Exploratory study of mindfulness for inpatients with chronic gastrointestinal pain: does it reduce pain related distress and increase confidence in pain self-management?

Rebecca Ellis

D.Clin.Psy. thesis (Volume 1)

2015

University College London

UCL Doctorate in Clinical Psychology

Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

Name: Rebecca Ellis

Date: 18/06/2015

Overview

Part 1: Literature review. A systematic review of seven randomised controlled trials that examined the efficacy of mindfulness-based interventions for Irritable Bowel Syndrome. The aim was to replicate an existing meta-analysis, critically evaluate design and theoretical issues raised by the studies and discuss recommendations for future research.

Part 2: Empirical paper. A mixed methods study evaluated the use of a guided self-help mindfulness course (using a book and audio guided meditations based on MBSR) with 15 inpatients with gastrointestinal pain. Change in pain distress and intensity were quantitatively assessed at multiple time points and graphically analysed. Change in psychological distress, self-efficacy, pain acceptance and mindfulness skills were quantitatively assessed at baseline and endpoint and analysed for reliable and clinically significant change. Interviews were used to qualitatively explore the usefulness and applicability of the mindfulness course with this patient group. Pain distress reduced over the duration of the course and improvements in quality of life reported. For those able to complete, the course was experienced as straightforward and useful, even when experiencing intense pain. Significant challenges and barriers to completing the course were experienced by many participants mostly related to the disruption of living with chronic pain and illness.

Part 3: Critical appraisal. Reflections on the process of conducting the empirical study are discussed.

Table of Contents

List of Tables

Part1: Literature review

Part 2: Empirical paper

List of Figures

Part 1: Literature review

Part 2: Empirical paper

Acknowledgements

Firstly I would like to thank Dr Amanda Williams for her advice and encouragement over the past two and a half years of completing this research. Her knowledge of the research area was invaluable as well as her consistent support throughout the process.

Secondly I would also like to thank all of the gastrointestinal pain patients who took part in this study. Their willingness to complete interviews and questionnaires as well as find the time for mindfulness practice whilst living with chronic pain was inspiring. I would also like to thank all of the staff at University College London Hospital who supported this research, especially to the nursing staff including the ward sisters Ebenezer Philips, Maria Ridulme and Estralita Balentogo.

Finally I would like to thank Greg for supporting me through the last year in particular, and understanding in the way only someone who has done this themselves can.

Part 1: Literature review

Mindfulness-based therapies for Irritable Bowel Syndrome

Abstract

Background. Irritable Bowel Syndrome (IBS) is a common disorder characterised by abdominal pain and alteration of bowel habits and is defined by an absence of structural or anatomical abnormality. Current explanations emphasise the importance of psychological processing and dysfunction of the brain-gut axis. Psychological interventions including CBT and psychotherapy have shown some benefits for individuals with IBS. Mindfulness has been hypothesised as an appropriate avenue for research due to its applicability to the function of the brain-gut axis.

Aims. To review published accounts of randomised controlled trials of mindfulness-based therapies for IBS against questions of theoretical and design issues.

Method. A systematic search of Pubmed, EBSCO, Cochrane, PsychINFO, AMED, Medline, and Embase was undertaken. Nine papers describing seven randomised controlled trials were included.

Results. A previous meta-analysis including eight of the nine papers found that mindfulness-based interventions were effective at reducing symptom severity (d=0.59, 95% CI 0.33 to 0.86) and improving quality of life (d=0.56, 95% CI 0.34 to 0.79) in IBS (Aucoin, Lalonde-Parsi & Cooley, 2014). The study findings are then discussed alongside theoretical and design issues.

Conclusions. Tentative recommendations are made for wider availability of mindfulness-based interventions for IBS patients, focussing on patients who wish to explore a psychological model of coping with IBS. More research is needed on the importance of between-session practice and specific mindfulness techniques. Recommendations are also made to further investigate the role of non-specific placebo effects in the effective management of IBS.

Introduction

IBS

Definition. Irritable Bowel Syndrome (IBS) is a functional gastrointestinal (GI) disorder for which there is no known structural or anatomical explanation. It differs from Irritable Bowel Disease (IBD) where structural and anatomical malformations are apparent such as in Ulcerative Colitis or Crohn's Disease.

Symptoms. Symptoms of IBS include abdominal pain or discomfort, altered bowel habits (diarrhoea and/or constipation), and bloating (Longstreth et al., 2006). Symptoms are usually not stable but occur over a chronic relapsing-remitting course. Several different diagnostic criteria exist for IBS and the most commonly used in clinics and research is the Rome III criteria (Drossman, 2006). These criteria specify that abdominal pain or discomfort must occur on at least three days each month and be associated with changes in frequency or form of stool, with onset of symptoms a minimum of six months prior to diagnosis.

Prevalence. Prevalence estimates vary between 2% and 17% in the general population (Hungin, Whorwell, Tack, & Mearin, 2003; Mearin et al., 2001) depending on the diagnostic criteria used, but many individuals do not receive a formal diagnosis. It is more common in women than men (Spiller et al., 2007).

Comorbidity. Patients with IBS often also meet diagnostic criteria for Axis I mood disorders such as depression and anxiety at rates of between 40% and 94 % (Whitehead, Palsson, & Jones, 2002) and at a prevalence rates higher than that for general medical patients or patients with a diagnosis of IBD (Palsson & Drossman, 2005). Higher rates of comorbidity are seen in patients attending tertiary care than in community samples. Stressful life events often precede onset of symptoms and

patients report that stress exacerbates their IBS symptoms (Palsson & Drossman, 2005).

Impact. Although IBS has a benign prognosis, the symptoms can have a serious impact on health-related quality of life (Chang, 2004), often resulting in greater impairment than in similar diseases with an identifiable organic basis. Compared to the general US population, patients with IBS reported significantly worse health-related quality of life in all eight domains (physical functioning, physical role limitations, bodily pain, emotional wellbeing, emotional role limitations, energy/fatigue, social functioning and general health) on the SF-36 health-related quality of life measure. In addition, except for the physical functioning subscale, IBS patients reported significantly worse health-related quality of life on all subscales compared to patients with gastroesophageal reflux disease (GERD) , and worse energy/fatigue, bodily pain, emotional wellbeing and social functioning than patients with end-stage renal disease (Gralnek, Hays, Kilbourne, Naliboff, & Mayer, 2000).

Qualitative research has similarly emphasised the extent of the impact of IBS on individuals including extensive impact on daily living, emotional well-being and self-identity (Farndale & Roberts, 2011). A systematic review of the qualitative literature focussing on the impact IBS has on the lives of adults who are diagnosed with it concluded that "living with IBS…colors the person's whole existence" (Håkanson, 2014, p.223) with limitations including being unable to move about freely, fulfil commitments at work, maintain social activities, uphold or develop close and/or sexual relationships or to live a life spontaneously. Other themes to emerge from the qualitative literature on the impact on IBS on individuals include feelings of shame from the embarrassing nature of symptoms, and feeling unable to

trust their bodies (Håkanson, 2014; Jakobsson, Ringstrom, Sjövall, & Simrén, 2013; Rønnevig, Vandvik, & Bergbom, 2009). Patients with long-term experience of living with IBS described overall improvement over time, but of living chronically in intermittent states of well-being and illness, and of eventually finding effective strategies for their bodies (Jakobsson et al., 2013).

Biopsychosocial model of IBS

The biopsychosocial model of illness and disease was proposed by Engel (1977) as an alternative to the predominant biomedical model. Although no explicit biomedical model was ever proposed, it is conceptualised as modelling health and illness according to identifiable organic factors. The biomedical model is a useful way to conceptualise many diseases and their treatments, but it lacks a specific focus on psychological and social factors. In contrast the biopsychosocial model proposes that psychological and social factors reciprocally influence biological disease processes.

IBS has been conceptualised within a biopsychosocial model (Drossman, 1998) with psychological and social stressors being reciprocally linked with biological changes to gut motility and visceral sensitivity. These reciprocal relationships are best explained by reference to the brain-gut axis.

Brain-gut axis

The brain-gut axis describes a continuous feedback loop between enteric nervous system (ENS) sensory neurons in the intestines, colon and rectum (which together form the gastrointestinal tract) and motor responses generated in the central nervous system (CNS) (Burnett & Drossman, 2004). Gastrointestinal nerve signals are carried along the autonomic nervous system and rarely enter conscious

perception in a healthy individual. They also do not convey information about touch and temperature, but about distension, torsion, and similar effects.

