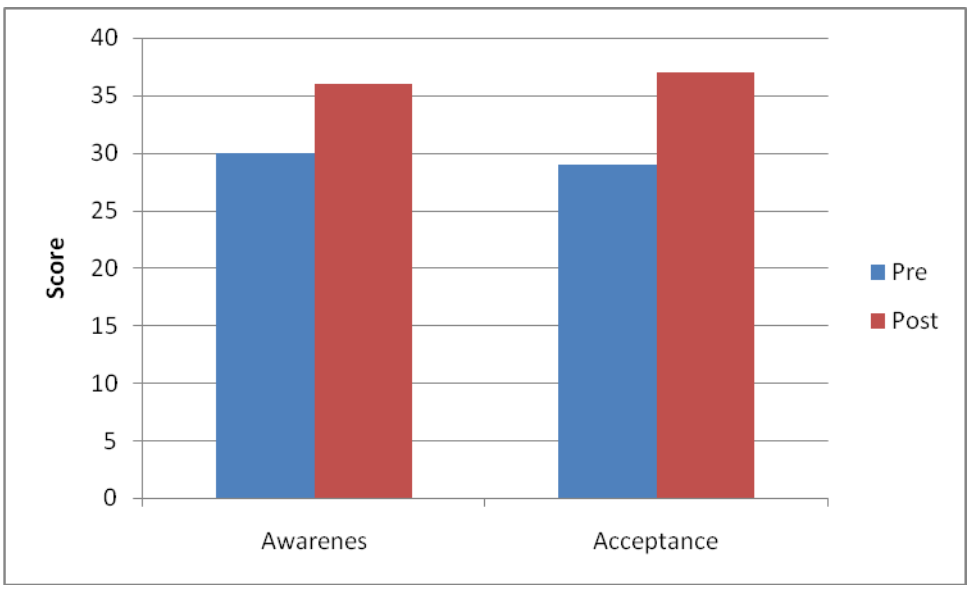
Change in general QoL at post-intervention (see Figure 4.2.18) was not clinically significant and none of the QoL domains showed significant reliable change.

Figure 4.2.19 Participant 4: Quality of life domains at pre- and post-intervention



4.2.4.4. Awareness & Acceptance

Figure 4.2.20 Participant 4: Awareness and Acceptance at pre- and post-intervention

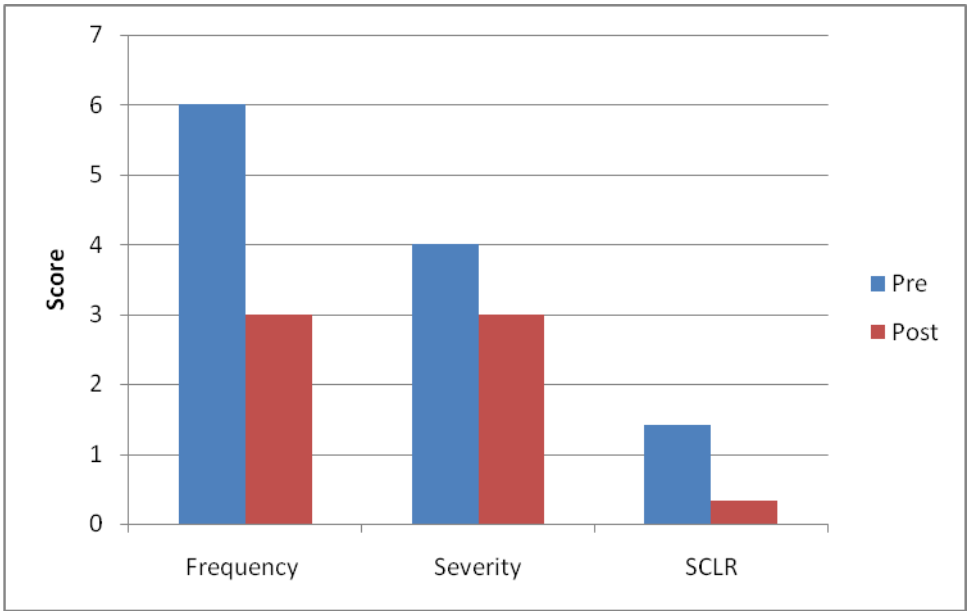


The increase in Awareness shown by participant 4 at post-intervention (see Figure 4.2.20) was significant using the reliable change index (RCI: 2.34) and this was clinically significant, putting the participant's score in the range of a non-clinical sample. Changes in Acceptance were not significant on the reliable change index (1.53).

4.2.5. Participant 5

4.2.5.1. Symptoms

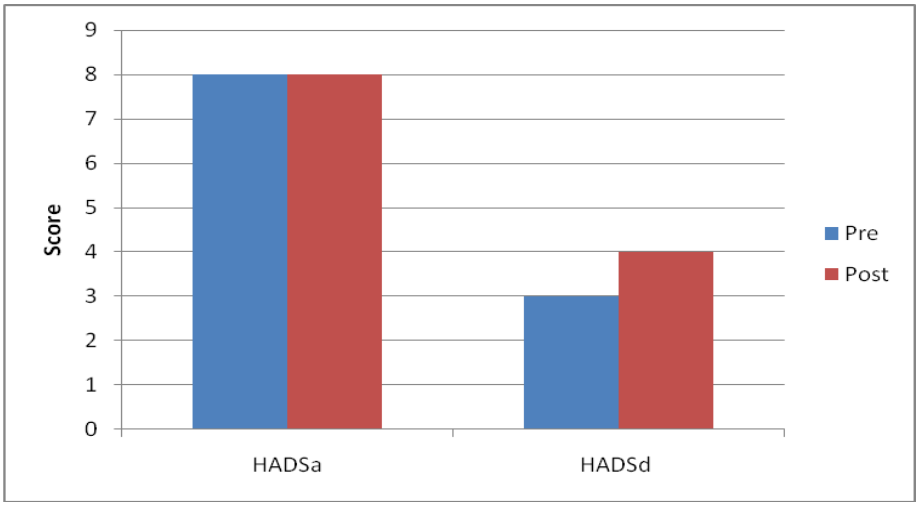
Figure 4.2.21 Participant 5: Pre- and post-intervention scores on symptom measures



Reduction in symptom frequency (see Figure 4.2.21) was clinically significant for participant 5, though change in severity was not. Change on the somatic subscale of the SCL-90-R was significant on the reliable change index (RCI: 2.43). The change was clinically significant, placing participant 5's score within the range of a non-clinical sample.

4.2.5.2. Psychological distress

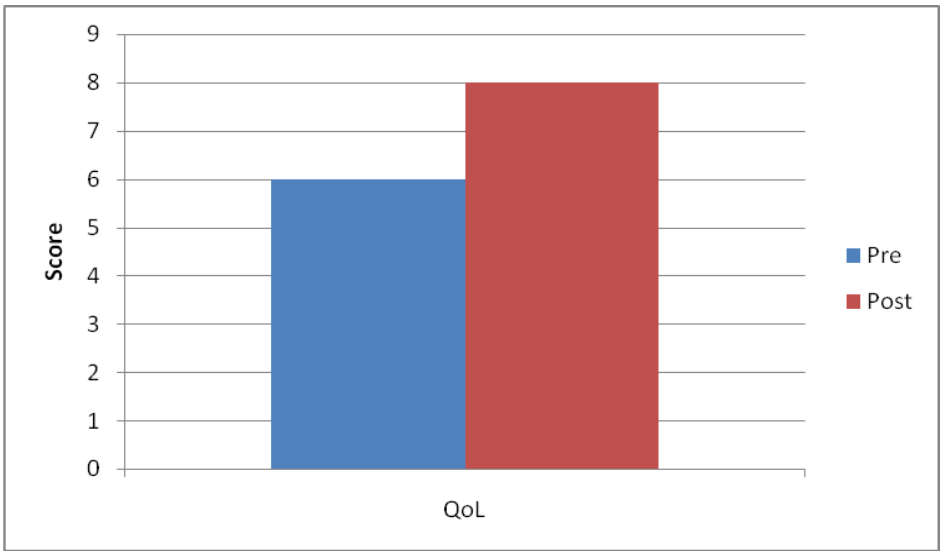
Figure 4.2.22 Participant 5: Pre- and post-intervention scores on HADS anxiety and depression scales



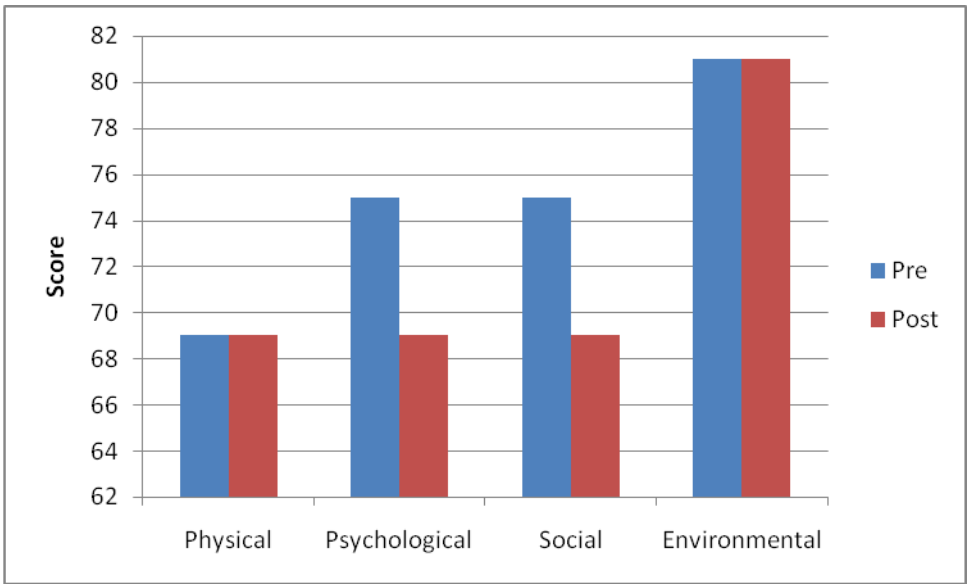
Participant 5 showed no change in anxiety, and change on the depression scale of the HADS (see Figure 4.2.22) did not reach the reliable change index cut-off for significance.

4.2.5.3. Quality of Life

Figure 4.2.23 Participant 5: General quality of life at pre- and post-intervention

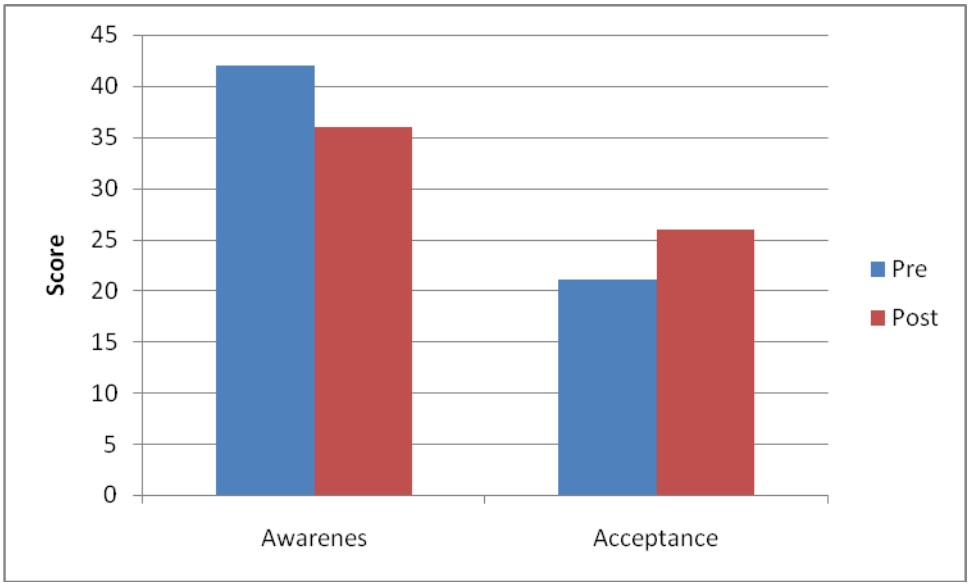


Improvement in general QoL (see Figure 4.2.23) was clinically significant, however none of the domains showed significant reliable change.



4.2.5.4. Awareness & Acceptance

Figure 4.2.24 Participant 5: Awareness and Acceptance at pre- and post-intervention



Participant 5 showed a reduction on the Awareness subscale of the PHLMS (see Figure 4.2.24) which was significant on the reliable change index (RCI: -2.34), however this was in the direction of reduced rather than increased awareness.

4.3. Participant feedback on the intervention

Four of the participants who returned the post-intervention questionnaires completed the final section which asked for feedback on the self-help intervention. Comments from participants suggested that they found the booklet and CD intervention easy to follow. Feedback also suggested that the intervention's flexibility was helpful in that it could be done where and when it suited participants. One participant commented that they found the increase in awareness particularly positive.

Recommendations to improve the booklet included a suggestion that the booklet could be made more appealing by using colour images. Another participant commented that face to face or group sessions could improve the intervention.

5. Additional Discussion

Some of this study's outcomes were discussed in the journal article in Chapter 3. Discussion which was not included in this article can be found in the following sections.

5.1. Outcomes of the study

5.1.1. Relationship between mindfulness and outcomes

As there was no active control to compare outcomes against, improvements observed could be due to participants being part of a research study. In an attempt to address this, correlations between change in mindfulness and change in outcome variables were carried out to assess if improved mindfulness was associated with improvements in outcome. Interestingly, the only significant relationship identified was a positive relationship between changes on the awareness subscale of the PHLMS mindfulness measures and changes in symptoms measured on the SCL-90-R somatic subscale. This suggests that increased awareness was related with worsening symptoms. As with more positive results, given the small sample and limited power, interpretations of these finding are tentative. One hypothesis could be, however, that increased awareness results in people with MUS noticing their symptoms more acutely. This might imply that participants carrying out the self-help MBSR did not have the guidance to control their awareness in the non-judgemental and accepting way that is the aim of mindfulness-based interventions.

The results identified in this study, though limited, suggest that levels of acceptance could be improved through self-help MBSR. No clear association was found, however, between the improvements in acceptance and the improvements in symptom frequency made by the completer sample. As a result these limited findings do not provide evidence to support Cardacciotto and colleagues' proposal that improvements in acceptance play an important role in reducing mood problems (Cardaciotto *et al.*, 2008).

Most studies of MBSR for people with MUS do not include a measure of mindfulness; of those that do, fewer still look at the relationship between changes in mindfulness and changes in outcome. One study evaluating MBSR for IBS which did include a mindfulness measure (the FFMQ), and carried out such correlations, did not find a relationship between improvements in mindfulness and improvements in anxiety at post-intervention, or at six month follow-up (Kearney *et al.*, 2011b). They did identify a relationship, however, when changes were analysed across the three time points. This could mean that mindfulness measures are not sufficiently capturing mindfulness, or that there is another psychological process responsible for the change that is occurring, which is not encapsulated in mindfulness and its associated measures.

5.1.2. Outcomes by participant

Looking at the changes in outcomes observed in individual participants (see Chapter 4.2) provides us with information about if changes were reliable and clinically significant for patients. These results showed that four of the five participants who

completed the intervention showed reliable and clinically significant change on one or more of the outcome measures. Reliable and clinically significant reduction in symptoms (as measured on the SCL-90-R somatic symptom subscale) and improvements in physical QoL were observed in two participants. Changes in anxiety, psychological QoL and Awareness met the criteria for both reliable and clinically significant change in one participant each.