In healthy gastrointestinal functioning, the links between CNS processing (such as emotions) and gastrointestinal sensory and motor functions are familiar in everyday life. For example, stress, anxiety and worry are often accompanied by abdominal symptoms such as the sensation of 'butterflies in the stomach', abdominal pain or an urge to go to the toilet (Mönnikes et al., 2001). In certain individuals however, changes to the brain-gut axis leads to hypersensitivity, and visceral signals from the gut (which would not usually be consciously perceived), are experienced as discomfort or pain. This can result in many different clinical presentations, one of which is IBS where pain and discomfort are experienced in relation to altered gastrointestinal function (Mayer & Tillisch, 2011). Neural changes of the CNS can be observed in patients with IBS using functional magnetic resonance imaging (fMRI). Differences of activation in regions associated with emotional arousal (pregenual anterior cingulate cortex, amygdala) and regions involved with endogenous pain modulation have been shown following rectal balloon distension (Tillisch, Mayer, & Labus, 2011). It is suggested that the symptoms of IBS continue to occur due to structural changes in the brain, spinal cord and gut (Seminowicz et al., 2010).

Psychological interventions for IBS

As psychological factors are an important component of the biopsychosocial model of IBS, psychological interventions have the potential to impact on individuals' experience of symptoms.

As a group, psychological treatments have been shown to have a small but consistent impact on reduction of IBS symptoms (Drossman, 1999; Ford, Talley,

Schoenfeld, Quigley, & Moayyedi, 2009; Pajak, Lackner, & Kamboj, 2013). Psychological treatments have also been found to be equally effective as antidepressants in reducing the number of participants with persistent IBS symptoms following treatment (relative risk of 0.67 and 0.66 respectively) (Ford et al., 2009). Cognitive behaviour therapy (CBT), hypnosis and psychodynamic interpersonal therapy have been shown to be effective in reducing abdominal pain, bowel dysfunction, depression and anxiety in different subsets of patients with IBS (Spiller et al., 2007).

CBT. CBT for IBS includes changing IBS-related behaviours such as avoidance of situations thought to trigger symptoms (for example restrictions of certain foods, avoiding lengthy durations away from home or going far from known toilet locations) which become unhelpful as they can increase gastro-specific anxiety and maintain/worsen symptoms. This is done by using graded exposure and working towards valued goals such as attending specific social events, or maintaining physical activity. It also includes challenging cognitions and beliefs about IBS and ways of processing internal and external information about symptoms, such as catastrophising, worry and depressive thinking. Patients with IBS who believed that their symptoms were associated with serious pathology reported more intense symptoms and used fewer adaptive coping strategies (Drossman et al., 1999). Evidence for the efficacy of CBT in reducing IBS symptoms and improving quality of life is mixed and meta-analyses have shown small but positive improvements following CBT interventions (Zijdenbos, de Wit, van der Heijden, Rubin, & Quartero, 2009).

Hypnosis. Clinical hypnosis is the second most commonly researched therapy for IBS. Hypnosis induces an altered mental state of heightened receptivity

and uses therapeutic imagery and verbal suggestions to influence both mental and physiological changes. When used with IBS patients hypnotherapy aims to produce physical relaxation, especially of the gastrointestinal region, reduce attention to sensations of discomfort from the intestines, reduce perception of threat and enhance perception of control over symptoms (Palsson & Drossman, 2005). Studies have shown a reduction in unhelpful IBS-related cognitions, affective symptoms and an improvement of gastrointestinal symptoms following hypnosis (Palsson, Turner, Johnson, Burnett, & Whitehead, 2002). A Cochrane review was unable to conclude on the efficacy of hypnotherapy for IBS as only four trials met inclusion criteria for the review and all were of low methodological quality, but findings from the individual studies showed positive effects on abdominal pain and IBS symptoms in patients who did not respond to standard medical therapy (Webb, Kukuruzovic, Catto-Smith, & Sawyer, 2008).

Psychodynamic interpersonal therapy. The aim of psychodynamic interpersonal therapy for IBS is to enable the patient to gain insight into the context in which symptoms developed, such as changes in relationships or life stressors and it also aims to highlight the link between emotions and bowel symptoms (Spiller et al., 2007). Although studies of psychodynamic interpersonal therapy for IBS have had low methodological quality, small improvements have been shown on IBS symptoms (Zijdenbos et al., 2009).

Guthrie and colleagues used a 12 week psychotherapy protocol for patients with chronic, refractory IBS. This involved an initial three hour session aimed at fostering a strong therapeutic alliance and then six further 45 minute sessions spread over the 12 weeks. Compared to an equal number of 'supportive listening' sessions, psychodynamic psychotherapy led to significant improvements on both

psychological and physical symptoms, analysis suggested that the improvement in bowel symptoms was mediated by the improvement in psychological factors (Guthrie, Creed, Dawson, & Tomenson, 1993). Using the same psychotherapy protocol but comparing to treatment with a selective serotonin reuptake inhibitor (SSRI) antidepressant or treatment as usual (TAU), no significant changes in abdominal pain were observed, but both the psychotherapy and SSRI groups showed significant improvement in health-related quality of life (Creed et al., 2003). Out of the 257 patients recruited to that study, 107 met criteria for a concurrent psychiatric disorder. Although improvements on the psychiatric domains were correlated with improvements in health-related quality of life, they could not account for all of it (Creed et al., 2005).

Relaxation training. Relaxation training uses techniques such as progressive muscular relaxation, meditation and biofeedback to help patients reduce physical tension. It is often used as a component in other psychological interventions such as CBT and when studied as an intervention on its own, effects have been positive but small and unreliable (Zijdenbos et al., 2009). Progressive muscular relaxation focuses on skeletal muscle as opposed to the viscera and so any improvement in IBS symptoms would be related to the effect of general relaxation of the whole body, rather than specific effects on the gut.

Mindfulness

More recently, attention has turned towards the potential benefits of mindfulness-based therapies with IBS patients. Mindfulness can be described as bringing one's attention to present moment experiences in an open, curious and accepting manner, without immediately attaching value judgements such as good or

bad (Kabat-Zinn, 1990). It has been conceptualised as a capacity inherent in all humans, but which varies within and between individuals (Brown & Ryan, 2003).

History

The practices of mindfulness have been in use in Eastern traditions for over 2500 years and developed within Buddhist traditions. In the 1970s, the principles of non-judgemental, present-moment awareness and meditation began to be used more widely in Western cultures. The first structured programme to use mindfulness was developed by Jon Kabat-Zinn in the USA for use with patients with chronic pain and physical health problems (Kabat-Zinn, Lipworth, & Burney, 1985). A second widespread structured mindfulness programme was later developed by Mark Williams and others in the UK for recovered recurrently depressed patients to prevent depressive relapse (Segal, Williams, & Teasdale, 2002).

Mindfulness-Based Stress Reduction (MBSR). Kabat-Zinn developed MBSR as an eight week group programme for chronically ill people to cope more effectively with their distress (Kabat-Zinn, Lipworth, Burney, & Sellers, 1986). The intensive course involves two and a half hours instructed mindfulness practise per week, a seven hour mindfulness retreat halfway, and consistent daily practice of meditation at home for at least 45 minutes a day.

MBSR is made up of three different techniques. The ‘body scan’ involves sequentially turning attention to each part of body, focusing uncritically on any sensation or feeling in the body as it is experienced and using awareness of the breath and relaxation. The ‘sitting meditation’ involves paying attention to the breath or on the movement of the abdomen, as well as on other perceptions. It also encourages awareness of the stream of thoughts and distractions that repeatedly enter the mind, but with a non-judgemental attitude. The third element is ‘hatha yoga’

practice which includes straightforward stretches, breathing exercises, and development of posture designed to relax the muscles in the body and build strength.

Mindfulness-Based Cognitive Therapy (MBCT). MBCT was developed by researchers at the University of Oxford (Segal et al., 2002). They combined aspects of mindfulness with elements from CBT aimed at preventing the recurrence of depression. MBCT was based on MBSR and shares many features. Several different meditations are introduced across the eight week group programme including 'the body scan', 'mindful movement' and different length 'sitting meditations'.

Acceptance and Commitment therapy (ACT). Mindfulness is also a component of ACT (Hayes, Strosahl, & Wilson, 1999). In contrast to CBT, where the focus might be to challenge unhelpful thoughts and behaviours in response to feelings, in ACT the aim is to accept and acknowledge difficult thoughts and sensations and instead to commit to actions that facilitate values-congruent living (Hayes et al., 1999). In this framework, mindfulness is used to increase contact with the present moment and encourages awareness and acceptance.

Efficacy of mindfulness in pain and health conditions. Initial studies of MBSR comprised of patients with chronic pain from a variety of disorders (including musculoskeletal, neurological, gastrointestinal and cardiac pain). Findings from these studies reported significant improvements of pain ratings and physical symptoms (Kabat-Zinn et al., 1985), maintained at four year follow-up for improvement of physical and psychological symptoms (Kabat-Zinn et al., 1986).

Meta-analyses have reported the efficacy of mindfulness-based therapies on reducing pain (Baer, 2003; Grossman, Niemann, Schmidt, & Walach, 2004; Reiner, Tibi, & Lipsitz, 2013). Another meta-analysis with more stringent measures of inclusion criteria reported a lack of evidence for specific effects of mindfulness on

pain reduction but strong evidence for non-specific effects, improvement of depressive symptoms and improvements in coping with pain (Chiesa & Serretti, 2011). Mindfulness-based therapies have also been found to be effective in improving pain, physical symptoms and health-related quality of life in chronic fatigue syndrome and fibromyalgia (Lakhan & Schofield, 2013), cancer, coronary artery disease and obesity (Grossman et al., 2004).

Efficacy of mindfulness with IBS. Mindfulness-based interventions may be particularly applicable in treating IBS symptoms as it could act on the brain-gut axis. As previously discussed, the brain-gut axis describes a reciprocal feedback loop between neurones in the gut and the brain. In cases such as IBS, over time the normal functioning of the gut and signalling along the brain-gut axis changes. Benign signals representing normal gastrointestinal functioning become processed as pain and discomfort in the brain. This in turn changes the descending signals from the brain, altering gastrointestinal functioning and leading to changes in bowel habits. Changes in brain regions related to pain processing have been shown to change after repeated mindfulness practice (Zeidan et al., 2011) in general pain conditions. It can therefore be expected that mindfulness will alter brain regions involved in the brain-gut axis related to the expression of IBS symptoms. This would be achieved through the practices of mindfulness encouraging awareness of physical sensations, in a non-judgmental way that uncouples the anxiety and fear related to symptoms. With repeated practice this could change signalling along the brain-gut axis towards 'normal' functioning (Garland et al., 2012).

Two systematic reviews have reported effect sizes for the impact of mindfulness-based therapies on IBS symptom severity and quality of life. Lakhan and Schofield (2013) included three randomised controlled trials (RCTs) of

mindfulness-based therapies for IBS in a meta-analysis of twelve studies of mindfulness-based therapies for somatisation disorders[1] (the other studies in the review focussed on fibromyalgia, chronic fatigue syndrome or mixed somatisation disorders). Small to moderate effects of mindfulness on pain, symptom severity, depression, anxiety and quality of life were reported, and the effects were most consistent for IBS, with none of the analysed outcomes showing deterioration in the IBS studies. Effect sizes for the three IBS studies were medium for improvement in symptom severity (0.70, 95% CI 0.44 to 0.96) and medium for quality of life (0.56, 95% CI 0.31 to 0.82).

Aucoin et al. (2014) performed a meta-analysis of mindfulness-based therapies in the treatment of functional gastrointestinal disorders (despite their search strategy allowing for inclusion of any FGID, only studies investigating IBS or IBS-type symptoms were found). Six of the seven studies reported significant improvements in IBS symptom severity and quality of life following mindfulness-based therapy. The one study which did not report an improvement in symptoms or quality of life recruited participants in remission of IBD and with either IBS symptoms or high perceived stress (and therefore would not have met official diagnostic criteria for IBS). However subgroup analysis of only those IBD patients with IBS-type symptoms (and not just high perceived stress levels) indicated that mindfulness was effective in reducing symptom severity (Berrill, Sadlier, Hood, &

[1] The term somatisation disorders used in this context included any disorders "characterised by chronic, medically unexplained, treatment-resistant symptoms, combining psychological distress with chronic physical pain or discomfort" (p2, Lakhan & Schofield, 2013). This definition included IBS. However, this term will not be used to refer to IBS later in this review as it is an inclusive term defining many different syndromes, and the use of the term IBS better defines the population of interest in this review.

Green, 2014). Overall effect sizes were medium for improvement in symptom severity at post treatment (0.59, 95% CI 0.33 to 0.86) and medium for quality of life (0.56, 95% CI 0.47 to 0.79).

Both systematic reviews inform researchers and clinicians about the efficacy of mindfulness-based therapies for IBS based on current published RCTs. They do not, however, review the components of the mindfulness-based therapies used in the studies, or assess the quality of the interventions (rather than the quality of the trial methodologies). Current evidence about mindfulness-based therapies needs to be reviewed to assess which components or quality criteria are essential and which are flexible whilst still providing positive patient outcomes.

Aims of review

This review aims to extend the findings from the Aucoin, et al. (2014) meta-analysis of RCTs of mindfulness-based therapies for functional gastrointestinal disorders. Although their search criteria allowed for inclusion of any functional gastrointestinal disorder, only studies describing IBS or IBS-type symptoms were found. This review focusses on IBS and not all functional gastrointestinal disorders as there is very little published evidence on FGIDs that are not IBS. The Aucoin et al. (2014) review was chosen over the Lakhan and Schofield (2013) review as it was more recent and focussed exclusively on IBS-type symptoms rather than somatisation disorders in general which would allow for discussion of the findings with reference to literature on the brain-gut axis. This review intends to look more closely at the interventions themselves and answer the following questions:

1. What are the rationales for offering mindfulness-based therapies to individuals with IBS symptoms and how do the mindfulness based therapies chosen express these?

2. How do the study designs affect the generalisability of findings?

3. What conceptual issues should inform future trial designs?

Methods

Systematic search strategy

This review was based on the published search strategy of Aucoin et al. (2014). Their search incorporated three electronic databases (Pubmed, EBSCO, and Cochrane). This review extended the search to include four further databases (PsychINFO, AMED, Medline, and Embase) selected to ensure that no relevant papers were overlooked from psychological or alternative medicine journal sources.

To identify papers examining mindfulness-based therapies, the following search terms were combined (mindfulness OR MBCT OR MBSR OR mindfulness-based cognitive therapy OR mindfulness-based stress reduction OR mindful$), and to locate literature examining populations with functional gastrointestinal disorders, the following search terms were combined (functional gastrointestinal OR functional bowel OR colonic disease functional OR colonic disease OR functional abdominal pain OR IBS OR irritable bowel OR spastic colon OR irritable colon OR constipation OR diarrh$ OR bloating OR distention OR gastroesophageal reflux OR GERD OR dysphagia OR functional dyspepsia). These two terms were then combined with an AND function. The searches were limited to studies in humans from the earliest date available until October 2014.

Results

A total of 282 records were identified from the databases searched as shown in Table 1.

Table 1

Search results

Database	Description of database	N of studies
Pubmed	Contains biomedical literature, including all data from the National Center for Biotechnology Information (NCBI) at the US National Library of Medicine (NLM)	48
EBSCO	Contains professional literature of nursing, allied health, biomedicine, and healthcare	17
Cochrane	The Cochrane Library contains full-text information on the effects of interventions in health care	41
PsychINFO	Contains literature in psychology and psychological aspects of related disciplines	22
AMED	The Allied and Complementary Medicine Database contains references to articles on allied and alternative medicine. Many of the journals covered are not indexed by any other biomedical sources	0
Medline	Contains journal articles from the National Library of Medicine. Covers medicine, nursing, dentistry, veterinary medicine, the health care system, and the preclinical sciences	59
EMBASE	Comprehensive pharmacological and biomedical database renowned for extensive indexing of drug information	95

After duplicates were removed, 175 papers remained. The titles and abstracts of these 175 were read and papers excluded according to predetermined criteria as applied by Aucoin et al. (2014) and shown in Table 2. These exclusion criteria were: not describing a RCT of a mindfulness-based therapy (MBT) for use with a functional gastrointestinal disorder (FGID) population, an article reviewing findings

from other studies only, protocol only, participants aged <18, no measurement of FGID symptoms, combined with other types of pain, and no control group.

Table 2

Reasons for excluding studies based on titles and abstracts

Exclusion criteria	Number of studies excluded
Not a RCT of MBT for FGID	137
Review article	14
Protocol only	4
Paediatric sample	1
FGID symptoms not measured	2
Combined with other types of pain	1
Lack of control	3

Following screening of the titles and abstracts of the original 175 papers using the exclusion criteria stated, the remaining 13 full-text articles were retrieved and read and four were excluded as detailed in Table 3.