There were a number of cases where changes were either reliable, but their post-intervention score did not fall below the cut-off for clinical significance, or their scores fell within the range typical of the 'normal' population, but that the change did not meet the criteria for it to be considered reliable.

The clinical significance calculations suggest that all participants who completed the intervention experienced clinically significant levels of symptom frequency at post-intervention. While reliable change could not be calculated for this outcome, due to lack of information on scale reliability, it is interesting to note that symptoms were reduced to this level in all participants. This complements the analyses of statistical significance (see Chapter 3.3) which found symptom frequency to reduce significantly.

Other than symptom frequency, the results do not show a clear pattern of change. Changes in anxiety and physical QoL were observed in two of the four participants who showed reliable and clinical change on one of the outcome measures but the other changes were only observed in one participant each. Again, this fits with the statistical analyses which showed that of the outcome measures only symptom frequency showed a statistically significant change at post-intervention.

These reliable and clinical change analyses help to identify where change has been reliable, and if participants have moved into a range typical of a non-clinical population. It does not, of course, tell us to what extent this has had a meaningful impact for an individual on their functioning and well-being. For example, a patient who has a relatively high anxiety score pre-intervention may show reliable change but not clinically significant change because there post-intervention score was not low enough. This person may, however, experience a greater benefit than the individual whose final score fell into the clinically significant range.

The results show, however that it is possible that the MBSR intervention may impact on people with a range of different symptoms in a range on different ways. The individual results suggest that there is the potential for change in a range of different areas following the MBSR intervention including symptoms, anxiety and quality of life. Further investigation is needed to identify if the intervention is effective, in what cases, and in what areas change is observed.

5.2. The roles of awareness and acceptance

Lower levels of awareness have been identified in clinical samples when compared with non-clinical samples (Cardaciotto *et al.*, 2008). The current study found, however, that participants' baseline levels of awareness were relatively high, and comparable with the non-clinical sample seen by Cardaccioto, raising the questions of if, and why, people with MUS have higher levels of awareness than other clinical samples. Theories of conscious awareness, including that by Gallagher (2005), propose that it plays little part in our daily life and that automatic bodily processes

remain largely outside our sphere of awareness. Gallagher goes on to suggest, however, that at times processes and sensations which would normally go unnoticed can be brought to the surface by changes in cognition or physiology, and that these can interfere with the normal functioning of what are usually unconscious processes. Similarly, the two stage model of medically unexplained symptoms proposed by Rief & Barsky (2005) posits that chronic stress and over-arousal generate bodily symptoms, and that these symptoms are then selected for conscious attention through a number of contributing factors including depression, health anxiety and uncertainty regarding symptom origins. They suggest that these factors lead to 'faulty filtering' and an increase in the perception of symptoms. Though conclusions about the reason for the relatively high levels of baseline awareness in the participants cannot be drawn from this study, these models of MUS provide one way of understanding this finding.

The high baseline levels of awareness identified in participants also highlights the different processes or factors involved in mindfulness. It has been proposed that the first component of MBSR involves the regulation of attention and awareness (Bishop *et al.*, 2004). The results in the current study suggest, however, that high levels of awareness alone do not improve symptoms and distress in people with MUS. Instead, they support the idea that the second component of mindfulness, which involves a stance of openness, curiosity, and acceptance, is also necessary. So while awareness is associated with mindfulness (Cardaciotto *et al.*, 2008) it is only one facet, and does not equate with mindfulness. In fact, as seen in the models outlined above, being 'aware' can maintain symptoms, while paying attention on purpose, in the present

moment and without judgement, can lead to increased levels of acceptance, and potentially the associated improvements in symptoms and psychological distress that have been identified previously (Cardaciotto *et al.*, 2008). This differentiation between general awareness and conscious, open, non-judgemental awareness could explain the finding that increased awareness was associated with higher reported levels of symptoms (see Chapter 5.1.1), with increases in this general awareness (separate from acceptance or mindfulness) being related to increased symptom reporting.

5.3. Changes to the original project

The design and projected recruitment for the original study was led by prevalence figures for patients with MUS attending primary care, and the guidance of GPs who reported that they saw such patients regularly, and would be keen to have something to offer them. As a result, the study was designed as a randomised controlled trial, aiming to enrol 90 participants who would be randomly allocated to the intervention and 'treatment-as-usual' conditions. Recruitment began in this way, however at a much slower rate than anticipated. During this time contact was maintained with the practices in person, by email and by phone, to try to ensure that project recruitment was kept in mind and to answer any questions or difficulties that arose in the practices.

The project was expanded so that practices could search their databases for patients with relevant diagnostic labels, review them to identify that they met the diagnostic criteria, then send appropriate patients a participant information pack. Patients

identified by their GP as meeting the criteria were then sent the project information packs by the practice. Only one of the smaller practices took up this alternative method of recruitment, with other practices citing time and resource limitations for not doing so. Patients with fibromyalgia were also added to the inclusion criteria following feedback from GPs. In addition, two further GP practices were signed up to the study to aid recruitment.

Despite these adjustments, it became clear that initial estimates regarding recruitment were not going to be met. As such, the design of the study was adapted to the within-subjects design outlined in Study 1. While this would reduce the robustness of the findings, with any changes unable to be compared to a control group, it was decided that a smaller number of participants in a within-subjects study would be preferable to the same smaller number of participants being split between control and intervention groups, limiting further the potential to evaluate the intervention. Furthermore, the study was initially designed to include a three month follow-up however, due to the length of time that it took to recruit participants, it was not possible to carry out this follow-up.

5.4. Potential reasons for recruitment difficulties

Exploring some of the reasons behind the recruitment difficulties was important, initially as a means of adjusting the project, and later as a means of guiding future practice recruiting such participants.

5.4.1. Patient issues

GPs were not asked to keep data regarding which, or how many, patients they introduced the project to as the investigator was aware, from experience and an initial GP focus group, that the time and effort required by GPs to carry out their role needed to be kept to a minimum. As a result, it is unclear how many potentially suitable patients were introduced to the project but were not interested, or took the pack but did not complete and return the forms to the project team. Feedback from GPs suggests that there were patients who were given a participant information pack but who did not complete and return the project paperwork to enrol in the study.

While getting conclusive reasons for the low uptake is difficult there are a number of potential reasons which could help to explain the low uptake. Firstly, the introduction that GPs were asked to give patients about the project was kept very brief and was focused solely on introducing the idea of the project to patients, who would then have to go away and read about it in their own time. In addition, though GPs had been briefed about the intervention they did not have the intervention to give to patients as, for the purposes of the project, completed consent and baseline measures were needed before participants received this. As such, patients may have agreed to take a pack but did not go away and read the information, or they read the information but decided that they were no longer interested.

Another possibility is that, depending on how long they have had their symptoms, some patients with MUS may not have been ready to consider managing their symptoms as their focus may still be on finding a cause and a remedy. Furthermore, patients who have had their symptoms for a long time might be very entrenched in

the biomedical model, and as result not be open to trying something more psychological. The psychological aspect of this intervention was not emphasised to participants as it had been identified that some patients with MUS can be put-off by the term 'psychological' due to the mistaken belief that this means that their symptoms are perceived as being 'all in the head' (Stone *et al.*, 2002). As the lead researcher worked in psychological services, and return envelopes were addressed to the psychology department, potential participants could have been put off by this connection.

5.4.2. GP issues

Despite the possible reasons for patients not participating in the project, discussions with contacts in the medical practices during recruitment suggested that they were not giving out as many project information packs as had been anticipated. A number of different explanations for this were proposed by GPs, including: not seeing patients who met the inclusion criteria; seeing patients with MUS not included in the criteria; having difficulty remembering to offer involvement to potential participants, and not diagnosing patients with these labels.

Other reasons for GPs not introducing the project were considered. One possibility was that GPs did not thinking that the MBSR intervention would be useful for potential participants, or that they thought the self-help aspect of the intervention would not be suitable for their patients.

5.5. Reflections on recruitment difficulties

Recruitment was clearly a major challenge experienced when carrying out this study and these difficulties have limited the evaluation of the intervention and its ability to generate generalisable conclusions about its use in this population. As a result, considering what could have been done differently to avoid or better deal with these difficulties has proved to be an important aspect of the project.

During the course of recruitment numerous changes were implemented in an attempt to deal with the recruitment difficulties, including: maintaining contact with GPs and practices, involving more practices in recruitment, broadening the inclusion criteria, adding an additional method of recruitment, and changing the design to a within-subjects design. While these changes may have had some impact on the final number of patients recruited to the project they clearly were not sufficient to increase numbers to the planned level. On reflection there are a number of things which could have been done differently at different stages of the process which may have avoided the pit-falls experienced, and these considerations may be of use to researchers recruiting in this area, or using similar methods in the future.

Firstly, despite good relationships with GPs and medical practices, and their initial enthusiasm for the project, recruitment through GPs was difficult and the anticipated numbers of patients who could be recruited did not materialise. The reasons for this are investigated in Study 2 and will not be repeated here, however difficulties were experienced across practices, and a number of reasons were identified which led to GPs struggling to recruit patients to this study. As a result, though the aim was to evaluate the intervention in way which was as close how the intervention would be

offered as possible, the difficulties faced when requiring GPs to recruit meant that any benefit gained through this ecological style of recruitment was lost by the low numbers recruited. Consequently, the study was unable to carry out an appropriately powered evaluation. For this reason, those who intend to recruit participants via GP practices would benefit from considering the issues that have been highlighted here.

An alternative option to recruiting through GPs would have been to recruit people with MUS from relevant organisations, groups or internet forums. While there are drawbacks to this method of recruitment, including the non-clinical setting and potential participant self-selection bias, initial well-powered studies evaluating the intervention in these more ideal conditions could help guide more rigorous ecological studies in the future.

For a number of reasons, including delays gaining ethical approval, the time available to carry out recruitment and intervention was limited. Though the initial timescales appeared appropriate, with scope for flexibility to deal with problems that arose, the project had sufficient leeway to deal with the ethics delays, however it did not allow for as much flexibility when the project recruitment then proved problematic. For this reason, starting time-limited projects as early as possible, and building in a greater time contingency than might expected can only help when carrying out such studies. Having said this, opening recruitment to non-NHS patients would not have had to go back through NHS ethical review, which is one of the reasons why changing the study can take time. If this had been carried out when initial problems with recruitment were identified then recruitment could have been

expanded to a separate group of participants, not recruited by their GP, in time to complete the intervention.

In addition, if there was more flexibility with regards to the timescale of this project a small initial pilot study would have proven invaluable in terms of highlighting any recruitment problems or other issues with the design which could then be adjusted prior to the implementation of the more comprehensive study.

Even if the design of the study and its recruitment were not changed drastically there are a number of other changes which could have been done, or could have been included in the original study design, which could have improved recruitment, or provided better feedback on why recruitment was not working as planned. Firstly, while it might have placed a greater burden on GPs, having a method of getting feedback from patients who were offered inclusion but did not participate would be very valuable, as understanding their reasons for not signing up for the project could have informed current and future study design and recruitment. Similarly, building in a system where feedback could be gained from those participants who started but did not complete the intervention would also help to understand who might benefit from this, and why.

Another possible flaw of recruitment was that GPs did not have access to the intervention booklets and CDs. It was considered necessary to get the completed baseline measures prior to the patient being given the intervention booklet, however in hindsight giving GPs a sample intervention booklet may have increased their connection to , understanding of, and enthusiasm for the intervention which might have improved recruitment.

One final reflection is that having no face-to-face contact with a therapist who knows the intervention is likely to have reduced the likelihood of patients engaging with, and completing, the intervention. Though this was originally planned as a self-help intervention which could be given out by GPs, with no therapist input, it is possible that the intervention might prove more useful in a guided self-help model where there is limited contact with a therapist. This would not only allow greater opportunity to engage patients in the intervention, and help to manage any difficulties that arise, but also provides greater possibility of gathering qualitative patient feedback on the intervention.

5.6. Limitations of the study

Limitations relating to the study's small sample size and lack of control group were considered in the journal article discussion (Chapter 3.4) and will not be repeated here. Instead, this section discusses some of the study's additional shortcomings.

Information about the education level or type of employment of the participants involved was not gathered. Given the size of this study, meaningful comparisons of these areas could not have been made. However, though more recent comparisons could not be identified, the Scottish Borders was ranked 30th of 32 Scottish local authorities in terms of median gross weekly earnings in 2011 (Pike, 2012). While the development of the intervention booklet included an attempt to ensure that the content was understandable by people from the general population, and did not require high levels of education to understand, it is possible that the attrition level, or

outcomes found, could have been impacted upon by participant education level as this was not be explored.

One of the drawbacks of evaluating a self-help intervention is that it is not possible to objectively say to what extent participants carried out the intervention. For example, in many MBSR studies, participants are usually considered to have completed the MBSR programme if they attend four out of the eight sessions (Schmidt *et al.*, 2011; Sephton *et al.*, 2007). So while participants who returned the post-intervention questionnaire reported the degree to which they carried out the intervention there was no independent measure which could be used to evaluate dose-response rates for the intervention.

5.7. Implications for practice

While the results of this study are not able to support the evidence-based use of a self-help MBSR intervention for patients with MUS, the findings may still have implications for practice.

Limited change was observed in levels of awareness in those who completed the intervention, however improvements were made in their levels of acceptance. As self-help based MBSR interventions have received little investigation until now, this improvement in levels of acceptance provides some support for the idea that MBSR could be carried out in this way, by some patients. A small randomised control study of a self-help based acceptance and commitment therapy (ACT) -- a third-wave cognitive behaviour therapy which includes mindfulness strategies to increase psychological flexibility -- for people with chronic pain, was conducted recently

(Johnston *et al.*, 2010). Though the small sample size (6 in the intervention; 8 in the control group) limited the generalisability of their results, they did find that anxiety, QoL and acceptance improved in the intervention group. ACT and MBSR are distinct therapies, however their third-wave focus on changing the function or process of psychological experiences rather than changing or modifying their content, and their use of mindfulness as a core component, mean that they share important similarities. This suggests that use of self-help interventions using mindfulness techniques can be acceptable and beneficial to those who experience physical symptoms such as pain.

Participants in Johnston's study reported, however, that they found the mindfulness parts of the book to be one of the most difficult parts of the intervention. So while the results of this, and the current study, suggest that self-help interventions using third wave therapies might be useful for patients with physical symptoms, it is possible that mindfulness is difficult to master in a self-help context. Again, larger studies would be needed for self-help interventions of this kind to be properly evaluated. Such studies would benefit from exploring how far mindfulness can be learned in this way, and if there are certain patient characteristics which make it more or less likely for them to engage in and complete the intervention.

Two-thirds of patients in the current study who completed baseline measures did not complete post-intervention measures, which suggests that they may not have completed the intervention. It is possible, therefore, that self-help MBSR may only be acceptable for, and beneficial to, a relatively small proportion of patients with MUS. Equally, further investigation may find the self-help intervention to have

relatively small effect on outcomes. Despite this, given the particularly low cost to implement the self-help intervention, the size of the MUS population, and the considerable cost to the NHS of managing these conditions, if benefits were identified it could potentially have a considerable impact across services as a whole.