Table 3

Reasons for excluding studies based on full text

Exclusion criteria	Number of studies excluded
Reported same results as another included study	1
Included other somatic disorders	2
Only mechanisms of action reported	1

Following this, nine papers were left which met the inclusion criteria. All included papers described IBS or IBS-type symptoms, no papers describing other FGIDs were found therefore this review will discuss the findings only as relating to IBS/IBS-type symptoms. The reference lists of these papers were searched and no further studies were identified. Therefore, nine papers are included in this review.

The literature search strategy and application of exclusion criteria resulted in nine papers being included in this review, the details of which are described in Table 4 below. First a summary of findings of the effectiveness of mindfulness for IBS symptoms are presented and then the papers are discussed according to three proposed review questions:

1. What are the rationales for offering mindfulness-based therapies to individuals with IBS symptoms and how do the mindfulness-based therapies chosen reflect these?
2. How do the study designs impact the generalisability of findings?
3. Which conceptual issues should inform future trial designs?

n.b. Four of the nine papers in this review have come from the same research group and have the same first author (Ljótsson). In order to maintain clarity when discussing the papers I will refer to (Ljótsson, Falk, et al., 2010) as Ljótsson 1 et al. (2010), (Ljótsson, Hedman, Lindfors, et al., 2011) as Ljótsson 2 et al. (2011), (Ljótsson, Hedman, Andersson, et al., 2011) as Ljótsson 3 et al. (2011) and (*Ljótsson, Andersson, Andersson, et al., 2011*) *as Ljótsson 4 et al. (2011).*

Table 4

Characteristics of studies

Author (date)	**Population *Recruitment source***	**N Exp (% female)**	**N Control (% female)**	**Intervention**	**Intervention delivery**	**Intervention duration**	**Control**	**Assessed outcomes**	**Outcomes at end of intervention**	**Months follow up**	**Outcomes at follow up**
Ljótsson 3 et al. (2011)	IBS *(self-referral from community)*	98	97	Exposure-based CBT (ICBT)	Internet (same protocol as Ljótsson 1 et al (2010)	10 weeks	Stress management	IBS symptoms (GSRS-IBS), QoL (IBS-QoL), GI specific anxiety (VSI),negative thoughts about bowel function (CFSBD), stress (PSS), depression and anxiety (HADS)	Significant improvements in both groups but significantly greater in the active group for symptom severity, QoL, GI specific anxiety and negative thoughts about bowel function, no differences between groups on stress or depression and anxiety	6	Improvements maintained at follow up. Significant differences between groups on % reporting adequate relief from IBS pain/discomfort (65% vs. 44%)
Zernicke et al. (2013)	IBS *(gastroenterologist and self-referrals)*	43 (90%)	47 (87%)	MBSR	Face to face groups	8 weeks(8x90 minute sessions + 1x3 hour retreat)	Waiting list	IBS symptom severity (IBS-SSS), QoL (IBS-QoL), mood (POMS), stress (C-SOSI), spirituality (FACIT-sp)	Significant improvements in IBS symptoms, QoL, mood, stress and spirituality	6	Improvements of IBS symptoms and QoL maintained at follow up, difference between MBSR and control group no longer significant (waitlist also improved), rebound effects on stress and mood in MBSR group
Ljótsson 1 et al. (2010)	IBS *(self-referral from community)*	42 (83%)	43	Mindfulness + CBT (exposure)	Internet delivered self-help, access to an online forum, email/telephone contact with a psychologist	10 weeks	Wait list	IBS symptom severity (gastrointestinal symptom diary) (GSRS-IBS), QoL (IBS-QoL), GI specific anxiety (VSI) depression (MADRS-S), disability (Sheehan Disability Scales)	Significant large effects on IBS symptoms, (40% of MG showed clinically significant improvement vs. 2% in the control group) and QoL, moderate effects on GI specific anxiety and small effects on depression and disability	3	Improvements in IBS symptoms maintained, further significant improvements in QoL
Ljótsson 2 et al. (2011)	Reports follow up data from Ljótsson et al (2010)	75 (included control group after cross over)	N/A							15-18 (mean=16.4)	Improvements in IBS symptoms, QoL and GI specific anxiety maintained. 59% report adequate relief from IBS pain or discomfort

Gaylord et al. (2011)	IBS *(self-referral from community)*	36 (100%)	39	Mindfulness-based stress and pain management programme	Group	8 weeks (8x2 hour sessions + 1x4 hour session)	Support group	IBS symptom severity (IBS-SS total score), pain (abdominal pain subscale of IBS-SS), QoL (IBS-QoL), depression (BSI-18), anxiety (BSI-18)	Significant decreases in symptom severity between groups, clinically significant improvement seen in 69% MG and 45% SG, non-significant changes in QoL, psychological distress or visceral anxiety	3	Further decreases in symptom severity, changes in QoL, psychological distress and visceral anxiety reach significance
Faurot et al. (2014)	Reports follow up data from Gaylord et al (2011)	33	35							12	Further significant decreases in symptom severity, psychological distress and visceral anxiety and significant improvement in QoL vs. SG
Berrill et al. (2014)	IBD patients in remission with IBS symptoms or high perceived stress levels *(gastroenterology clinics)*	33 (76%)	33	Multi convergent therapy (mindfulness meditation + cognitive behavioural components)	Face to face individual	16 weeks (6x40 minute sessions)	TAU	QoL (IBDQ), relapse rate (FC), stress (RDHS, PSQ, WCC)	Non-significant increase in QoL (IBDQ) scores in active vs. control; differences reach significance if only the subgroup with IBS symptoms at baseline are included. No differences in relapse rates of IBD (FC), both groups showed a reduction in stress that did not reach statistical significance	12	Improvement in QoL (IBDQ) remains non-significant
Ljótsson 4 et al. (2011)	IBS *(gastroenterology clinics consecutive sampling)*	30 (77%)	31 (71%)	Exposure-based CBT (ICBT)	Internet (same protocol as Ljótsson et al (2010)	10 weeks	Waiting list	IBS symptoms (GSRS-IBS), healthcare costs (TIC-P), QoL (IBS-QoL), GI specific anxiety (VSI), disability (Sheehan Disability Scales)	Significant medium effect sizes for improvements of IBS symptoms, QoL, GI specific anxiety for treatment completers, small effect sizes if using ITT analysis, ICBT was shown to be cost-effective	12	Improvements maintained at follow up and increased for QoL
Zomorodi et al. (2014)	IBS *(hospital and gastroenterology clinics)*	12 (50%)	24 (48%)	MBSR	Face to face groups	8 weeks (8x2 hour sessions)	12 IBS in CBT group, 12 healthy controls	IBS disease intensity (gastroenterologist completed questionnaire)	Not reported	2	IBS disease intensity reduced in MBSR group compared to CBT group or control, many data not reported

ICBT= Internet-based Cognitive Behavioural Therapy, GSRS-IBS=Global Symptoms Rating Scale- Irritable Bowel Syndrome, IBS-Qol=Irritable Bowel Syndrome Quality of Life, VSI=Visceral Sensitivity Index, CFSBD=Cognitive Scale for Functional Bowel Disorders, PSS=Perceived Stress Scale, HADS=Hospital Anxiety and Depression Scale, QoL=quality of life, GI=gastrointestinal, MBSR=mindfulness-based stress reduction, IBS-SSS=Irritable Bowel Syndrome Symptom Specific Scale, POMS=Profile of Mood States, C-SOSI=Calgary Symptoms of Stress Inventory, FACIT-sp=Functional Assessment of Chronic Illness Therapy-spiritual wellbeing scale, MADRS-S=Montgomery Asberg Depression Rating Scale-Self report, MG=mindfulness group, BSI-18=Brief Symptom Inventory-18, SG=support group, IBD=irritable bowel disease, TAU=treatment as usual, IBDQ=Irritable Bowel Disorder Questionnaire, FC=faecal calproctin level, RDHS=Revised Daily Hassle Scale, PSQ=Perceived Stress Questionnaire, WCC=Ways of Coping Checklist, TIC-P=Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry, ITT=intention to treat analysis

Summary of findings of effectiveness of mindfulness for IBS symptoms

Table 5 shows the effect sizes of mindfulness-based interventions on IBS symptom severity and quality of life. These findings are taken from Aucoin et al. (2014). Effect sizes for the additional paper including in this review (Faurot et al., 2014) could not be calculated as standard deviations were not reported.