The argument for increasing access to psychological therapies in Scotland has been made for a number of years now (Scottish Executive, 2006). This has driven a move towards stepped or matched care models of psychological intervention where intensity of patient input is kept to the minimum needed, whilst still achieving good clinical outcomes (Scottish Executive, 2008). Having a similar model of care for patients with MUS, through the development and evaluation of self-help materials, in addition to group and one-to-one interventions, would appear to be beneficial not only for patients, but also financially for the NHS. Participants who completed follow-up questionnaires had lower levels of anxiety and depression at baseline than those who did not. This suggests that the intervention is more acceptable, and possibly more appropriate, for this population than for those with higher levels of anxiety and depression. While this theory requires more evidence to support it, it would fit within the matched care model, with self-help interventions being easily accessed by patients with less severe or complex problems, and who are not appropriate for, or willing to attend, individual or group interventions.

Though it was not originally designed for use in this area it is possible that clinically, and perhaps from a research perspective, this intervention might be better provided to those who already have contact with mental health services. During the initial development of the intervention staff from a community mental health team

reviewed and commented on the booklet. The feedback was very positive, with staff reporting that they would like to be able to offer it to their patients. In this setting patients could be introduced to the intervention by a nurse, OT, psychologist or other team member who could provide motivation and guidance initially, something which is difficult for a GP to provide. Another option would be to follow the model of the ACT self-help intervention (Johnston *et al.*, 2010) where weekly phone call support was included in the intervention. Though this would increase the necessary clinical input, and the resulting cost of the intervention, it is possible that including this type of support would keep patients engaged in the intervention and produce better outcomes as a result.

5.8. Implications for research

Firm conclusions about how far self-help MBSR can improve mindfulness in participants with MUS, and to what extent these improvements are associated with changes in symptoms, QoL and psychological distress, could not be drawn from this study due to the low sample size. As so many studies of MBSR for MUS lack a measure of mindfulness the process of change that is identified in these studies cannot be fully explored or understood. Having a better understanding of the psychological mechanisms responsible for change in MBSR would aid the development and refinement of such interventions, and could have implications for how they are provided, and guide who they are offered to. Including mindfulness measures in studies involving mindfulness-based interventions could not only confirm that mindfulness improves as a result of the interventions, and identify if changes in outcomes are associated with these improvements in mindfulness, they

could also help to provide a better understanding of the mechanisms involved in therapeutic change in mindfulness and MBSR.

Numerous attempts have been made to develop and evaluate interventions for patients with MUS in primary care but an effective treatment model has yet to be established. For example, studies of a re-attribution intervention delivered by trained GPs (Larische *et al.*, 2004), and CBT provided by GPs in primary care have been found to be no more efficacious than treatment as usual (Arnold *et al.*, 2009; Sumathipala *et al.*, 2008). Self-help CBT for IBS has been found to have some benefit in reducing reported symptoms in patients with MUS, but had no impact on anxiety or depression (Moss-Morris *et al.*, 2010). Encouragingly, however, in addition to the study by Johnston *et al. (2010),* a recent study has found improvements in QoL and IBS behaviours following an ACT-based guided self-help intervention for IBS (Ferreira, 2011).

The results of the current study do not show that this self-help MBSR intervention can improve on the outcomes observed in these interventions, however the treatment of MUS in primary care requires further investigation and the results found show sufficient improvement in outcomes to focus further research in this area.

In addition to exploring the efficacy of self-help MBSR in improving patient outcomes, as patients with MUS have high health service utilisation costs (Barsky *et al.*, 2001), and the number of somatic symptoms that patients have correlates with these costs (Tylee & Gandhi, 2005), an economic costs-benefits analysis of the intervention would be an important area for future research to consider. This could

be carried out by comparing participants' attendance at their GP, or other medical contact, over the six months prior to, and the six months following, the intervention. This would provide a way of evaluating direct economic benefit of the intervention, though it would not take into account broader economic issues such as the ability to work or number of sick days, for example.

5.9. Conclusions

The original study was designed to be a randomised controlled trial with a substantially greater sample size than the current study, and a follow-up assessment. This was adapted in a number of ways due to difficulties with recruitment, resulting in the current study. Potential reasons for the limited recruitment were considered from both patient and GP perspective, and feedback from GPs suggested that they were experiencing a number of issues which meant that recruitment was lower than it could have been.

No expected relationship was identified between increased mindfulness factors and improvements in psychological distress, QoL or symptoms. The only relationship identified was between increased awareness and increased symptoms, implying that the self-help intervention may not have been sufficient to develop the mindful awareness necessary to have a positive effect on symptoms. The results of this study emphasise the different aspects or factors involved in mindfulness, highlighting the difference between general awareness and the present moment, curious and non-judgemental nature of mindful awareness which MBSR attempts to foster.

The current research cannot support the evidence-based use of the self-help MBSR intervention for patients with MUS due to its limited findings. However, the findings suggest that further study would be warranted to ascertain if self-help interventions such as this can increase mindfulness in this population, and if this results in improvements in psychological distress, QoL or symptoms. The potential benefits to patient wellbeing, and financially to the NHS and wider economy, make this an area worth pursuing. A suitably powered sample size would be required for the intervention to be appropriately evaluated, however. To do this effectively, a greater understanding of the recruitment difficulties faced in this study could help to adjust, or provide alternative, recruitment strategies and similar problems could be avoided.

Study 2

Reasons for the Difficulty Recruiting Participants to Study 1

Abstract

Background: Difficulty recruiting patients to Study 1 through routine GP appointments led to limitations in the evaluation of the intervention. Limited research exists exploring this area, but it suggests that brief focussed questionnaires can be used to explore these difficulties with GPs. The aim of this study was to understand some of the difficulties experienced with a view to informing future research and intervention implementation.

Method: Practices were contacted and asked if they would prefer paper or web-based questionnaires. Thirty-five GPs involved in recruitment to Study 2 were sent the questionnaire which asked them to rate how true they found ten statements to be on a five-point Likert scale. They were also asked to estimate the number of patients they had introduced the project to.

Results: Twenty-two (63%) GPs completed and returned the questionnaire. Three statements were scored higher than the others. The first two were related to finding it hard to prioritise amongst competing demands and forgetting to offer patients participation as they were very busy. The third was that GPs saw patients with medically unexplained symptoms but they did not meet the inclusion criteria.

Conclusions: Recruitment appears to have been impacted on by GP finding it difficult to prioritise, being busy and forgetting, and seeing patients who had MUS but who did not fit the inclusion criteria. As a result, alternative ways of evaluating this type of intervention, including recruiting participants through relevant organisations, may need to be considered to evaluate their efficacy.

6. Study 2 Introduction

Despite changes to the initial project (see Discussion, Chapter 5.3), involving more practices in recruitment; broadening inclusion criteria to include fibromyalgia; offering a different way of recruiting participants; changing the study to a within-subjects design as described in the Methods section (Chapter 0); and on-going contact with the practices, recruitment to the pilot project remained considerably lower than anticipated. As a result, a better understanding of the difficulties recruiting participants to Study 1 was sought, which led to this additional study being carried out. Despite initial positive responses from GPs about involvement in the study, once recruitment was underway they reported difficulties. The rationale behind this study was, therefore, to try to understand these recruitment difficulties through a questionnaire to GPs involved in Study 1. Such findings could have implications for the design and implementation of future research in addition to helping to inform how the intervention might be best used in practice.

Prior to beginning Study 2, GPs from a number of practices involved in the recruitment of participants for Study 1 were canvassed on possible options for the study. Options were: a) for a small number of GPs to be involved in interviews about their experience of recruitment and their thoughts around medically unexplained symptoms more generally; or b) for all GPs involved in Study 1 to be given a short questionnaire around potential recruitment difficulties. Their response was unanimous, reporting a preference for questionnaires, with a prediction that there would be a higher chance of a reasonable number of short questionnaires being

completed than there would be of an appropriate number of GPs committing to take part in interviews (due to time commitments and other demands being placed on them).

6.1. Literature on difficulties recruiting patients

There is a considerable literature exploring the difficulties carrying out collaborative clinical research within healthcare systems such as the NHS. Most of this research has focused on difficulties *engaging* health professionals in research, with less attention given to the barriers that those health professional who have agreed to take part have faced when *recruiting patients*. Despite this, difficulties arising when GPs have agreed to introduce research to patients during consultations are not uncommon (Fairhurst & Dowrick, 1996; Hetherton *et al.*, 2004; Mason *et al.*, 2007). Hetherton and colleagues' study (2004), comparing computerised CBT, psychologist-lead CBT, and treatment as usual by GPs, relied on GPs introducing the study to potential patients. They only recruited five participants within a three month period (prompting modification of the study design) and 17 within a year. The researchers then gave a questionnaire to GPs involved in recruitment to identify potential barriers to recruitment. This drew on a questionnaire developed by Fairhurst and Dowrick (1996) when their RCT had to be abandoned due to GPs recruiting insufficient numbers of patients. Some GPs reported that the questionnaire given by Hetherton and colleagues to identify barriers to recruitment was too long and they asked to be interviewed to feed back their thoughts.

The questionnaires and interviews by Hetherton *et al*. found that GPs felt faced with a dilemma between the care of their patients and research interests. For example, GPs felt uncomfortable about patients being randomised to conditions and this often resulted in the research not being introduced to patients. GPs were also concerned that the intervention would not meet the needs of the patients, and felt uncomfortable about raising the research due to its potential to impact on the consultation. In addition, Hetherton *et al*. identified that GPs found it difficult to prioritise the study in the face of competing demands.

A qualitative study, also exploring the barriers experienced in this type of recruitment, was carried out by Mason and colleagues (2007). Their analysis of interviews with GPs found that a desire to protect the doctor–patient relationship, a perceived lack of skill and confidence in introducing research to patients, and priority being given to clinical and administrative matters over research participation, were the main themes that arose.

6.2. Maximising questionnaire response rates

Getting adequate response rates to questionnaires can be difficult, particularly when the number of individuals who can be included in the study is limited. Research in this area suggests a number of things that can be done to maximise responses. When using online questionnaires a short, simple format (Crawford *et al.*, 2001), an introductory letter or email including details of the estimated time to complete (Porter, 2004), and emphasising anonymity (Michaelidou & Dibb, 2006), have all been found to increase response rates.

A single reminder email has been found to double response rates (Crawford *et al.*, 2001), while another study found that each additional contact, up to a maximum of four (pre-questionnaire contact, questionnaire, and two reminders), continued to yield increased response rates (Schaefer & Dillman, 1998). Acknowledging that GPs get a lot of questionnaires, and as such response rates are not always very high, Barclay *et al.* (2001) carried out a study into how to maximise GPs' response rates to postal questionnaires. They also found that response rates rose with each of three contacts (initial contact: 36.9%; first reminder: 14.9%; and second reminder: 11.4%) but that responses flattened out at this point, with another prompt yielding only 4%. Including the initial request and three additional reminders, Barclay *et al.* achieved a final response rate of 67.7%.

Web-based questionnaires have become increasingly popular due to their ability to collect a large amount of data relatively quickly, and the fact that data is automatically collated, eliminating the need for researchers to input it individually. A study by Kaplowitz *et al*. (2004) found that, in a population that knows how to use the internet and has easy access to it, a web-based survey achieves similar response rates to those delivered by mail. In addition, web-based surveys can include a message to inform users when an item has not been completed which can reduce, or eliminate, missing data (Michaelidou & Dibb, 2006). It has been suggested that using a mixed mode design, where both paper and web-based options are offered might increase respondents' motivation to complete the questionnaire (Dillman, 2007; Schaefer & Dillman, 1998).

6.3. Aim of the study

Study 2 explores the reasons for the recruitment difficulties experienced in Study 1 with a view to aiding the design and implementation of similar research in the future. In addition, the results of this study could provide guidance on how the intervention evaluated in Study 1 might be better implemented in practice.

7. Study 2 Methods

7.1. Ethical considerations

The only ethical concern identified for this study was around GP confidentiality. As a result, questionnaires were anonymous and GPs were informed of this on the questionnaire. The South of Scotland Research Ethics Committee 3 approved this amendment to the initial project (Appendix 8), as did NHS Research and Development (Appendix 9).

7.2. Participants

Initially, contact was made with the relevant person in each of the eight medical practices involved in Study 1 to inform them of this extension to the project, and to agree the method of questionnaire distribution. All practices involved in Study 1were asked to participate in the current study. Seven out of the eight practices involved agreed for the questionnaires to be distributed to their GPs. On discussion with the eighth practice (with ten GPs) it was agreed that their GPs would not to be sent the questionnaire due to difficult circumstances that they were dealing with at the time. All GPs in the seven participating practices were sent the questionnaire. These 35 GPs were considered potential participants.

7.3. Measures

The lead researcher developed a questionnaire to be completed by GPs in participating practices. The content of the questionnaire was developed based on

informal feedback from GPs, information from previous research, and guidance from a GP who had also experienced difficulties recruiting patients through GPs. As a result of feedback from GPs, and evidence from previous studies of this kind, the questionnaire was kept as short as possible. The questionnaire consisted of:

- A question asking respondents to confirm that they were a GP.
- A question asking if they knew about the project.
- A question asking them to estimate the number of people they discussed the Study 1 project with.
- Ten statements to be rated on a 5-point Likert scale from "5 - Always true" to "1-Never true".
- One free text box for respondents to identify any other issues that they thought might be responsible for the difficulty in recruiting participants.

A paper version of the questionnaire was produced (see Appendix 11) in addition to a web-based version which was put on www.surveymonkey.com. Both versions included an introduction, reminding the GPs of the project that was being referred to, and explaining why they were being asked to complete it. It also informed them that the information gathered was anonymous, and it gave an estimated completion time.

The web-based questionnaire automatically prompted GPs to complete any required questions that were missed. All questions were mandatory except the last question which asked them to identify any additional reasons for the difficulties recruiting. The web-based questionnaire kept a record of the number of questionnaires that were started, and the number that were completed.

7.4. Procedures

Contact was made with each of the medical practices involved to introduce this extension to the project and to discuss whether the web-based or paper versions, or a combination, would be preferable to GPs in their practice. Most practices favoured the web-based questionnaire, with one practice using a mixture of paper and online versions. In addition to the initial request to complete the questionnaire two additional prompts were sent to GPs asking them to complete the questionnaire if they had not already done so.

Data from completed web-based questionnaires were automatically collated. Data from paper questionnaires were transferred to the web-based survey.

7.5. Analysis

Descriptive statistics were used to analyse the results of this study due to its design. Barclay and colleagues' study of GPs had a response rate of 63% with two reminders in addition to the initial contact (Barclay *et al.*, 2001). Due to previous contact with the medical practices, and their involvement in the study, a relatively high response rate was anticipated. However taking into account sick leave, annual leave, training, or GPs being out of the office for other reasons, a response rate similar to that found by Barclay *et al*. was expected.

Information was gathered about the number of GPs who were unaware of the project. Means and standard deviations were calculated for each of the statements, with a possible range from one to five. A mean score of one suggests that all GPs felt a statement was 'never true', and a mean score of five indicating all GPs felt the

statement was ‘always true’. The percentage and number of GPs who gave each response was also calculated.

8. Study 2 Results

Twenty-two (63%) of a potential 35 questionnaires were completed and returned. All 19 surveys that were started online were completed. Of the 22 completed forms, all respondents confirmed that they were a GP and 21 (95.4%) reported that they were aware of the research project. The mean number of patients that individual GPs estimated they had introduced the project to was 2.27 (*SD*: 2.45), with a median of 1, a mode of 1, and a range of 0 to10.

Mean scores, and the number and percentage of GPs who give each score for each of the ten statements can be seen in Table 8.1.

Three statements, 8, 7 and 3, showed the highest mean scores, with means above 3 ('occasionally true'). Statement 8, suggesting that it was difficult to prioritise the study in the face of competing demands, was scored highest, with a mean score of 3.73 (*SD*: 1.4), between 'occasionally true' and 'usually true'. Over two-thirds of GPs rated this statement as either 'almost always' or 'usually true'.

Statement number 7, which proposed that GPs were very busy and forgot to offer potential patients inclusion in the project, was the next highest scoring statement. The mean score for this statement was 3.50 (*SD*: 1.10), between 'occasionally true' and 'usually true'. Almost a quarter of GPs reported that this statement was always true.

Table 8.1 Percentage (and number) of GPs giving each response (modal rating in bold) and mean score

Statement	Almost always true - 5	Usually true - 4	Occasionally true - 3	Usually not true - 2	Almost never true -1	Mean score (*SD*)
1. I did not see patients with medically unexplained symptoms	4.5% (1)	4.5% (1)	22.7% (5)	27.3% (6)	**40.9% (9)**	2.05 (1.13)
2. I do not diagnose patients with the labels given in the inclusion criteria.	13.6% (3)	22.7% (5)	4.5% (1)	27.3% (6)	**31.8% (7)**	2.59 (1.50)
3. I saw patients with MUS but they did not meet inclusion criteria.	18.2% (4)	27.3% (6)	**40.9% (9)**	0.0% (0)	13.6% (3)	3.36 (1.22)
4. I did not feel that taking part in the research project was right for the patients I saw.	4.5% (1)	13.6% (3)	**27.3% (6)**	**27.3% (6)**	**27.3% (6)**	2.41 (1.18)
5. I did not want to make extra demands on already distressed patients.	0.0% (0)	0.0% (0)	**36.4% (8)**	27.3% (6)	**36.4% (8)**	2.00 (0.87)
6. I did not think that self-help would be suitable for patients I saw.	0.0% (0)	4.5% (1)	**40.9% (9)**	31.8% (7)	22.7% (5)	2.27 (0.88)
7. I was very busy and forgot to offer potential patients inclusion in the project.	22.7% (5)	22.7% (5)	**40.9% (9)**	9.1% (2)	4.5% (1)	3.50 (1.10)
8. It was difficult to prioritise the study in the face of competing demands.	**40.9% (9)**	27.3% (6)	13.6% (3)	0.0% (0)	18.2% (4)	3.73 (1.49)
9. I think that a mindfulness approach would not be of benefit to the patients I saw.	0.0% (0)	4.5% (1)	27.3% (6)	**50.0% (11)**	18.2% (4)	2.18 (0.78)
10. I felt that raising the research could detract from the focus of the consultation.	0.0% (0)	27.3% (6)	**31.8% (7)**	18.2% (4)	22.7% (5)	2.64 (1.14)

Statement 3, suggesting that GPs saw patients with MUS but they did not meet inclusion criteria, was also a rated relatively highly with a mean score of 3.36 (*SD*: 1.22), between 'occasionally true' and 'usually true'. Nearly half of GPs rated statement 3 as 'usually' or 'almost always' true, with a further 41% reporting it to be 'occasionally true'.

Other statements showed more variation across GPs which resulted in lower mean scores. For example, GPs were split in their reported use of the diagnostic labels used in the inclusion criteria: statement 2 received a mean score of 2.59 (*SD*: 1.50), and though the majority of GPs stated that it was 'usually not' or 'almost never' true, over a third rated it as 'usually' or 'almost always' true. Similarly, while the majority of GPs (59%) rated it as 'usually not' or 'almost never' true, over 35% said that they 'occasionally' or 'usually' did not feel that taking part in the research project was right for the patients that they saw.

Despite relatively low mean scores, statements 5 and 6, relating to not wanting to make extra demands, and not thinking that self-help would be useful for patients, were most commonly rated 'occasionally true' by GPs. Furthermore, while the majority of GPs stated that it was usually not, or never true that they thought mindfulness would not be beneficial to the patients they saw, almost a third reported it to be 'occasionally' or 'usually' true.

Seven GPs provided comments about reasons for the difficulties experienced recruiting participants. No additional explanations were identified, however two patterns which support the quantitative data emerged from these comments. Some

comments emphasised the difficulties faced remembering to introduce the project when they were busy and faced other demands. Examples of this were:

> *In a busy surgery with 10 minute appointments just rarely had time to discuss.*
>
> *As GPs there's a lot to remember about different services/criteria etc and it's difficult to keep it all in your head!*

A comment about the inclusion criteria was also made.

> *Many of the MUS patients I have don't fit the diagnostic categories. It would have been helpful if these patients could have be included.*

This suggestion, that including patients with other medically unexplained symptoms might have been beneficial, also supports the quantitative findings.

9. Study 2 Discussion

9.1. Outcomes of study 2

All GPs who began the online questionnaire completed it, suggesting that the length and content of the questionnaire itself was acceptable to those who looked at it. Thirty-seven per cent of GPs did not complete the questionnaire, however, despite a total of three requests or reminders. This is consistent with one of the key results identified from the completed questionnaire: that GPs are very busy and find it difficult to remember, or to prioritise, involvement in research. The response rate is, however, comparable with previous research which also achieved a 63% response rate from an initial request and two reminders (Barclay *et al.*, 2001).

Three areas were identified as having the greatest impact on recruitment to Study 1.

9.1.1. Area 1: Inclusion criteria too limited

While GPs did see patients with MUS, those that they saw did not always meet the inclusion criteria for the project. During initial discussions with GPs about the development and evaluation of the intervention in Study 1 they suggested that specific categories -- such as irritable bowel, chronic fatigue and tension headaches -- be used in the inclusion criteria. They reported that they saw these MUS most commonly, and that such criteria would be easier to apply than a broad heading of "medically unexplained symptoms", which they thought was too loose.

Despite attempts to make recruitment to the project relatively inclusive, by recruiting patients with a range of MUS, rather than one specific diagnosis, many GPs appear

to have seen patients with MUS, but who were ineligible for the study. There are a wide range of diagnoses that are applied to MUS but many patients are not given a diagnosis. Nimnuan *et al.* (2001) found that no clear diagnosis can be given in 20-30% of primary care appointments, supporting the finding that a proportion of patients with MUS who are seen by GPs would not have met inclusion criteria for Study 1 as they would not have been given any of the labels in the inclusion criteria. There are number of reasons for this including lack of clarity about the aetiology of the symptoms, lack of treatment options, the presentation of symptoms not mapping onto any one diagnostic category, or understandable reservations on behalf of GPs about the utility of these diagnoses.

9.1.2. Area 2: GPs were busy and forget

The second area which explains some of the difficulty recruiting participants was that GPs were busy and forgot to offer potential participants inclusion in the project. Almost a quarter of GPs stated that this was almost always true of them, and the same proportion reporting it to usually be true. As a result, almost half of potential participants may have been missed as a result of this. So, despite GPs knowing about the project and being positive about involvement in it prior to implementation, the reality of a busy surgery and short consultation times appear to have been relatively widespread, resulting in not all potential participants being included. This finding supports previous research where time pressures and forgetfulness were found to be major factors in recruitment difficulties in primary care (Murphy *et al.*, 1992; Peto *et al.*, 1993).

9.1.3. Area 3: Difficulty prioritising the study

GPs found it difficult to prioritise recruitment to Study 1 given the other demands upon them, and this appears to have had a resulting impact upon recruitment rates. This ties-in closely with the second area, where GPs reported being very busy, and is consistent with conclusions drawn in previous research which identified that other things took priority ahead of recruiting for research in a busy practice (Hetherton *et al.*, 2004; Mason *et al.*, 2007). Anecdotal evidence from a GP, that GPs and medical practices were under pressure to meet targets (unrelated to MUS) during the recruitment period, and that as a result the study would not have been a high priority, also supports this finding.

9.1.4. Additional reasons for low recruitment

These three areas seem to have the most consistent impact on recruitment to Study 1, however the results suggest that other factors might also have had an impact, albeit less consistent or strong. One example of this is that GPs were split with regards to whether they used the diagnostic labels in the criteria, with a substantial minority (over 36%) indicating that they did not usually use them. This is consistent with a previous study which found that 23% of GPs did not diagnose chronic fatigue syndrome (Bazelmans *et al.*, 1999). It seems reasonable to suppose that the third of GPs who said they do not usually use the diagnostic labels would have been less likely to recruit potential patients as a result.

In addition, though not reported as consistently as the three areas outlined above, a considerable proportion of GPs: occasionally did not want to make demands on

patients; thought that the research was not appropriate for some patients; and thought that introducing the research would impact on the consultation. These findings suggest that when faced with a patient who meets the inclusion criteria GPs do not automatically introduce the research, and that many factors influence the decision of whether to do this. Akin to the conclusions drawn by Hetherton *et al.* (2004), this implies that clinical judgement is often involved when GPs are asked to recruit their patients to research, resulting in those who meet the criteria not always being offered inclusion in the study.

9.2. Numbers introduced to Study 1

An awareness of the time restraints already placed on GPs led to efforts to ensure that the level of input required by them to introduce Study 1 to patients was kept to a minimum. As such, GPs were not asked to keep a record of the patients who they gave project information packs to. This meant that there was no way of identifying how many patients were offered the packs, or what proportion of the packs given out were completed and returned. The estimation by GPs of how many patients they had introduced the project to provides a rough guide to possible numbers, however.

GPs who completed the questionnaire reported introducing the project to 2.27 patients, on average, though most GPs reported introducing the project to one, or no, patients. Based on reports by the GPs who completed the questionnaire, the project was introduced to at least 50 participants. If it was assumed that the all GPs involved in Study 1 would introduce the same number as those who completed the questionnaire for Study 2, then a total of around 102 would be expected. It seems

reasonable to assume, however, that GPs who did not respond to the questionnaire in the current study were likely to have been less involved in promoting Study 1. In addition, the practice that did not participate in Study 2 had been involved in the project later than other practices, and had experienced difficulties within the practice following implementation, making it likely that recruitment there was very low. For these reasons, while other patients may have been offered involvement in the project, it is likely that the total number of patients with whom participation was discussed was closer to 50 than the 102 noted above.

9.3. Reasons for patient non-participation

Even if one assumes that only 50 patients were introduced to the study, over two-thirds of these patients did not complete and return baseline measures. Naturally, we do not know why this is, though possible reasons include that on further discussion it became apparent that the patient was not eligible for the study; that the patient was not interested; or that they forgot to complete or return the measures. As return envelopes were addressed to *Psychological Services* another factor could be that continuing stigma and misperceptions about psychological services (Aromaa *et al.*, 2011) might have prevented patients from engaging in the project.

Another possible explanation is that some patients that repeatedly attend their GP with MUS may be focused on finding a cause or a cure, or checking that nothing else has been missed. For this population, looking at symptom management may feel like giving up. This could be tied in with the fact that, though GPs largely knew about the project and its rationale, they did not have the intervention to give or show to patients

in the consultation. It is possible that as a result of this that they lacked sufficient knowledge, enthusiasm or confidence to engage patients in the project.

High levels of depression and low mood have been identified in patients with medically unexplained symptoms (Aromaa *et al.*, 2011; Bleichhardt *et al.*, 2004; Escobar *et al.*, 1998) and the low motivation and self-efficacy often experienced by such conditions may make it hard to opt in to, and then complete, a self-help intervention without more active guidance. Study 1 found that none of the participants who scored above the clinical cut-off for moderate depression at baseline completed follow-up measures. In addition to influencing completion of the intervention it is likely that higher levels of depression might also influence initial participation in such studies.

9.4. Implications for future research

The MBSR self-help intervention was initially developed out of a perceived need within primary care, identified both by GPs and patients with MUS. Study 1 tried to evaluate the MBSR intervention in an ecologically valid way, however the difficulties experienced recruiting participants like this limited the conclusions that could be drawn. Findings from this study suggest that the time and role demands placed on GPs make it very difficult for them to remember and to prioritise the recruitment of patients to research, even when their role in the study is kept to a minimum. In addition, it appears that GPs can be caught between their roles as a clinician and as a recruiter to research, and that their clinical judgement can play an important role in whether or not patients are recruited to research studies.

One possible way to avoid these issues of GPs' limited time and decision making impacting on recruitment in future research would be to run detailed searches of practice databases to identify potential participants, and contact them directly rather than GPs trying to remember during routine consultations. However, a limitation with this alternative method, as evidenced in this study, is that around a third of GPs do not regularly use the diagnostic labels used in the inclusion criteria, and even those that do use these terms might not code them as such. As a result patients with diagnoses used by the current study (such as fibromyalgia) would be difficult to identify through this type of search.

An alternative option would be to pilot the intervention in a different way, initially, in order to evaluate its efficacy under more optimal circumstances prior to evaluating its effectiveness in primary care. This could be done by enrolling participants through support groups or related organisations. Though this would not provide results that could be generalised directly to clinical practice, greater information about any potential benefits could better inform more ecological studies in the future. Alternatively, the intervention could be evaluated within a guided self-help framework where participants would be introduced to the intervention by a practitioner who could provide on-going engagement, motivation and guidance – something that GPs are not in a position to offer. The direct patient contact involved in such a guided self-help model would provide the opportunity for more direct and detailed feedback from patients, which could be used to adapt and refine the intervention.

In addition, though guidance was sought from patients with MUS during the development of the self-help intervention, the extent of this was limited and more in-depth investigation into what patients with MUS want, and how they view symptom management, would benefit this area of clinical research greatly. A qualitative study exploring these areas could provide a clearer basis for developing and evaluating this, and other, interventions in the future. Furthermore, studies recruiting participants in a similar way to Study 1 would benefit from asking patients who were introduced to the project, but did not participate, why this was. This could help in the development and modification of interventions which are not only effective, but also acceptable to patients with MUS.

9.5. Implications for practice

The difficulties faced by GPs in recruiting participants to Study 1 raised questions about whether GPs would give patients the intervention in practice, if they had it to offer patients outside the constraints of a research project, or if they did not see the benefits of the intervention for the population. The findings of this study suggest that the recruitment difficulties were not due to GPs being opposed to the intervention, but instead were largely to do with having limited time, and struggling to prioritise or remember to introduce the project. While having the ability to look at and show patients the booklet and CD might make GPs more likely to offer the intervention, it could also be beneficial to provide information and reminders to GPs about such interventions when they are introduced into practice.

9.6. Limitations of the study

The questionnaire was designed to be short enough for GPs to be likely to complete it. While this seemed successful, with all GPs who started the online questionnaire completing it, it did mean that the number of questions was limited and more detailed reasons for the difficulties could not be established. For example, the findings of the current study suggest that recruitment is impacted on by other demands on GPs, but we cannot unpick what types of demands these were. Additionally, though some statements were rated more highly than others, a definite causal relationship between these findings and difficulties recruiting cannot be made.

It is also important to keep in mind that GPs were providing reasons after the event and that there is the potential for bias in terms of memory, desirability of response and in those who opted to respond. GPs who did not engage with Study 1 are likely to be under-represented amongst those who completed the Study 2 questionnaire, and the reasons for their non-participation in Study 1may differ from those given by the current respondents.