Table 5

Effect sizes of mindfulness-based interventions on IBS symptoms and quality of life

Author & date	**IBS severity at end of intervention**	**IBS severity at postintervention follow-up**	**Quality of life**
Berrill et al. (2014)	.41	.33	--
Gaylord et al. (2011)	.36	.15	.24
Faurot et al. (2014)	--	--	--
Ljótsson 1 et al. (2010)	1.21	--	--
Ljótsson 2 et al. (2011)	--	--	.96
Ljótsson 3 et al. (2011)	.78	--	.79
Ljótsson 4 et al. (2011)	.35	.42	.51
Zernicke et al. (2013)	.50	.16	.45
Zomorodi et al. (2014)	--	1.16	--
Pooled effects	**.59 (95% CI= .33 to .86)**	**.35 (95% CI= .11 to .59)**	**.56 (95% CI= .34 to .79)**

Quality assessment of the reviewed papers revealed unclear or high risk of bias using the Cochrane risk of bias assessment, largely related to inconsistent blinding of participants and absence of blinding of facilitators (although this is an inherent difficulty in most trials of psychological therapies), and incomplete data due to high rates of attrition.

1. What are the rationales for offering mindfulness-based therapies to individuals with IBS symptoms and how do the mindfulness based therapies chosen reflect these?

Mindfulness-based therapies are a relatively recent area of research in IBS. Researchers have chosen to investigate its effectiveness for IBS and their reasons for doing so may vary and are not always described. First I will review what the studies stated were the problems related to IBS and then whether the interventions investigated in the studies were designed to specifically target the stated problems. The types of mindfulness-based therapies used in each of the studies will then be discussed, along with the choice of approach and then to what extent the studies discuss possible mechanisms through which their chosen intervention targeted the specified problems related to IBS.

What do the studies state are the problems related to IBS? The nine papers together described the results from seven studies, with Faurot et al. (2014) and Ljótsson 2 et al. (2011) describing follow up results of already published studies (Gaylord et al., 2011 and Ljótsson 1 et al., 2010 respectively). Table 6 shows the breakdown of what each of the papers stated were the problems related to IBS.

Table 6

Stated problems related to IBS

Author & date	Burden of symptoms	Reduced health-related quality of life	Societal costs	Psychiatric co-morbidity
Berrill et al. (2014)		X		
Gaylord et al. (2011)	X	X	X	
Faurot et al. (2014)	X	X	X	
Ljótsson 1 et al. (2010)	X	X	X	
Ljótsson 2 et al. (2011)			X	
Ljótsson 3 et al. (2011)	X		X	
Ljótsson 4 et al. (2011)		X	X	
Zernicke et al. (2013)	X			
Zomorodi et al. (2014)		X		X

Three papers described the primary problems of IBS to be symptoms including abdominal pain (Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Zernicke et al., 2013) whilst four others described reduced quality of life to be the primary problem related to IBS (Berrill et al., 2014; Ljótsson 1, et al., 2010; Ljótsson 4, et al., 2011; Zomorodi, Abdi, & Tabatabaee, 2014). Only one study (Gaylord et al., 2011) reported both symptoms and reduced quality of life to be the primary problems related to IBS. Additional stated problems related to IBS were societal costs such as health care burden and lost productivity due to days off work (Gaylord et al., 2011: Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011). Although several studies mentioned high levels of comorbidity of IBS with psychological disorders, only Zomorodi et al. (2014) described this as a problem related to IBS. Overall the studies did not go into details about the problems of IBS that their studies proposed to address.

Are the interventions designed to target the specified problems of IBS?

In order to clarify the rationale for using mindfulness-based therapies for IBS, it might be expected that the authors would clarify which specific IBS-related problems they targeted with their intervention. Three studies made no direct comment about which problems of IBS they used the intervention to target (Berrill et al., 2014; Zernicke et al., 2013; Zomorodi et al., 2014). The remaining four studies (Gaylord et al., 2011; Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011) all stated that they expected their intervention to target IBS symptoms and lead to an improvement in symptomatology. Gaylord et al. (2011) substantiated their expectations by discussing previous findings of MBSR in reducing stress and pain, stating that pain is a prominent symptom in IBS and stress exacerbates IBS symptoms, and so concluding that MBSR should be a reasonable treatment approach. Ljótsson 1 et al. (2010) and Ljótsson 2 et al. (2011) were even more specific in their expectations of how a mindfulness intervention would target problems related to IBS: they stated that their treatment approach (mindfulness and CBT) targeted GI-specific anxiety (GSA) and IBS-related avoidance behaviours. As GSA is thought to maintain symptoms of IBS through positive feedback loops between symptoms and anxiety, treatment would therefore lead to a decrease in IBS symptoms. All three studies from the Swedish research group (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011) also expected that their mindfulness interventions would also lead to improvement in quality of life. Although several studies had previously cited high healthcare burden and lost work days as a problem of IBS, only Ljótsson 4 et al. (2011) stated that they expected their intervention to be cost-effective and to lead to reductions in these associated societal costs.

Types of mindfulness therapy used. Many different therapeutic approaches/protocols have been developed and researched that include mindfulness as a central component (MBSR, MBCT, ACT, DBT), as well as mindfulness being delivered in separate idiosyncratic protocols. The seven studies included in this review covered a range of mindfulness-based therapies, each with differences in approach that may have influenced their results. Only one study used the well-researched and manualised MBSR approach (Zernicke et al., 2013). Delivered in a group format over eight weeks with a retreat towards the end of the programme, it purported to follow the MBSR protocol but with reduced session lengths (90 minutes as opposed to the original 150 minute sessions and with a half as opposed to a full day retreat). The authors stated that these changes were due to practical limitations of their therapeutic setting. A second study (Gaylord et al., 2011) used an adapted version of MBSR they called a "mindfulness-based stress and pain management programme", adapted for an IBS population by encouraging the use of mindfulness to notice sensations in the abdominal region. This was also delivered in a group format over eight weeks with reduced session lengths (two hour weekly sessions and a half day retreat).

Four studies reported using mindfulness-based protocols which included elements of CBT (Berrill et al., 2014; Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011). Berrill et al. (2014) reported using "multi-convergent therapy" (MCT) which they stated had mindfulness as the central component of therapy alongside aspects of CBT. Delivered in an individual format in six 40 minute sessions spread over 16 weeks, MCT had a much reduced contact time compared to the group-based approaches. All three studies from the Swedish research group (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al.,

2011; Ljótsson 4 et al., 2011) used the same protocol that they called "internet delivered cognitive behavioural therapy" (ICBT), a 10 week protocol originally developed as a group treatment (Ljótsson, Andréewitch, et al., 2010). Participants received the treatment as a text-based self-help manual (delivered via the internet but on printer friendly pages) divided into five steps. The first four steps (intended to be delivered weekly) provided psychoeducation and mindfulness instruction. The fifth step gave instructions on IBS-related exposure exercises and how to use mindfulness during them and was intended to be followed for five weeks. Whilst participants received the internet-delivered therapy individually, they had access to a closed online forum for all participants and were encouraged to post group discussions on it. Zomorodi et al. (2014) provided no details of the mindfulness intervention used in their study.

Choice of approach. None of the studies explicitly stated their rationale for choosing the particular mindfulness-based approach they adopted. Gaylord et al. (2011) described the research evidence for the efficacy of MBSR with chronic functional disorders and so by extension the reader is led to assume that this is the reason why they chose to deliver an adapted version of the MBSR protocol. However, they do not discuss any reasons for why MBSR was selected above alternative mindfulness-based approaches. The three studies using the ICBT protocol (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011) provided a rationale for the exposure component of their protocol with reference to its efficacy in previous research, but again did not provide any information for the selection of the mindfulness component. No rationale for intervention choice was provided by the remaining three studies (Berrill et al., 2014; Zernicke et al., 2013; Zomorodi et al. 2014).

Proposed mechanisms. In order for readers and future researchers to be confident of the internal validity of any reported improvements in IBS following a mindfulness-based intervention, the proposed mechanisms of the approach should be discussed.

Berrill et al. (2014) did not describe any proposed mechanisms for how their mindfulness-based therapy would lead to improved outcomes for patients with IBS symptoms, only that they hypothesised that it would, and that a reduction in IBS symptoms would then lead to an improvement in quality of life. Zomorodi et al. (2014) was equally vague on description of proposed mechanisms of mindfulness for IBS, stating that mindfulness would 'affect' the brain-gut axis and thereby reduce symptoms.