The study also focuses solely on the difficulties identified from GPs' perspectives. While potential reasons for limited uptake by patients were considered there was no direct input from patients in these considerations.

9.7. Conclusions

This study suggests that there were three main issues which played a relatively consistent role, across GPs, in hindering the recruitment of participants to Study 1. These included being busy and forgetting, finding it difficult to prioritise the

research, and seeing patients who had MUS but who did not fit the inclusion criteria. In addition, there was evidence that GPs might not have introduced the study to patients as their role as a clinician took priority over their role in the research. Recruiting participants through GPs in this way is, therefore, not ideal. As a result, alternative methods of recruitment for this type of study, through support groups or other relevant organisations for example, should be considered. This would mean that the efficacy of interventions, such as the self-help MBSR intervention outlined in Study1, could be evaluated prior to seeking to determine effectiveness.

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11. Appendices

Appendix 1. Systematic review excluded studies & quality criteria scoring guidelines

Appendix 1a. Table of studies excluded at second screening and reason for exclusion

Study	Reason for exclusion
Asare et al. (2011)	Journal letter
Astin et al. (2003)	MBSR not sole intervention (also Qigong movement therapy)
Ernst et al. (2007)	No English version available
Fjorback et al. (2011	Published conference abstract
Gaylord et al. (2011a)	Published conference abstract
Kearney et al. (2010a)	Published conference abstract
Kearney et al. (2010b)	Published conference abstract
Kearney et al. (2011)	Published conference abstract
Pauzano-Slam (2005)	Thesis - could not be sourced and author could not be reached
Surawy et al. (2005)	MBSR not sole intervention (combined with MBCT)
Weissbecker et al. (2002)	Not an outcome study
Zernicke et al. (2011)	Published conference abstract

Appendix 1b. Quality criteria scoring guidelines

i. Eligibility criteria are specified	
Well-covered (2)	Inclusion criteria clearly detailed
Adequately addressed (1)	Inclusion criteria are not outlined clearly, though they can be ascertained from the details given.
Poorly addressed (0)	Some information is given about eligibility for the trial, though it could not be confidently replicated.
Not addressed (0)	
Not applicable (0)	

ii. Patients are recruited in a clinical setting	
Well-covered (2)	It is clear that patients have been recruited in a clinical setting and all (or random sample of) eligible potential participants were invited.
Adequately addressed (1)	Patients recruited in a clinical setting but potential bias in those approached that wasn't part of inclusion/exclusion criteria.
Poorly addressed (0)	Patients recruited in a clinical setting but clear bias in those approached that was not part of inclusion/exclusion criteria.
Not addressed (0)	Not recruited in a clinical setting
Not applicable (0)	

iii. A control group is used	
Well-covered (2)	A suitable control group is carried out alongside the experimental intervention group. This could be a TAU, waiting list or an active control group.
Adequately addressed (1)	An alternative intervention group is included but no control group.
Poorly addressed (0)	
Not addressed (0)	
Not applicable (0)	

iv. At least 1 of the therapists was experienced or trained in teaching mindfulness	
Well-covered (2)	Evidence provided to show that at least one of the trainers was experienced or trained in teaching mindfulness (yrs experience etc)
Adequately addressed (1)	It is stated that one of the therapists is experienced or trained in mindfulness but no evidence is given to support this.
Poorly addressed (0)	Some information about the therapist's experience given but does not suggest 'experienced'.
Not addressed (0)	No description of the therapist's experience is given.
Not applicable (0)	

v. Measures of psychological distress are robust	
Well-covered (2)	Outcome measures robust for this population (valid, reliable - HADS, etc.)
Adequately addressed (1)	Outcome measures acceptable validity/psychometrics, or good robustness but not the most valid for this population. (GSI of SCL-R-90/BDI etc)
Poorly addressed (0)	Outcome measures poorly described and less robust.
Not addressed (0)	
Not applicable (0)	

vi. Similar levels of psychological distress at baseline	
Well-covered (2)	Clear details of differences in psychological distress at baseline, between groups. Sufficiently alike or controlled.
Adequately addressed (1)	Reasonable detail of psychological distress measure between groups, and somewhat alike at baseline.
Poorly addressed (0)	Measured but limited description, poorly alike at baseline.
Not addressed (0)	
Not applicable (0)	

vii. The intervention is both sufficiently defined and delivered as planned (i.e. demonstrates good fidelity).	
Well-covered (2)	The intervention is clearly outlined and shows good treatment fidelity – could be replicated.
Adequately addressed (1)	Some detail about the intervention, evidence of alteration of intervention from its original form.
Poorly addressed (0)	Unclear definition of the intervention and its fidelity.
Not addressed (0)	
Not applicable (0)	

viii. The assignment of subjects to treatment and control groups is randomised	
Well-covered (2)	Randomisation is clearly described using an appropriate method
Adequately addressed (1)	It is stated that randomisation is carried out, but no explanation of method.
Poorly addressed (0)	Randomisation is stated, but not using appropriate method.
Not addressed (0)	
Not applicable (0)	

ix. Sample size adequate for analyses	
Well-covered (2)	The number of participants who completed pre- and post-intervention measures was sufficient to enable Power of at least 0.8 for simple main effects (uncontrolled trials) and interaction effects (where 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Adequately addressed (1)	The number of participants who completed pre- and post-intervention measures was sufficient to enable Power of at least 0.7 for simple main effects (uncontrolled trials) and interaction effects (where 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Poorly addressed (0)	The number of participants who completed pre- and post-intervention measures did not enable Power of at least 0.7 for simple main effects and interaction effects (where there are 2+ groups). Effect size was anticipated to be medium and alpha was 0.05.
Not addressed (0)	
Not applicable (0)	

x. Levels of attrition are reported, acceptable, and equivalent for treatment versus control	
Well-covered (2)	Levels of attrition (from allocation to group to completion of post intervention measures) are clearly detailed for both treatment and control groups (where present) and are sufficiently alike between conditions (within 10% of each other and less than 20% of total participants)
Adequately addressed (1)	Reasonable description of attrition (from allocation to group to completion of post intervention measures), somewhat alike between conditions (within 20% of each other), less than 30% of total participants.
Poorly addressed (0)	Poorly described (lacking specifics), or significantly different between conditions.
Not addressed (0)	Not described
Not applicable (0)	

xi. The intervention is evaluated for an appropriate duration	
Well-covered (2)	Follow-up carried out for a minimum of 3 months (must include psychological distress measure)
Adequately addressed (1)	Follow-up carried out for a minimum of 1 month (must include psychological distress measure)
Poorly addressed (0)	Follow-up less than one month
Not addressed (0)	No follow-up
Not applicable (0)	

xii. Appropriate analysis	
Well-covered (2)	Analysis described sufficiently to determine that analyses conducted appropriately at post-intervention - appropriate statistics used, ITT where there is attrition.
Adequately addressed (1)	Reasonably clear that appropriate analysis carried out at post-intervention - appropriate statistics used, ITT where there is attrition – maybe lacking in clarity/detail about.
Poorly addressed (0)	Inappropriate analyses or not addressing attrition, where relevant, at post-intervention.
Not addressed (0)	
Not applicable (0)	

Appendix 2. Author guidelines for Psychosomatic Medicine

Manuscript formatting: Electronic manuscripts should be formatted so text is double-spaced (including references and tables) on 8 1/2"x 11" paper size. When submitting a manuscript, describe in a brief cover letter the paper's objectives and significance. The editor welcomes, but is not bound by, suggestions for possible peer reviewers.

On the cover page, include the title, full names of author(s), with degrees and academic or professional affiliations, and the complete address, telephone number, fax number, and e-mail address of the author to whom proofs and correspondence should be sent. Indicate the total number of words contained in the manuscript, and the number of tables and figures; the word count should include the body of the paper, the references and the tables. If the title exceeds 45 characters, supply an abbreviated running title of fewer than 46 spaces. Indicate whether the work was supported by the National Institutes of Health; Wellcome Trust, Howard Hughes Medical Institute, or others. If no support was received, please indicate that as well. Potential conflicts of interest should also be reported. Number pages consecutively beginning with the abstract page. Manuscripts should be no longer than 6,500 words.

Abstract: All papers should include a brief initial abstract of not more than 250 words followed by up to 6 key words for indexing. Abstracts should be submitted in outline format, using the bolded headings of Objective, Methods, Results, Conclusions, and, if applicable, Trial Registration. After the

keywords, list all acronyms used in text, e.g., DBP = diastolic blood pressure; BMI = body mass index.

Tables and Illustrations: Tables should be double-spaced, including all headings, and should have a descriptive title. Each table should be numbered sequentially in Arabic numerals and begin on a new page. When preparing tables, if appropriate to the data, include the number of subjects, the statistical tests or estimation techniques used, p values, and some measure of variability (standard deviations, standard errors or confidence intervals) for any estimates (e.g., means, differences, proportions) presented. For figures, please do not use three-dimensional graphs for two-dimensional data.

For line artwork, submit high-resolution digital files, 1200 dpi (please, no screens behind graphs). Please do not embed digital art in Microsoft Word or other word-processor files. For publishing, we require TIFF, EPS, or PowerPoint files. A separate sheet of legends for illustrations should be included. Authors wishing to use color figures will incur a fee to defray the associated printing costs. For further graphical details, seehttp://cpc.cadmus.com/da/guidelines.asp.

References and Footnotes: In the text, citation of references is by full-sized numbers in parentheses. Footnotes to the text are indicated by Arabic numeral superscripts numbered consecutively throughout the paper and placed at the foot of each page on which they are cited. List references in the order cited in the text. Number references consecutively, using Arabic

numerals. References should be typed double-spaced and placed at the end of the text beginning on a separate page. List all authors; do not use "et al." The reference list should not include personal communications or manuscripts submitted but not accepted for publication. References should be styled as follows:

Book: Tomb DA. Psychiatry. 5th ed. Baltimore: Williams & Wilkins; 1994.

Edited Book: Gorman JR, Locke SE. Neural, endocrine, and immune interactions. In: Kaplan HI, Sadock BJ, editors. Comprehensive textbook of psychiatry. vol 1. 5th ed. Baltimore: Williams & Wilkins; 1989. p. 111-25.

Journals: Irvine J, Baker B, Smith J, Jandciu S, Paquette M, Cairns J, Connolly S, Roberts R, Gent M, Dorian P. Poor adherence to placebo or amiodarone therapy predicts mortality: results from the CAMIAT study. Psychosom Med 1999;61:566-75.

Periodical abbreviations should follow those given by Index Medicus. Correct journal abbreviations can be found by searching at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=journals

Upon acceptance of an article, authors will be asked to transfer copyright to the American Psychosomatic Society to ensure the widest possible dissemination of information under the U.S. Copyright Law. After acceptance, manuscripts are forwarded to the publisher, and questions regarding publication, reprints, proofs, etc. should be addressed to LWW. The

corresponding author receives proofs within several weeks of acceptance.

Corrections should be to the publisher within 48 hours of receipt.

Appendix 3. South of Scotland Research Ethics Committee 3 ethical approval

Lothian NHS Board

South East Scotland Research
Ethics Committee 03
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
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www.nhslothian.scot.nhs.uk
Date
Our Ref
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Direct Line 0131 465 5674
Email joyce.clearie@nhslothian.scot.nhs.uk

17 November 2011

Mrs Sarah McLaren
Trainee Clinical Psychologist
NHS Borders
12/14 Roxburgh St
Galashiels
TD1 1PF

Dear Mrs McLaren

Study title: **The development of a mindfulness-based self help booklet for those presenting with medically unexplained symptoms, and its evaluation using a randomly controlled trial measuring patient wellbeing and GP attendance.**

REC reference: **11/SS/0084**

The Research Ethics Committee reviewed the above application at the meeting held on 16 November 2011. Thank you for attending to discuss the study.

Ethical opinion

This study aims to look at the effectiveness of a self-help booklet for people with symptoms with no medical explanation. This research aims to develop and evaluate a self management booklet to investigate if such resources could reduce the impact of these symptoms on patient wellbeing and the economic impact on the NHS. A mindfulness based stress reduction (MBSR) focus will be used in the booklet as it has proved useful with other medical symptoms and as such might be more acceptable to patients who might reject more overtly psychological therapies. Potential participants will be identified by their GPs and given a pack including a booklet of baseline

questionnaires measuring symptoms, mood, quality of life and mindfulness. Participants who return the consent form and questionnaire will then be randomised to either the intervention group or treatment as usual group. The intervention group will receive the self help pack which will outline an 8-week mindfulness-based intervention. Measures will be sent to both groups following the eight week intervention phase and again at three and twelve month follow-up. In addition information about GP attendance in the six months prior to intervention and in the three and twelve months post intervention will be gathered. In discussion, the Committee noted the following ethical issues. It was noted that an earlier version of this study had previously been given an unfavourable opinion by WoSRES. The Committee felt that the researcher had adequately addressed the issues raised by that committee. The researcher was asked to clarify her recruitment procedure and she confirmed that participants would be recruited by their GPs. The Committee raised some concerns over a methodological issue in that potential for study results to be biased by the additional care and attention participants would receive through participating in this study rather than benefits of MBSR booklet. The researcher was asked to clarify what was meant by reference in information sheet to follow up measures and she explained this.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

[Other conditions specified by the REC]

- Where appropriate, letters should be addressed to named person rather than 'Dear Sir/Madam'
- Unreturned reminder letter. New second sentence to include statement along the lines of - apologies if you have sent questionnaire in last few days.
- Check and ensure where appropriate that the correct NHS Borders details are given throughout the documentation e.g. Replace contact details of Lothian Complaints Department with Borders Complaints Department
- Remove inappropriate researcher signature section at bottom of consent form
- Self-Help Booklet - Reword last sentence page 18 - *..then let go of meal*
  - Do final typographical check of compete document. For example
  - Page 19 typo should read lie down.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Investigator CV	CI	11 August 2011
Investigator CV	Academic supervisor	20 July 2011
Letter of invitation to participant	1.2 Baseline pack letter	01 November 2011
Other: Letter Pack1 Letter sent with booklet	1.2	01 November 2011
Other: Letter questionnaire Letter sent with ?	1.2	01 November 2011
Other: Letter TAU arm	1.2	10 August 2011
Other: Letter to unreturned	1.2	01 November 2011
Other: Mindfulness Booklet	1.1	01 November 2011
Other: Copy of unfav opinion letter		07 October 2011
Participant Consent Form: PCF	1.2	01 November 2011

Dr Christine West
Chair

Email: joyce.cleanie@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Ms Gemma Watson*
Dr Tom Cripps, Clinicla Governance Support Team - NHS Borders

South East Scotland Research Ethics Committee 03

Attendance at Committee meeting on 16 November 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Tan Chee-Wee	Lecturer in Physiotherapy	No	
Dr Jan Gill	Senior Lecturer in Physiology and Pharmacology	Yes	
Reverend Denise Herbert	Rector	Yes	
Ms Joanne Mair	University manager	No	
Ms Karen Mathews	Nurse	Yes	
Mr Hugh Olson	Lawyer	No	
Mr Alec Richard	Researcher	Yes	
Dr Derek Santos	Lecturer and course leader (research methods)	No	
Dr Kevin Smith	Lecturer	Yes	
Mr Warwick Taylor	Retired	Yes	
Mrs Anne Tod	Retired	Yes	
Dr Christine West	Gynaecology	Yes	
Mrs Louisa Wilson	Senior Research Monitor	Yes	
Mrs Helen Margaret Wright		Yes	
Mr Vipin Zamvar	Cardiothoracic Surgeon	No	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Alex Bailey	Scientific Officer
Ms Joyce Cleanie	Coordinator

Appendix 4. NHS Borders Research & Development Committee approval

NHS Borders

Research Administration
Clinical Governance

Mrs Sarah McLaren
NHS Borders
12-14 Roxburgh Street
Galashiels
TD1 1PF

Clinical Office
Borders General Hospital
Melrose
Roxburghshire TD6 9BS

Telephone 01896 826719
Fax 01896 826040
www.nhsborders.org.uk

Date 29/12/2011

Our Ref 11/BORD/17

Enquiries to Joy Borowska
Extension 01896 826717
Email
research.governance@borders.scot.nhs.uk

Dear Mrs McLaren

11/BORD/17 Self help booklet for symptoms with no known medical origin

Thank you for sending details of your study to NHS Borders. I can confirm that the Research Governance Committee has reviewed the documentation, and on this basis I am pleased to inform you that this study has management approval for commencement within NHS Borders.