The remaining five studies provided more details on proposed mechanisms. Gaylord et al. (2011) admitted that "to date mechanisms are poorly understood" but hypothesised several possibilities. They proposed that psychological treatments in general can act directly on the brain-gut axis by modifying the perception of sensations from the gut, or indirectly by reducing unhelpful thoughts, negative emotions and stress that influence the brain-gut axis and lead to disturbance of the gut. They also stated that neurocognitive research on mindfulness has demonstrated changes in neural activation in regions associated with interoception (perception of internal stimuli) and emotional regulation following training in mindfulness. As IBS has been associated with heightened perception of gut-related pain and anxiety, they proposed that mindfulness may improve IBS symptoms by influencing this interoception. They went further to state that "mindfulness training for IBS may act through a number of therapeutic mechanisms, including increasing non-reactivity to gut-focused anxieties and catastrophic thoughts about the ability to manage pain;

enhancing awareness of IBS symptoms as innocuous interoceptive signals rather than threats to wellbeing; decreasing psychophysiological stress; and facilitating attentional disengagement from gut sensations and obsessive thoughts about visceral function" (Gaylord et al, 2011, p. 1686). Using the data from Gaylord et al. (2011), Garland et al. (2012) furthered the discussion on proposed mechanisms by conducting a path analysis on mediators between mindfulness therapy and improvement in IBS symptoms and quality of life. Their resultant model proposed that mindfulness therapy "led to increased nonreactivity to cognitions, emotions, and physiological sensations which in turn was associated with decreased visceral sensitivity" (Garland et al., 2012, p.598).

Although with differing levels of specificity, the three studies discussed so far all proposed that mindfulness-based therapies would lead to a reduction in IBS symptoms (which would then presumably lead to an improvement in quality of life and/or decreased associated costs and burdens). In contrast, the other four studies (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011; Zernicke et al., 2013) proposed the reverse order of influence; that mindfulness-based approaches would lead to improvement in quality of life and that that would then influence symptoms, not necessarily by improving them, but by improving coping or decreasing burden.

The three studies from the Swedish research group (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011) all suggested that in their ICBT protocols that (1) mindful exposure to IBS symptoms and related GI-specific anxiety (GSA) would lead to extinction of symptom-related anxiety; and (2) mindfulness-mediated acceptance of symptoms, as opposed to avoidance or

attempts at control, would lead to an improved quality of life. Reduction of GSA and increases in quality of life would then lead to a decreased burden of symptoms.

Zernicke et al. (2013) proposed that mindfulness would increase IBS patients' coping with IBS symptoms by facilitating monitoring and regulation of their own arousal. They suggested that this would allow patients with IBS to "gain awareness and evaluate problems with greater emotional stability". Increased coping with symptoms would presumably lead to improvements in quality of life and decreased symptoms burden.

2. How do the study designs affect generalisability of findings?

The second question this review aims to answer is how the designs of the studies included in the review influence the generalisability of their findings, and in extension to this question, how future studies may adapt their designs to increase the relevance of any findings.

Participants/samples. One important aspect of study design is to recruit participant samples representative of the population of interest. This means including as many of the characteristics of interest as possible, whilst keeping the sample as homogenous as possible to reduce introducing error from extraneous variables.

IBS Rome criteria. Berrill et al. (2014) was the only study in this review that did not recruit participants diagnosed with IBS. They recruited participants with diagnoses of IBD (either Crohn's or ulcerative colitis) in clinical remission (judged by the affected individual and her/his physician) and with either symptoms of IBS (according to Rome III criteria) or high perceived stress levels. Their rationale was that previous reviews had concluded that psychological therapies were not effective in improving symptoms or quality of life for IBD patients but suggested that research should focus on the potential benefits for certain subgroups of IBD patients

(Timmer et al., 2011). The remaining six studies recruited participants with IBS according to Rome criteria, Gaylord et al. (2011) used Rome II criteria, and Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011), Ljótsson 3 et al. (2011), Ljótsson 4 et al. (2011), Zernicke et al. (2013) and Zomorodi et al. (2014) used Rome III criteria as their benchmark.

The Rome II and III criteria are identical except for Rome II stating that symptoms are required to be present for at least 12 (non consecutive) weeks out of the previous 12 months, whereas Rome III requires symptoms to be present at least three days per month and to have persisted for at least three months with first onset of symptoms at least six months prior to diagnosis. Although the slightly stricter criteria of Rome II means that participants in the Gaylord et al. (2011) study may have represented a slightly more severe subset of patients with IBS compared to the remaining studies, the difference is small and unlikely to have a large effect.

Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) and Ljótsson 3 et al. (2011) required their self-referred participants to declare that they had received a diagnosis of IBS and checked for presence of 'alarm symptoms' that would lead to exclusion, but did not check IBS diagnoses themselves and so were unable to conclusively state that their sample met Rome III criteria. In Ljótsson 3 however, the IBS diagnoses were all made by gastroenterologists, as was the case in Gaylord et al. (2011), Zernicke et al. (2013) and Zomorodi et al. (2014), either as part of the study or prior to inclusion but verified by medical records. Severity of IBS symptoms pre-intervention for participants who self declared that they met Rome III criteria in Ljótsson 1 et al. (2010), Ljótsson 2 et al. (2011) and Ljótsson 3 et al. (2011) was greater than for the participants who were assessed as meeting Rome III criteria by a gastroenterologist in Ljótsson 4 et al. (2011). It is therefore unlikely that the lack of

gastroenterologist confirmation of diagnosis led to inclusion of non-representative participants.

Recruitment locations. Berrill et al. (2014) recruited participants from Wales, UK, Gaylord et al. (2011) recruited from North Carolina, USA, Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011), Ljótsson 3 et al. (2011) and Ljótsson 4 et al. (2011) all recruited from Stockholm County, Sweden, Zernicke et al. (2013) recruited from Alberta, Canada and Zomorodi et al. (2014) from Tehran, Iran. Most studies made contact with potential participants through gastroenterological clinics, either by reviewing medical records for suitable participants, or identifying potential participants when they attended gastroenterological consultations (Berrill et al., 2014; Gaylord et al., 2011; Ljótsson 4 et al., 2011; Zernicke et al. 2013; Zomorodi et al., 2014). Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) and Ljótsson 3 et al. (2011) exclusively accepted self-referrals from interested individuals following advertisements in online discussion forums, newspapers, websites or flyers at gastroenterology clinics. Gaylord et al. (2011) and Zernicke et al. (2013) accepted self-referrals as well as approaching participants directly. These differences in recruitment methods may have led to participant samples with different levels of motivation and interest in the study, and possibly different baseline levels of symptomatology. The self-referral method used by Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) and Ljótsson 3 et al. (2011) is likely to have led to a sample that included participants with high levels of motivation to take part (they volunteered without prompting), high likelihood of believing the intervention will benefit them and so more motivated to complete the intervention (for example “take the correct dose”) and be more likely to be at a stage in their life of living with IBS where they have already tried alternative methods of management and are now ready and willing

to try a psychological approach. Contrast this to the sample method used in Ljótsson 4 et al. (2011) where participants were identified from consecutive first visits to a gastroenterologist and almost all eligible participants were invited to take part in the study. This group is more likely to have had a much shorter duration of living with IBS (as this was their first visit to a gastroenterologist), less likely to have already fully explored alternative management options such as diet and medication and so may have lower levels of motivation for, and belief in, the possibility for a psychological intervention to have benefit, or the necessity to try a psychological approach at that time. Ljótsson 4 et al. (2011) commented on this difference, noting the much higher attrition and non-completion rates in their sample compared to earlier studies from their research group (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011).

Exclusion criteria- were Axis I disorders excluded? There is a high level of comorbidity in adults, up to 94% (Whitehead et al., 2002), between IBS and psychiatric diagnoses including DSM 5 Axis I disorders such as anxiety and depression. Representative samples would reflect these high levels of comorbidity by including participants with diagnosed/non-diagnosed psychiatric disorders.

Berrill et al. (2014) included participants with comorbid diagnoses of psychiatric disorders, including those taking psychotropic medication (as long as this had not changed in the previous three months), but excluded those that had received psychological therapy. A total of 47 participants were excluded from participation but no data were provided as to what proportion of these had previously received psychological therapy, or for what disorder.

Gaylord et al. (2011) excluded participants with a diagnosis of mental illness with psychosis, or those who had had an inpatient admission for a psychiatric

disorder in the previous two years. This resulted in 12 exclusions. This would presumably have enabled participants with psychological/psychiatric difficulties without psychosis or recent inpatient admissions to take part in the study, increasing representativeness of the sample.

Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) and Ljótsson 3 et al. (2011) used online screening tools to identify potential participants with severe depressive symptoms, suicidal ideation, and substance dependence, followed by a diagnostic interview over the phone, and they then excluded these participants. Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) additionally excluded participants with psychosis, manic episodes or anorexia, although these criteria only resulted in two exclusions, one for severe depressive symptoms, and one for suicidal ideation. In Ljótsson 3 et al. (2011), two participants were excluded for severe depressive symptoms.