It is a condition of approval that everyone involved in this study abides by the guidelines/protocols implemented by NHS Borders with respect to confidentiality and Research Governance. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek advice if you are unsure.

Please advise the R&D Office immediately of any changes to the project such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Borders. Please also advise the R&D office when recruitment has been completed and when the study has been fully completed.

Amendments to the protocol will require approval from the ethics committee that approved your study. Please inform this office when recruitment has closed and when the study has been completed. Please quote the reference number stated above in all correspondence.

May I take this opportunity to wish you every success with your project? Please do not hesitate to contact the R&D Office should you require any further assistance.
Yours sincerely

Thomas Cripps
Associate Medical Director (Clinical Governance)
CC NRSCC

Appendix 5. The University of Edinburgh Clinical Psychology training programme methodological approval

UNIVERSITY OF EDINBURGH / NHS SCOTLAND

CLINICAL PSYCHOLOGY TRAINING PROGRAMME

FEEDBACK SHEET FOR THESIS PROPOSAL FORM (Not R1)

(Please Note that this is <u>not</u> the form for the Research 1 Assessed Thesis proposals)

Marker: Ethel Quayle Date Marked:30.10.11

Trainee: Sarah Miller

Proposal Title: The evaluation of a mindfulness-based self-help booklet for those with medically unexplained symptoms in primary care.

COMMENTS ON PROJECT VIABILITY

Please provide feedback on potential risks to the project, the ways in which these may be addressed and any recommended or required changes to the project. Please ensure that it is clear which (if any) changes are required.

The proposal provides an extensive review of the relevant literature which provides a good justification for the proposed research. The research hypotheses and methodology is clearly outlined. Using GP attendance is clearly one way of looking at the impact on health-related behaviours, but it might be useful to discriminate between attendance because of MUS symptoms and attendance for other reasons? For example, if the participant and fallen on ice and broken their leg they might have a high number of appointments but these would not be related to MUS. I am not clear from the proposal how you ascertain if the self-help package has been used or whether any improvement might be related to other factors, such as change in medication? Information given about sample size and proposed analysis is clearly presented, along with the rationale for achieving this. This is a well-presented and interesting proposal.

MARKER'S RECOMMENDATION FOR PROJECT (PLEASE CIRCLE ONE OPTION BELOW):

1. The project should proceed in broadly its current form √
2. The project should proceed broadly in its current form subject to outlined revisions (these should be clear from feedback above)
3. The project should not proceed in its current form and should be reviewed further by the Research Committee

Appendix 6. Participant information pack

Appendix 6a: Participant information sheet

Participant Information Sheet

Self-help booklet for symptoms with no known medical origin

Contact details: 12/14 Roxburgh Street, NHS Borders, Galashiels, TD1 1PF.
Tel.: 01896 668821 Email: sarah.mclaren@borders.scot.nhs.uk

You are being invited to take part in a research study. Before you decide whether you would like to take part, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information and discuss it with others if you wish. You may also want to ask the researcher questions about the study before you decide whether you wish to take part.

What is the aim of the study?
We know that there are many people who suffer from symptoms where a medical cause has not been identified, despite thorough investigation. There is evidence that mindfulness based stress reduction is a programme which can help people manage symptoms of illness and pain, including those where a medical explanation has not been found. Self-help has also been found to be beneficial to those with similar symptoms. This study aims to look at the effectiveness of a self-help booklet for people with symptoms with no medical explanation, both for the patient and as a cost to the NHS.

Why have I been chosen?
You have been asked if you would like to participate as your GP has carried out thorough investigation of your symptoms and has not identified a medical explanation for them.

Do I have to take part?
No. It is entirely up to you whether you would like to take part in this study. If you decide to take part you should complete the consent form and questionnaire enclosed and return it them in the envelope provided. You will be free to withdraw at any time and without giving a reason.

What would be involved if I choose to take part?
If you choose to take part in this study, you will be asked to complete a questionnaire. The questionnaire will ask you questions about your symptoms, how you have been feeling, and about your view of your symptoms. It will take approximately 10 minutes to complete. Once you have completed the consent form and the questionnaire, you will be asked to return them to the researcher in the pre-paid envelope enclosed in the pack.

Participants will then be randomly allocated either to the intervention group, who will be sent the booklet which outlines an eight week self-help intervention, and the "treatment as usual" group. After eight weeks, all participants will be sent a second questionnaire, which will be similar to the one already completed, and asked to complete this and return this in the pre-paid envelope enclosed.

All participants will receive follow-up measures after another three months, and those in the intervention group will receive a final set 12 months after the end of the intervention. Participants in the "treatment as usual" group will be sent the booklet after the three month follow-up measures have been completed.

Will the information I give you be confidential?
All the information collected in the study will be kept in the strictest of confidence by the researcher, who is bound by the same duty of confidentiality as your GP. Participant names and addressed are needed so that packs can be sent out, and so information

regarding attendance at GP can be gathered from medical records. Data gathered will be anonymised, however, so that no one will be identifiable from the data or final report.

The information will not be shared with anyone else involved with you. If you have any questions about this aspect of the study, please feel free to contact the researcher.

What are the possible disadvantages or risks of taking part?
It is not thought that there are disadvantages to taking part in this study other than the time that is required to complete the questionnaires, and putting the self-help booklet into practice.

What are the possible benefits of taking part?
The aim of the study is to get information that may help us to provide better support for those who have often very distressing and disabling symptoms that have no medical explanation. This may not have an immediate benefit for you but may benefit others in the future. The information will help us find out if more research needs to be done in this area, and to see if new services need to be set up to help people with similar symptoms get the support that they need to manage them.

Can I get feedback about the study findings?
Once the research study is finished, we would like to give you the chance to find out what we have learned. If you would like to receive feedback about the study please contact us and we will send you a broad outline of the study's findings, or they will be made available online.

What will happen to the results of the study?
The researcher will write up the results of the study as part of her doctoral thesis. We also hope to publish the results of the study in a specialist mental health journal. The findings of the research will also be shared with GPs so that they may be able to better support people with medically unexplained symptoms. No one participating in the study would be able to be identified in the results or publications arising from this research.

Who has reviewed the study?
The study proposal has been reviewed by Ethel Quayle at The University of Edinburgh. A favourable ethical opinion has been obtained from South East Scotland REC. NHS management approval has also been obtained.

If you have any further questions about the study please contact Sarah McLaren on: 01896 668821 or email: sarah.mclaren@borders.scot.nhs.uk

If you would like to discuss this study with someone independent of the study please contact: April Quigley on 01896 668821

Thank you for taking the time to read this information sheet and for considering whether you would like to take part.

Yours sincerely,

Sarah McLaren

If you wish to make a complaint about the study please contact:
Complaints Officer, NHS Borders, Borders General Hospital, Melrose, TD6 9BS.
Telephone: 01896 82671

Version 1.4, 19/12/11

Appendix 6b: Patient introduction letter

12/14 Roxburgh Street
NHS Borders
Galashiels
TD1 1PF

01896 668821

Dear Sir/Madam,

Thank you for your interest in this research project. You should find enclosed an information sheet about the project which will explain what would be involved in participating.

When you have read the information sheet, if you would like to be involved in the project please complete the consent form and questionnaire and post them back to me in the enclosed envelope. If you have any questions or concerns about the project, please do not hesitate to contact me on the number above.

Thank you again for your time.

Yours faithfully,

Sarah McLaren

(Lead researcher)

Appendix 6c: Consent form

Consent form

Self-help booklet for symptoms with no known medical origin

Please tick each box to confirm you have read and agree, and sign and date below:

- I confirm that I have read and understand the information sheet dated 10/08/11 for the above study. ☐
- I have had the opportunity to consider the information, ask questions And have had these answered satisfactorily. ☐
- 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. ☐
- I understand that relevant sections of my medical records and data collected during the study may be looked at by responsible individuals from Edinburgh University where it is relevant to this research. I give permission for these individuals to have access to my records. ☐
- I agree to take part in the above research study. ☐

Signature: _____ Date: _____

Name: _____

Address: _____

_____

_____

_____

If you agree to the above, please sign your name and fill in your name and address on this sheet and return alongside your completed questionnaire.

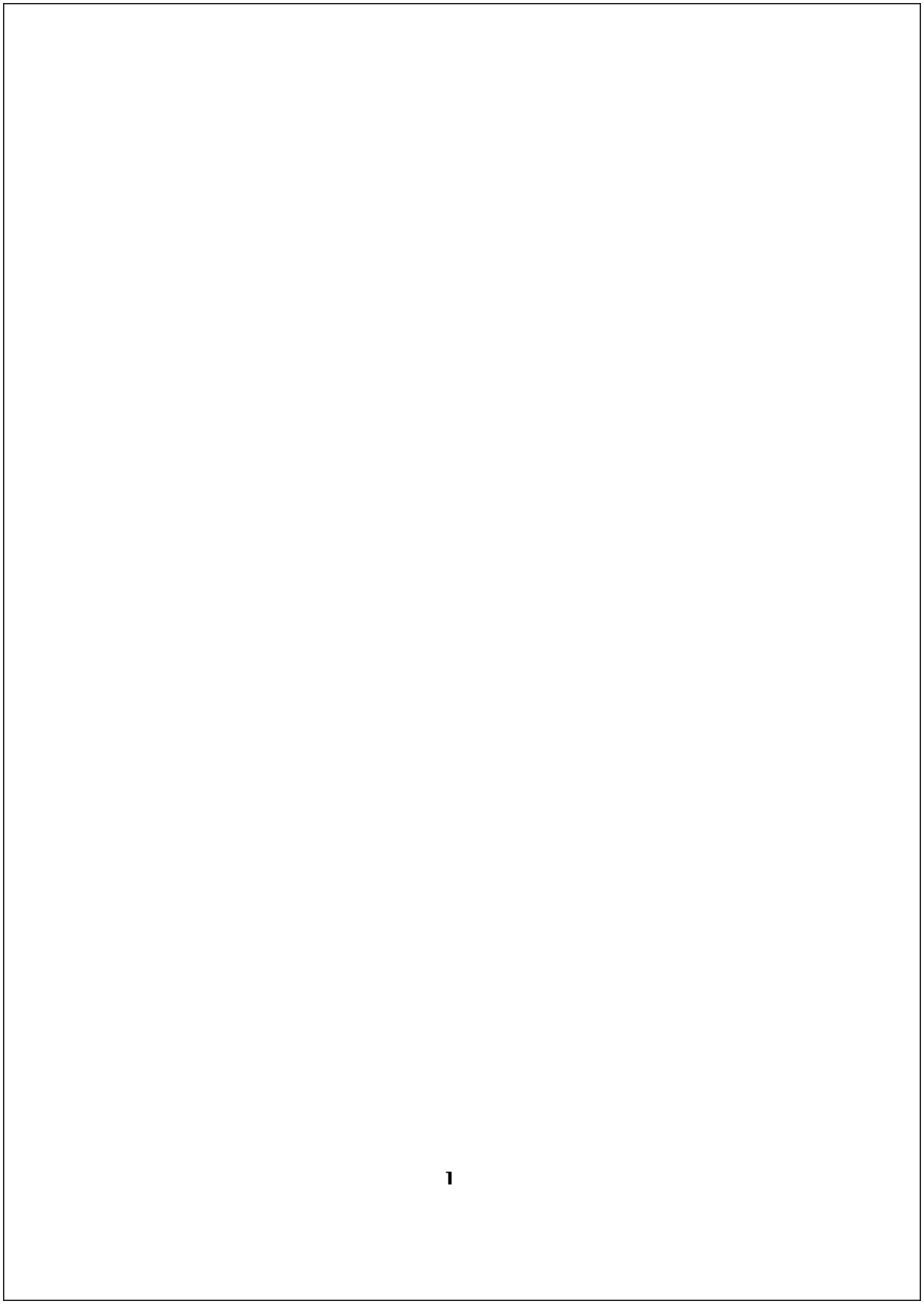
Appendix 7. Intervention booklet

Helping you control your symptoms
Instead of them controlling you

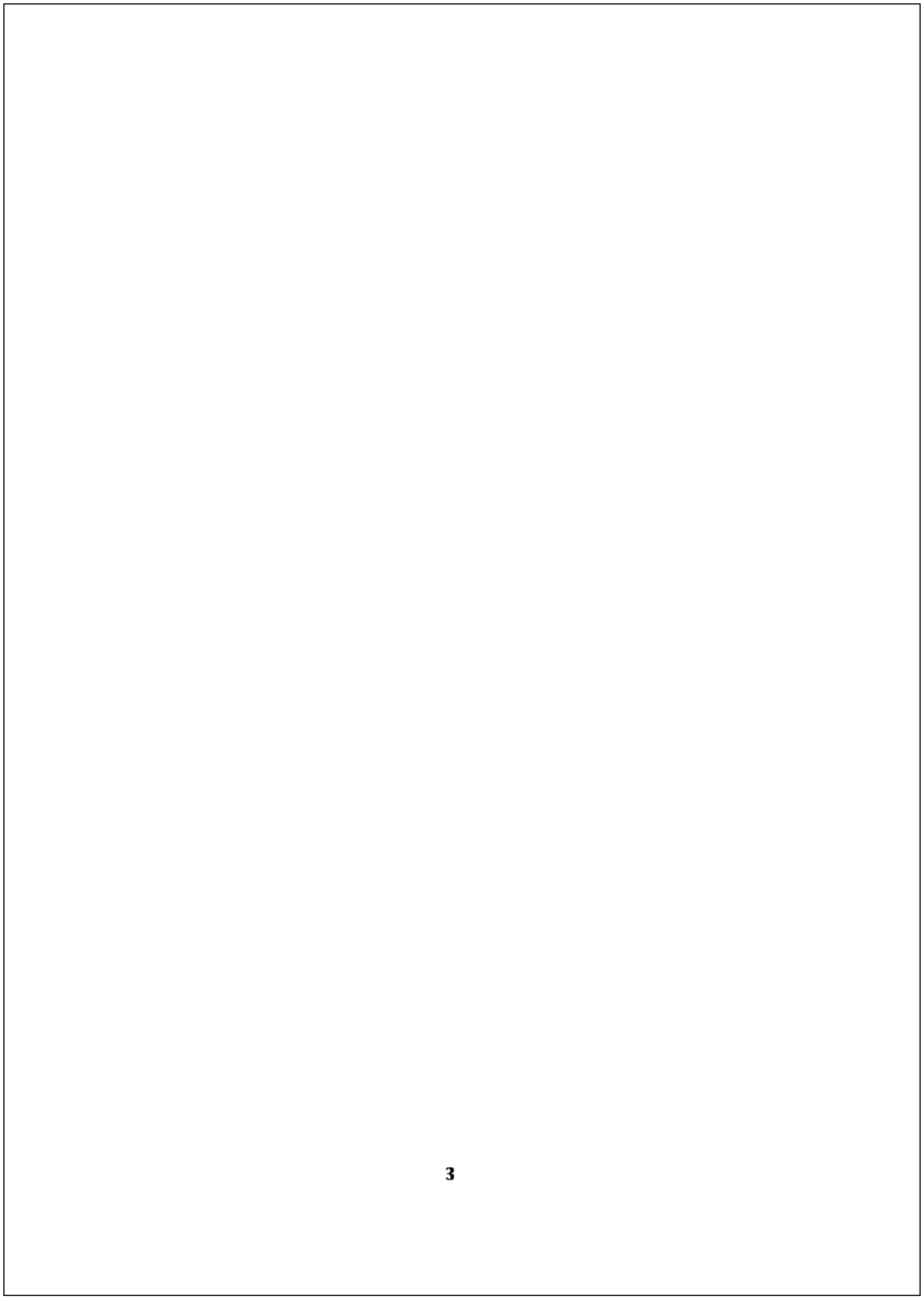
A mindful way towards managing physical symptoms

Self-help booklet for symptoms with no known medical origin

Version 1.3, 11/01/12



Contents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Introduction to Mindfulness

Many people experience physical symptoms that can not be explained by a specific underlying cause. These symptoms are very real, and can have a major effect on a person's life, health and wellbeing. It is thought that 10% of the general population has some sort of ongoing physical symptom. In fact, studies show that a third of the time, when a patient seeks medical care, a cause for their concerns is not found.