Ljótsson 4 et al. (2011) excluded any potential participants "judged to be highly unsuitable for ICBT for somatic or psychological reasons as assessed by the gastroenterologist" resulting in two participants being excluded for "psychiatric reasons" (p. 3). No further details are provided and so it is unknown whether these represented common psychological problems such as depression and anxiety or other issues such as psychosis, or what criteria theses assessments were based on.

Zernicke et al. (2013) had the most exclusive criteria for participants: "concurrent self-reported diagnosis of a DSM-IV Axis I mood, anxiety, or psychotic disorder" (p. 387). In their discussion, Zernicke et al. (2013) comment that this exclusion criterion limits the generalisability of their findings because of the high prevalence rates of mood and anxiety disorder within IBS populations, but that they did it for a "clean sample"(p.394). One of the findings of the Zernicke et al. (2013) study is an improvement in mood following the MBSR programme, so it would be

interesting to know whether inclusion of participants with mood or anxiety disorders would have resulted in even greater observed improvement in mood following MBSR, or less. At entry into the study participants' scores on the Profile of Mood States (POMS) questionnaire were 48.6 (s.d. 36.7) in the MBSR group and 50.1 (s.d. 36.3) in the control group. This was a much higher score than for a normative adult sample which reported scores of 14.8 (s.d. 32.7) for men and 20.3 (s.d. 33.1) for women (Nyenhuis, Yamamoto, Lucheta, Terrien, & Parmentier, 1999). Following treatment scores had fallen to 28.5 (s.d. 45.9) in the MBSR group and 37.4 (s.d. 41.8) in the control group, remaining higher than the normative population. Given the evidence of efficacy of MBSR in improving symptoms/quality of life for individuals with mood or anxiety disorders, and for those with IBS, it would be reasonable to assume that for individuals with comorbid mood/anxiety disorders and IBS, MBSR could lead to benefits through several different therapeutic mechanisms.

Zomorodi et al. (2014) published no information about inclusion/exclusion of psychiatric disorders. Of the studies that stated the number of potential participants excluded on the basis of concurrent psychological/psychiatric diagnoses, the excluded participants represent between 1-16% of the eventual sample. Comparing these relatively small numbers to the much higher published comorbid rates in the general IBS population, this suggests that many participants with comorbid psychological problems were included in the samples and therefore enhancing the generalisability of the findings.

Outcome measures - do they sample the targeted problems of IBS? There was a high degree of overlap in the outcome measures used in the 7 studies. Two studies used IBS symptom severity as the primary outcome of their study, measured by the Irritable Bowel Syndrome Symptom Severity Scale (IBS-SSS) (Gaylord et al.,

2011; Zernicke et al. 2013). The three studies from the Swedish research group also used IBS symptom severity as their primary outcome measure, but used the Gastrointestinal Symptoms Rating Scale modified for patients with IBS (GSRS-IBS) as their measure. Zomorodi et al. (2014) also stated IBS symptom severity as primary outcome but provided little detail of their measurement tool other than describing it as a questionnaire based on Rome III criteria and used by a gastroenterologist to ascertain IBS disease severity. Berrill et al. (2014) was alone in the included studies in using quality of life as measured by the Inflammatory Bowel Disease Questionnaire (IBDQ) as the primary outcome measure, although they did also collect data on symptom severity using the IBS-SSS. All other studies measured quality of life using the Irritable Bowel Syndrome Quality of Life questionnaire (IBS-QoL) except for Zomorodi et al. (2014), who did not report quality of life data.

As the primary listed problems of IBS in most studies were the burden of symptoms of IBS and impact on quality of life, all the studies appear to have measured both of these constructs except for Zomorodi et al. (2014). Only one study (Ljótsson 4 et al., 2011) measured health economic data, despite many of the other studies stating high health economic costs to be a problem related to IBS.

Measures of stress - floor effects or using a wellbeing measure? In addition to the primary outcome measures of IBS symptom severity and quality of life, the majority of studies measured several secondary outcomes. The most common of these was mood/stress as shown in Table 7.

Table 7

Measures of mood/stress

Author & date	Mood measure	Stress measure	Symptom specific anxiety measure
Berrill et al. (2014)	HADS	RDHS PSQ	
Gaylord et al. (2011) Faurot et al. (2014)	BSI-18		VSI
Ljótsson 1 et al. (2010) Ljótsson 2 et al. (2011)	MADRS-S		VSI
Ljótsson 3 et al. (2011)	HADS	PSQ	VSI
Ljótsson 4 et al. (2011)			VSI
Zernicke et al. (2013)	POMS	C-SOSI	
Zomorodi et al. (2014)			

HADS= Hospital Anxiety and Depression scale, RDHS= Revised Daily Hassle Scale, PSQ= Perceived Stress Questionnaire, BSI-18= Brief Symptoms Inventory 18, MADRS-S= Montgomery Asberg Depression Rating Scale-Self report, POMS= Profile of Mood States, C-SOSI= Symptoms of Stress, VSI= Visceral Sensitivity Index

Berrill et al. (2014) used the Hospital Anxiety and Depression scale (HADS) as well as the Revised Daily Hassle Scale (RDHS) and the Perceived Stress Questionnaire (PSQ). Gaylord et al. (2011) used the Brief Symptoms Inventory 18 (BSI-18). Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011) used the Montgomery Asberg Depression Rating Scale-Self report (MADRS-S), whilst Ljótsson 3 also used the HADS as well as a 10 item version of the PSQ. Zernicke et al. (2013) used the Profile of Mood States (POMS) and Symptoms of Stress (C-SOSI). Gaylord et al. (2011) and all three studies from the Swedish research group measured gastrointestinal-specific anxiety using the Visceral Sensitivity Index (VSI). The VSI is a 15 item questionnaire that aims to measure the degree of anxiety related to gastrointestinal symptoms. It asks respondents to rate how much they agree with statements such as "I often worry about problems in my belly".

Of the four different measures of mood used across the studies, three were developed for use with medical populations (HADS, BSI and POMS) and only the MADRS-S was designed specifically for individuals with diagnosable depression. Although there are known links between levels of stress and IBS (for example stress exacerbating IBS symptoms), and high rates of comorbidity between IBS and psychiatric/psychological disorders (Whitehead et al., 2002), not everyone with IBS has high levels of anxiety or depression. It is therefore possible that the IBS patients rating their mood on the MADRS-S would have scored minimally on these measures pre-intervention resulting in it being very difficult to detect changes in the measures post-intervention (floor effects). However this does not appear to be the case in the data with the pre-intervention scores on the MADRS-S averaging around 25% of the possible total score, and the standard deviations being smaller than the mean and so not encompassing a score of zero.

Blinding or controlling for being unable to blind and credibility checks

In RCTs for pharmacological interventions, high quality designs use double or even triple blinding of treatment condition (either the participant, the participant and dose deliverer, or the participant, dose deliverer and data collector and/or data analyser are all unaware of which participants was in which trial arm). This is to control for expectancy of improvement, or placebo effects.

It is almost impossible to achieve blinding of therapists in psychological interventions, and very difficult to achieve blinding of patients, since the treatment and the comparison usually differ in ways that are easy to identify, such as the control condition often being shorter, involving less face to face contact, etc. Additionally, ethical practice of informed consent often requires that patients are

aware of the conditions of each arm of the trial, meaning that they are likely to be able to match features of each condition to their allocated treatment.

If blinding of participants is not possible, an alternative is to ask participants to rate the credibility of their allocated condition. In that way, outcomes can be compared against post-treatment guesses by participants about which condition they believed they received, and their level of belief in the efficacy of the treatment they were receiving (expectation of benefit). This is also good but not common practice in RCTs of pharmacological interventions: since side effects of drugs can unblind participants, participants should be asked at exit whether they believed they were in the active or placebo arm of the trial, and why.

Four of the seven RCTs reviewed did not use an active control condition. In Berrill et al. (2014), participants were either assigned to the mindfulness-based therapy or received medical treatment as usual (TAU) from their gastroenterology team. Therefore participants were aware of which condition they were in. Ljótsson 1 et al. (2010)/Ljótsson 2 et al. (2011), Ljótsson 4 et al. (2011), and Zernicke et al. (2013) all used TAU waitlist control groups. In their studies participants were either assigned to an immediate mindfulness-based therapy or were placed on a waiting list to receive the intervention several months later, and acted as controls during their waiting time. The participants in these studies would similarly not have been blinded as to treatment allocation and in addition may have had very low expectations of improvement during the waiting period as they knew they would receive the 'active' treatment in the future, though modest improvement on waiting lists are almost always seen due to the effects of being studied, paid attention to and having one's concerns validated.