These types of problems can be present even though there is no clear damage or disease. Such symptoms are often due to a complex interaction between physical factors, social factors and stress.

Regardless of the cause of your symptoms, this booklet will focus on helping you manage them through the introduction and practice of mindful awareness. Though its aim is not to cure your symptoms, it offers another way of coping with symptoms.

How to use this booklet

There are five steps in the booklet and it is suggested that you spend one or two weeks practicing each step before progressing. Each step introduces new techniques or methods to facilitate mindfulness. You may find that some are more difficult to engage with than others, though please try each one for at least a week or two. Many people discover that techniques which seemed difficult, odd or annoying initially actually become helpful or relaxing and valuable over time.

After reading this Introduction to Mindfulness section, begin with Step One (on page 8) and continue through the five steps over a period of around eight weeks.

What is mindfulness?

Mindfulness involves continually bringing your awareness back to what is going on right now whenever we get caught up in thoughts about the past, the future or into fantasy. It sounds easy but it takes more practice than you might think!

We spend much of our time on "automatic pilot," with our thoughts compulsively following habitual patterns that may reinforce distressing emotions. Mindfulness begins when we recognise our tendency to be on automatic pilot, trying to be aware and "in the moment."

Mindfulness can be brought to many objects of awareness including the body, breathing, emotions, thoughts and the sensory world around us. It can help us manage and appreciate emotions for what they really are - fleeting, changing and subject to our attitudes, which are often formed by external influences.

With mindfulness practice we can find a way not to be constantly distracted and pulled away from our experience, which can be rewarding.

Why might it be useful for me?

Physical symptoms are often annoying, causing discomfort and pain. However, how we respond to the symptoms impacts on our experience of them, with some of the distress that we experience being connected to our thoughts about them rather than the symptoms themselves.

Research has found mindfulness-based stress reduction to be helpful for managing symptoms both where a clear medical cause has been identified, and where it has not. This self-help booklet is based on this approach, aiming to help you develop skills to cope with your symptoms.

Mindfulness helps you to accept the symptoms that are there, while expanding your awareness of the areas that are not affected by your symptoms. Mindfulness does not look to get rid of symptoms. Instead it helps you to cope differently, and to reclaim parts of your life and experience that your symptoms have overshadowed.

The following exercises help by, rather than fighting against thoughts or becoming involved with them, getting you to sit back and "observe" them as if from a distance. As you observe them, you might find the thoughts about your symptoms becoming less stressful and as a result they can become more manageable.

Others have found that keeping a note of practice, and thoughts or reflections that arise from practice, can be helpful so notes pages have been included for your own use.

Tips for practice

According to Jon Kabat-Zinn, who developed the mindfulness based stress reduction programme, there are 7 attitudes with which to approach mindfulness. These attitudes are central to the practice of mindfulness and are helpful to keep in mind while carrying out your mindfulness practice.

- Non–judging: Become aware of whatever you are experiencing as it is, rather than categorising it as good or bad, like or dislike. Whatever your experience, just bring awareness to it.
- Patience: Change takes time. Promote your capacity to be patient.
- Beginner's mind: Allow yourself to be a beginner rather than an expert. 'In the beginner's mind there are many possibilities, in the expert's mind there are few.'

- Trust: Have confidence in the practice of mindfulness and in your inner self to guide you. Maintain an attitude of openness and curiosity.
- Non-striving: Do not struggle to experience anything different from what you are feeling, just let yourself to experience whatever your experience is.
- Acceptance: Acceptance doesn't mean resignation. Mindfulness is about accepting how you feel right now, rather than denying it. Acceptance first and then, later, change.
- Letting go: You don't need to try and hold on to pleasant experiences and push away unpleasant experiences. Let go of expectations, thoughts, judgments – they are all thoughts – just let them go.

Common frustrations

When beginning mindful practice, it is common to experience some, or all, of the following:

- Boredom
- Frustration
- Sleepiness
- Becoming disheartened that "goals" of practice (often developed unknowingly) have not been met.

These are all normal things to experience when beginning mindfulness practice. Try to adopt a non-judgemental, non-striving attitude. Thoughts like this can in fact be included in practice - for example, noticing them as judging thoughts and letting them go before returning awareness to the focus of the exercise.

Remember - be gentle with yourself and be aware of your limitations. If difficult emotions or thoughts come up while doing the following exercises speak to a friend, family member or your GP.

Step 1 (Weeks 1-2): Starting to become mindful

- Carry out the One minute breathing exercise (page 9) at least once a day (but more often if you can).
- Do the 10 minute Seated mindfulness exercise (page 10-11) with the attached CD or script every other day.
- Choose one routine mindful activity in your daily life and make a deliberate effort to bring moment-to-moment awareness to that activity each time you do it. This could be brushing your teeth, having a shower or washing the dishes.

  Simply focus in on knowing what you are doing as you are actually doing it.

If you are unable to do an exercise at any time, do not to worry about it. Just continue from where you are, or if you are unable to do one type of exercise (e.g. due to disability), simply substitute this with one of the other exercises.

Keep a record of your mindfulness practice on the "My notes on Step one" section on page 12. Note down any thoughts or reflections in the relevant box when you have carried out the exercise.

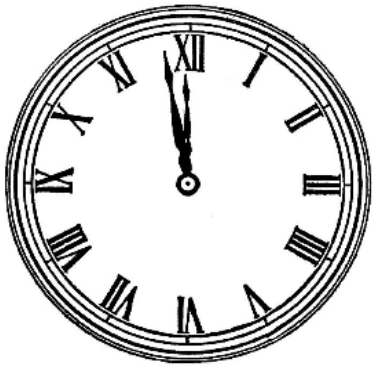
1: One minute breathing awareness

This is a simple exercise, and one that you can do anywhere at any time – it can take a bit of practice though.

- **For 60 seconds focus all your attention on your breathing. (It's just for one minute, but it can feel like a lot longer)**
- **Breathe normally.**
- **Be aware of thoughts as they come in to your mind (because they will). Make a mental note of what distracted you and then gently shift your awareness back to your breathing again.**

Remember **– don't worry if you find this hard to do, it takes practice.**

Use this exercise as often as you can throughout the day to take your mind back to your breath in the present moment. Over time, you will be able to gradually extend the duration of this exercise into longer and longer periods and it will facilitate other exercises.



2. Seated mindfulness

Put the CD on, select track 1 and follow the instructions. If you prefer, you can use a scripted version of the exercise, below.

Script

Find a place where you can remain quiet and uninterrupted for about 10 minutes. Sit in a straight backed chair with your feet on the floor and your spine straight. Or, sit on a cushion on the floor in cross-legged meditation pose. Keep your back straight.

1. Taking a few deep breaths to begin, focusing particularly on the out-breath – the letting go, and letting go of any tension in the body at the same time. Become aware of the stages of the breath (in, pause, out, pause), naming "in" and "out" breaths. After a few breaths, return to normal breathing.
2. Start bringing awareness to the sensations of the body – the points of contact with the ground, the points of touch and pressure where parts of the body are resting against the chair, cushion or floor. Bring awareness to the sensation of holding your posture.
3. Gradually broaden your awareness to include more and more sensations of the body. Be open to whatever sensations come into your awareness.
4. Slowly shift your awareness back to your breathing, and the sensation of this in your body. Following the rising and the falling of the abdomen, the chest, the rib-cage; feeling the entry and exit point of the breath at the tip of the nostrils.

   Rest your attention at a point in the body where the breath is felt most clearly. Watch for any tendency to want to control or

change your breath, simply allowing the breathing to happen in its own way.

5. At times you will notice your mind wandering into the realm of thinking, leaving the sensations of the breath and the body.

   Notice that there are many places that your mind likes to go to and that we have particular habitual places that we return to again and again: the past, the future, worries, planning, judging, a huge variety of thoughts.

   When you notice that your mind is no longer with the breath, congratulate yourselves for noticing. Do not judge yourself – it is the nature of the mind to wander. Simply acknowledge that you have been thinking, and gently redirect your attention back to the breath.

My notes on Step 1

Day	One min breathing	Seated mindfulness	Routine mindful activity
1 2 3			
4			
5 6 7 8			
9			
10			
11 12			
13			
14			

Step 2 (Weeks 3-4): Becoming aware of the pleasant

- Continue doing the Seated mindfulness with the CD or script (page 10-11) every other day.
- On the days that you don't do the Seated mindfulness, carry out the Body scan with the attached CD or script (page 14-16). The idea is to "fall awake" rather than asleep. If you have trouble with sleepiness do it with your eyes open.
- Practice the Three minute breathing space (page 17) once a day.
- Pay attention to your experience of pleasant events over the next week and try to become aware of body sensations, thoughts and emotions occurring with the pleasant event. Simply focus in on knowing what you are doing as you are actually doing it.
- Choose another everyday activity to be your routine mindful activity, bringing moment-to-moment awareness to it each time you do it.

As before, keep a record of your mindfulness practice on the page opposite. Note down when you did it, what you did and any comments following it.

3: The Body Scan

The aim of this exercise is to enable you to focus your attention while remaining aware of and accepting toward any sensation that may arise. In cases of pain and muscle tension, accepting sensations is more effective than trying to control them. It is also more relaxing. A few pointers before we begin:

- Find a comfortable place where you are unlikely to be disturbed.
- Dim the lights and silence your mobile phone. (You can set an alarm if that helps.)
- Wear comfortable clothes.
- You can lie on your back, with arms and legs spread comfortably or any other comfortable position.
- Focus on the way each part of your body feels without labelling the sensations as either "good" or "bad."
- When distracting thoughts arise, remain detached from them and gently return your attention to your breath and body.
- Don't worry about doing it right. You are doing it - that's all that matters.

Put the CD on, select track 2 and follow the instructions.

If you prefer, you can read though a scripted version of the body scan on the next page.

Body Scan - script

Let your eyes close gently. Notice your belly rising and falling as you breath in and out.

Be aware for a moment of your body as a whole and notice how it feels in contact with the floor or bed.

Breathing in slowly, focus your attention to your left foot. Feel your foot. Curl your toes once to fix your awareness to it.

Feel the sensations in your foot. Simply become aware of them. Bring awareness to your left lower leg. Accepting any tension or discomfort. If you do not feel anything, allow yourself to feel "not feeling anything". Slowly bringing awareness up through your leg.

If thoughts appear, that's fine. Gently come back to your breath.

Slowly inhaling while following your awareness up through your right leg. Exhale and slowly follow it back down. Now let go of your breath and remain with your foot.

Being aware of any sensation in your foot, calf, thigh... Accepting all sensations and feeling what happens.

Now take your attention to your stomach. Feeling it slowly rising as you breathe in. Sinking as you exhale. Your heart probably slows down. This is normal. Remaining aware of your stomach and your breath... up and down. Notice and allow yourself to feel any sensations.

Following the same procedure with your left hand and arm as you did with your leg. Clenching your fist to begin with, really focusing your awareness to your left hand. Breathe.

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Now taking your attention along the length of your arm, to your chest. Then down your right arm to your right hand. Remaining there. Breathe.

Bring your focus back up to your chest. Continuing to bring your awareness up along your neck and to your face. Gently clenching your jaw and releasing. Noticing sensations in your jaws, your throat. Feeling how the back of your head rests against the floor. Becoming aware of the top of your head.

Notice how everything is connected, resting gently on the floor. Breathe. Allowing yourself to be awareness of any sensations. Accepting them as a part of you. Return to your breath. You are big; sensations are small parts of you. They fluctuate, coming and going.

Breathe for a minute, feeling your body. Then begin sitting up, slowly.

Remember

- If you don't feel anything in a particular place at a particular time that is neither good nor bad – it is purely your experience in that moment.
- If you have problematic part of the body that keeps distracting you, or drawing your attention back, notice that it has happened and redirect your attention back to your toes, for example.
- As you move towards a problematic area remain open and receptive to sensations just as you did with other areas.
- When you are ready to leave this area continue to breathe while moving the focus of your attention on.

4: Three minute breathing space

The aim of this exercise is to help you step out of "automatic pilot" for 3 minutes.

- **Stop what you are doing and become aware of your posture. Sitting comfortably with your spine straight and your feet flat on the floor, or standing with your feet shoulder width apart with a straight back and shoulders relaxed and your arms hanging by your side.**
  - **You can have your eyes open or closed.**
  - **In your mind ask yourself, "How am I? How do I feel? What are my thoughts?"**
  - **Recognise and acknowledge your thoughts and experience, even if they are unwanted, for about a minute. Maintain a calm and kindly attitude towards your experience.**
- **Then, gently direct your full attention to your breathing. Notice each in breath and out breath. Do this for a couple of minutes, using the breathing to clear the mind and raise your awareness.**
- **Now expand your awareness of your breathing to your whole body.**
  - **Feel any tension or aches, and become aware of the sensations as you breathe in.**
  - **As you breathe out feel a softening of the sensations for a minute.**
- **As best you can, bring this expanded awareness to the next few moments of your day.**

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My notes on Step 2

Day	Seated (odd days) Body scan (even days)	3 min. breathing space	Routine mindful activity
1 2			
3			
4			
5 6			
7			
8			
9			
10 11 12			
13			
14			

Step 3 (Weeks 5-6): Increasing your mindful awareness

- Continue to do the Seated mindfulness (pages 10-11) and Body scan exercise (page 14-16) on alternate days. If you have been doing these for about 10 minutes each until now, try to extend the length of time you spend practicing these to 20 minutes each day.
- Introduce the Mindful eating exercise (page 20-21) and carry out one meal or snack mindfully each day.
- Carry out the Turning towards the unpleasant exercise (page 22) three times per week.
- Introduce mindfulness "dots" into your life by placing stickers on objects in your immediate environment (e.g. on your computer, telephone, bathroom mirror, the key hole at your office door) and use them to act as triggers to remind you to take a breath and become more aware again.
- Continue to apply the three minute breathing space when you are struggling with something. Apply the practice as a coping space for these difficult moments as they arise.

As always, be gentle with yourself and be aware of your limitations. If difficult emotions or thoughts come up while doing any of these exercises do find someone to speak to.

5: Mindful eating

Eating is an activity we engage in a few times every day. It can be a useful opportunity for mindfulness practice (although also perhaps difficult or challenging if you have issues about food).

For most of us, such an exercise can enhance our sense of enjoyment and appreciation of the food we eat. It can help us to retune into our sense of hunger and satiety, making sure that we do not overeat. Mindful eating can be very useful if we do have a tendency to overeat. It can also increase the likelihood of chewing food properly, reducing the tendency to eat quickly and aiding digestion.

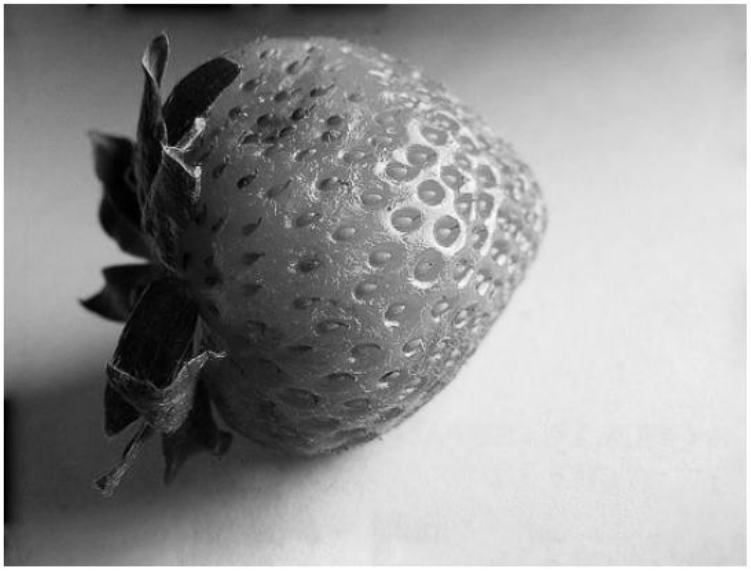
Choose a meal that you can eat with mindful awareness. Make sure that you are not going to be distracted by radio and television, and make the effort to sit with your meal at a table.

Sit down with your plate or bowl and observe what you are about to eat. Notice the colours, the textures and the ways in which the meal presents itself to you. Notice any fragrances coming from the food and any anticipation you may have for eating it.

You may find it helpful to reflect for a while upon where your meal has come from: all the people and animals involved across many parts of the world in its production, transportation, preparation, etc. Notice how you feel as you prepare to eat, paying attention to the process of lifting the food to your mouth, tasting, chewing, swallowing.

At what point does that mouthful disappear from your awareness? Notice how you respond to the food with all of your senses. Keep your attention upon the activity of eating, mouthful by mouthful. Notice any sense of pleasure, hunger, dissatisfaction, contentment. Notice how these change as you complete your meal.

Notice at what point you know that you have finished. And when it is over, take a breath, notice how you feel and move your awareness to the next part of your day.



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6: Turning towards the unpleasant

Lie sown or sit down as described in the seated mindfulness exercise. As you begin to relax, become aware of any unpleasant or painful sensations. Let yourself become aware of them with an attitude of compassion and gentle curiosity.

Keep remembering to breathe. We often hold our breath and become tense against pain and unpleasant sensations. Instead, see if you can use gentle breathes to soften towards the experience.

It is possible that you are more aware of a sense of resistance and tension than of the sensation itself. Try to become aware of this resistance a bit more directly – turning your attention towards it, like shining a light on something that's hidden in the dark. Allow it to soften a little with each breath in and out. Maybe you can feel the resistance soften with every breath.

As you become open to the sensations, notice what they are like and how they are always changing. At times it may feel hard and tight, and at others possibly a little softer. Or they may feel sharp for a while and then more tingly.

Attempt to notice where exactly the sensation is in your body. Try to be as precise as possible; you may notice that it is confined to a smaller area than you thought.

Be patient with any disturbed thoughts or feelings of fear or anxiety that may arise. Notice how these are also constantly changing. See if you can relax a little around whatever unpleasant experience you notice, and remember to soften your breath each time you notice you are tensing.

My notes on Step 3

Day	Seated (even days) Body scan (odd days)	Mindful eating	Turning towards unpleasant	3 min breathing space
1				
2				
3 4				
5				
6				
7				
8 9 10				
11				
12 13 14				

Step 4 (Week 7): Staying with things that are difficult

- Continue to do the Seated mindfulness exercise (page 10-11) Body scan (pages 14-16) and on alternate days. If you have been using the CD for the Body scan, try doing it without the CD this week if possible. Try to increase the time that you spend doing these exercises.
- Continue to eat one meal or snack a day mindfully (page 20-21).
- Introduce a period of Mindful walking (page 25) everyday – this is best done when you are not in a rush to be somewhere!
- Bring particular awareness to any experiences of difficulty arising this week, and use periods of your formal practice to work with this. Notice when you find yourself getting caught up in thoughts about unpleasant sensations or symptoms and use the techniques practiced in the Turning towards the unpleasant exercise (page 22).
- Continue to use the mindfulness "dots" placed throughout your house/life to act as triggers to remind you to take a breath and come back to full awareness.

7: Mindful walking

When practicing Mindful walking, our attention is on the process of walking. We can focus upon the sensations in the soles of the feet as they are placed and lifted, with the weight of our bodies shifting, the process of moving, lifting, stretching, placing.

We are feeling all the sensations of walking - in our feet, our legs, in our carriage and gait. We can be aware of the temperature of the outside air on our faces and hands and the warming of our bodies from the exertion. We can practice this awareness at any pace, but it helps if we are not rushing to get anywhere.

The aim is to be as present as we can with every step. If we drift off or get distracted by something, we just notice, and bring our attention back to the walking. Walk with awareness of walking and awareness of your breath, perhaps measuring your breath by your footsteps for a while.

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My notes on Step 4

Day	Seated (odd days) Body scan (even days)	Mindful eating Mindful walking	Turning towards unpleasant
1			
2			
3 4			
5 6 7			

Step 5 (Week 8): Your own mindful practice

- Continue your mindful practice each day. During this week you can decide each day what is right for you to do from your experience of the exercises practiced over the past seven weeks.
- Try the Loving kindness meditation (page 28). While some people can be put off by its name, many people find the exercise very helpful – calming the mind and body through cultivating compassion for yourself and others.
- Read through the Mindfulness in everyday life section (page 29) and try to become more aware of what is happening and what you are doing throughout the day.
- Consider ways that you will continue using the mindfulness practices you have been developing over the past eight weeks in day to day life.

8. Loving kindness - script

Become aware of your breathing, relax your body. Notice your energy settle into your body. See if certain phrases emerge that express what you wish most deeply for yourself, not just for today, but forever. Phrases should be big enough and general enough that you can ultimately wish them for all of life, for everyone everywhere.

Often phrases are things like "May I live in safety. May I be happy. May I be healthy. May I live with ease". Gently repeat these phrases over and over, let your mind rest on the phrases. Don't worry if you find that your attention wanders. Gently let go and begin again. "May I live in safety, be happy, be healthy, live with ease."

Think of somebody you care about - a friend, or someone who has helped you or inspires you. Think about them, say their name to yourself. Get a feeling for their presence, then direct the phrases of loving kindness to them. "May *you* live in safety, be happy, be healthy, live with ease."

Think of someone who's going through a difficult time. They may have experienced a loss, pain, or a difficult situation. Bring them to mind. "May *you* live in safety. Be happy. Be healthy, live with ease."

Now offer the same phrases to someone that's in your life, but that you don't know very well, that you don't have a particular feeling for, or against. Maybe it's someone in the local shop.

May all beings everywhere live in safety, be happy, be healthy, live with ease. Feel the energy of this aspiration extending out in front of you, to either side, behind you, above and below.

When you feel ready, open your eyes and see if you can bring this energy with you throughout the day.

Mindfulness practice in everyday life

Anything in our lives can be an opportunity to practice mindfulness, but it can be useful to identify a number of helpful triggers to remind ourselves to come back to the present moment.

The following situations may be helpful as mindfulness triggers. When we encounter them we can practice following a breath mindfully, bringing awareness to our bodies, and reconnecting to where we are and what we are doing. This only needs to take a few moments, but such moments of mindful awareness can have a calming and grounding influence in our lives.

Here are just a few examples. See if you can come up with some situations, which are useful in your own life.

- Passing through a doorway
- Stopping at traffic or pedestrian crossing
- Waiting for the kettle to boil
- Pausing before you answer the telephone
- Sitting with a cup of tea or coffee
- Feeling angry or irritated
- On wakening
- Lying down before sleep

My notes on Step 5

Day	Your own choice	Your own choice	Loving kindness	Everyday awareness
1 2				
3				
4 5				
6 7				

Attributions

This booklet was developed by Sarah McLaren, NHS Borders.

Thank you to those involved in guiding its development:

Dr Charlotte Procter, NHS Lothian

Dr Nick Bell, NHS Forth Valley

Dr April Quigley, NHS Borders

Dr Paul Graham Morris, the University of Edinburgh

Thanks also to those who have allowed their images to be used:

Cover: original image by Minerva Bloom on Photopedia

Page 5: original image by Jim Mead on Flickr

Page 23: original images from Dharma Crafts
www.dharmacrafts.com

Page 25: original image by Aqa Hu on Flickr

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The booklet could be cited as:

McLaren S., Procter C., Bell N., Quigley A., Morris P.G. (2011).
Helping you control your symptoms instead of them controlling you
Unpublished manuscript.

Appendix 8. Ethical approval for project amendment

Lothian NHS Board

South East Scotland Research
Ethics Committee 03
2-4 Waverley Gate
Edinburgh
EH1 3EG

Telephone 0131 536 9000
Fax 0131 536 9088

www.nhslothian.scot.nhs.uk
Date
Our reference
Enquiries to Joyce Clearie
Extension 35674

Direct Line 0131 4655674
Email joyce.clearie@nhslothian.scot.nhs.uk

24 April 2012

Mrs Sarah McLaren
Trainee Clinical Psychologist
NHS Borders
12/14 Roxburgh St
Galashiels
TD1 1PF

Dear Mrs McLaren

Study title:	**The development of a mindfulness-based self help booklet for those presenting with medically unexplained symptoms, and its evaluation using a randomly controlled trial measuring patient wellbeing and GP attendance.**
REC reference:	**11/SS/0084**
Amendment number:	
Amendment date:	**13 March 2012**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	1.3	13
Notice of Substantial Amendment (non-CTIMPs)		13

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

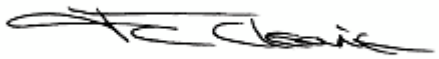
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/SS/0084: Please quote this number on all correspondence

Yours sincerely



Dr Christine West
Chair

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Copy to: Dr Tom Cripps, Clinical Governance Support Team - NHS Borders

Appendix 9. R&D approval for project amendment

NHS Borders

Research Administration
Clinical Governance & Quality

Clinical Office
Borders General Hospital
Melrose
Roxburghshire TD6 9BS

Telephone 01896 826719
Fax 01896 826040
www.nhsborders.org.uk

Mrs Sarah McLaren
NHS Borders
12-14 Roxburgh Street
Galashiels
TD1 1PF

Date 07 June 2012

Our Ref 11/BORD/17

Enquiries to Joy Borowska
Extension 01896 826717
Email research.governance@borders.scot.nhs.uk

Dear Mrs McLaren

11/BORD/17 Self help booklet for symptoms with no known medical origin- Amendment 1

Thank you for sending details of the amendments of your study to NHS Borders. I am pleased to inform you the amendments have been granted management approval the Research Governance Committee for commencement within NHS Borders.

Please advise the R&D Office immediately of any changes to the project such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Borders.

Please inform this office when recruitment has closed and when the study has been completed. Please quote the reference number stated above in all correspondence.

May I take this opportunity to wish you every success with your project. Please do not hesitate to contact the R&D Office should you require any further assistance.

Yours sincerely

Thomas Cripps

Thomas Cripps
Associate Medical Director (Clinical Governance)

cc

Appendix 10. Additional letters

Appendix 9a: Follow-up questionnaire letter

12/14 Roxburgh Street
NHS Borders
Galashiels
TD1 1PF

01896 668821

Dear ,

Thank you again for agreeing to participate in this research project.

You should find enclosed a questionnaire similar to the ones you have already completed. Please complete this and post it back to us in the pre-paid envelope provided.

If you have any questions or concerns whilst carrying this out, please do not hesitate to contact me on the number above.

Thank you again for your participation.

Yours faithfully,

Sarah McLaren

(Lead researcher)

Appendix 9b: Unreturned questionnaire letter

12/14 Roxburgh Street
NHS Borders
Galashiels
TD1 1PF

01896 668821

Dear [insert name here],

I have not received a completed questionnaire from you so I have enclosed another, alongside a pre-paid addressed envelope. Apologies if you have sent the questionnaire back in the last few days. If not, if you could take the 10-15 minutes to fill in the questionnaire and return it in the envelope provided we would be very grateful.

If you have any questions or concerns whilst carrying this out, please do not hesitate to contact me on the number above.

Thank you again for your participation.

Yours faithfully,

Sarah McLaren

(Lead researcher)

Appendix 11. GP questionnaire

Review of self-help project recruitment

Thank you for helping to recruit participants to our project evaluating a self-help booklet for patients with medically unexplained symptoms (MUS). Unfortunately the response rate has been lower than forecast and we are trying to understand why so that we can make future studies more helpful to GPs and patients.

Please take 2 minutes to complete this questionnaire. All responses will be anonymous. Please feel free to contact me on 07779007149 if you have any questions.

Thank you, Sarah McLaren.

1. Are you a GP? Yes No (please circle) if not please specify _____

2. Were you aware of this research project? Yes No (please circle)

3. Please estimate how many patients you have mentioned the project to: _____

4. Please rate how true you find each of the following statements by ticking the appropriate box:

	Almost always true	Usually true	Occasionally true	Usually not true	Almost never true
1. I did not see patients with medically unexplained symptoms.					
2. I do not diagnose patients with the labels given in the inclusion criteria.					
3. I saw patients with MUS but they did not meet inclusion criteria.					
4. I did not feel that taking part in the research project was right for the patients I saw.					
5. I did not want to make extra demands on already distressed patients.					
6. I did not think that self-help would be suitable for patients I saw.					
7. I was very busy and forgot to offer potential patients inclusion in the project.					
8. It was difficult to prioritise the study in the face of competing demands.					
9. I think that a mindfulness approach would not be of benefit to the patients I saw.					
10. I felt that raising the research could detract from the focus of the consultation.					

5. Please outline any other reasons that may help explain the difficulties recruiting participants:

_____

_____

_____

Thank you again for taking the time to complete this questionnaire.