Only three studies used active control groups. The intention with an active control group is, as far as possible, to match the 'active' treatment on non-specific elements (for example duration, therapist attention, "dose") and not to include any known 'active' elements. In their study, Gaylord et al. (2011) used an "IBS support group" as control condition. Although participants were not blinded to their allocation, the two treatments were presented as equal; patients were told that in previous studies both had been beneficial. All participants completed a credibility scale after their first treatment session, using the Borkovec and Nau attitudes towards treatments questionnaire (Borkovec & Nau, 1972). The authors reported no differences in the credibility ratings between the two groups, indicating that expectancy of benefit should have been approximately equal in both conditions. In addition to this, study staff involved in data collection and data management were masked to treatment allocation.

Ljótsson 3 et al. (2011) used "Internet stress management (ISM)" as the control condition in their study, designed to contain elements common to all psychological interventions (a rationale for treatment, psychoeducation, practice of new behaviours and therapeutic alliance). Participants were not told about the differences between the two treatments, and were informed that both had been shown to be beneficial in reducing IBS symptoms. Ljótsson 3 et al. (2011) also used the Borkovec and Nau credibility scale and reported equal scores in both groups.

Zomorodi et al. (2014) used two control groups, but one consisted of healthy participants receiving no intervention and so was irrelevant. The active control group included participants with IBS receiving weekly CBT sessions to match the intensity of intervention for the mindfulness group. The authors did not report any blinding of participants/researchers or use of credibility checks.

The use of active control groups, together with validated credibility checks in the Gaylord et al. (2011) and Ljótsson 3 et al. (2011) studies represents good practice and enables readers to have greater confidence that the observed differences between groups following the interventions were due to the particular intervention, rather than to expectations of benefit or nonspecific effects common to all interventions.

Participant adherence to the interventions. Once participants have been allocated to a particular treatment, it cannot be assumed that they will receive the intended "dose". They may not attend all sessions or complete the intended homework. Therefore in order to make conclusions about the efficacy (or inefficacy) of an intervention it is important for researchers to record attendance and adherence. Berrill et al. (2014) make no mention of monitoring participants' adherence. Gaylord et al. (2011) collected electronic daily diaries from participants including the number of minutes of mindfulness practice completed; they also reported the average number of sessions attended by participants.

Ljótsson 1 et al. (2010) reported "neither therapist adherence nor the treatment activity of other participants was assessed in the study" (p.537). However, they did report the number of steps of the intervention participants completed, and participants had to report homework exercises for each step before being given access to the next step. In addition, participant contact with therapists was monitored. Although participants were asked to complete weekly diaries, these were only collected at the end and so it is unknown when participants completed them. Ljótsson 3 et al. (2011) and Ljótsson 4 et al. (2011) make no mention of participants' adherence, but their studies closely matched that of Ljótsson 1 et al. (2010) and they are likely to have included a similar level of monitoring.

In Zernicke et al. (2013), participants kept daily meditation logs which were collected weekly, and facilitators recorded the number of sessions attended. The only mention of participant adherence in Zomorodi et al. (2014) was that in the CBT control condition, most participants did not complete their homework. It is unknown to what extent participants in the mindfulness group completed their homework.

Zernicke et al. (2013) was the only study that additionally analysed adherence to the intervention. They reported that treatment completers (attended five or more out of the eight classes) showed a 31% reduction in IBS symptoms following the intervention, compared to a 17% reduction for participants who attended fewer than five classes.

Protocol adherence. In addition to participants' adherence to an intervention, the degree to which the facilitators adhered to the protocol affects the strength of the conclusions that can be drawn from the findings. Only Gaylord et al. (2011) reported monitoring facilitators' compliance to their protocol through videotaping of sessions, and noted that no protocol deviations were observed. The three studies from the Swedish research group were all delivered via the internet and so intervention content and delivery was inherently standardised, but no explicit assessment of adherence to the manual was reported. Zernicke et al. (2013) and Zomorodi et al. (2014) make no mention of protocol adherence measures.

3. Which conceptual issues should inform future trial designs?

Placebo response. In the original Latin placebo means "I shall please" and the placebo effect describes "the beneficial... effect on health produced by a placebo that cannot be attributed to the properties of the placebo" (Placebo, n.d.).

The placebo response is usually spoken of as a 'nuisance' effect adding error to be controlled for (and resulting in the need for a matched control condition)

(Critelli & Neumann, 1984). In pharmacological trials the aim is to demonstrate drug effectiveness 'above and beyond' the effects of the placebo treatment (an existing drug or an inert substance).

Alternatively, the placebo response can be conceptualised not as a 'nuisance' but as an opportunity; evidence of the possibility for interventions conventionally thought of as 'inert' to have positive impact on health and wellbeing through patient expectations and through the procedures involved in any trial. In pharmacological trials for instance, the placebo response demonstrates that *even without an active drug* participants showed improvement in symptoms. Whilst understanding the components of the placebo effect may not help to develop better pharmacological substances, it may help develop better psychological approaches to healthcare as the placebo effect is mediated by psychological factors. The opportunity therefore is to identify what factors led to improvement in the placebo group? Or, alternatively, what are the 'active ingredients' of a placebo?

There are several different aspects of the placebo effect: regression to the mean, natural course of the disease, Hawthorne effect, expectancy of improvement, attention, social support, validation of experience and a sense of agency (Barnett, van der Pols, & Dobson, 2005; Hróbjartsson & Gøtzsche, 2010; Linde et al., 2007; Stewart-Williams & Podd, 2004). The first two are the least psychological in nature. Regression to the mean (a statistical phenomenon) and the natural course of a disease are unlikely to have a large effect in IBS trials as IBS is a chronic disorder, without common spontaneous remission (Tanaka, Kanazawa, Fukudo, & Drossman, 2011).

The remaining aspects are much more psychological in nature, although they can result in biological changes in the body such as changes in blood pressure (Meissner, 2011). The Hawthorne or observer effect refers to changes in

participants' behaviour caused by an awareness of being observed (Adair, 1984). The expectancy of improvement effect largely relies on learning and socialisation to healthcare situations where interaction with a practitioner is associated with improvement in symptoms. This can occur at a conscious level, and additionally at an unconscious level. Verbal associations activate association areas in the brain and the body can respond unconsciously producing a placebo response (Frenkel, 2008) with modulated pain processing occurring in the spinal cord during placebo analgesia (Eippert, Finsterbusch, Bingel, & Büchel, 2009).

The role of attention, social support and validation of patients' experiences can be grouped together in terms of representing the positive patient-practitioner relationship. This relationship is likely to lead to an improvement in patients' emotional and psychological wellbeing which then leads to improvement in symptoms, either directly through CNS involvement, or indirectly through better coping and improved health behaviours.

The final example, a sense of agency, refers to the situation where a participant's presence in a trial represents a deviation from a previous state of helplessness, for example their symptoms have not responded to other treatments and so taking part in a clinical trial provides a positive feeling of doing *something* rather than the despondency associated with doing *nothing*.

In essence, much of the 'placebo effect' could alternatively be thought of as a 'positive care effect' (Blease, 2012) as "the study of the placebo effect…is the study of the psychosocial context around the treatment and the patient, and it plays a crucial role in the therapeutic outcome" (Benedetti & Amanzio, 2011, p. 413).

IBS is a condition in which there is a high degree of placebo response with an average placebo response rate of 40.2% in pharmacological trials of IBS (Patel et al.,

2005) and 42.6% in complementary and alternative medicine trials of IBS (Dorn et al., 2007); this is in comparison to the mean placebo response rate in Crohn's disease of 19% (Su, Lichtenstein, Krok, Brensinger, & Lewis, 2004). Although placebo effects have been reported in almost all medical conditions, those disorders with a stronger link with psychological processes are likely to show a greater response (Hróbjartsson & Gøtzsche, 2010). It is therefore understandable that IBS would demonstrate a high placebo response rate as psychological factors are key to the manifestation of the syndrome. High placebo response rates have additionally been demonstrated in open-label placebo trials for IBS where participants were truthfully informed that they were receiving "inert or inactive pills, like sugar pills" and given a rationale for why the placebo might be effective (Kaptchuk et al., 2010).

Different control groups were used across the seven studies included in this review and so different degrees of placebo response may have operated. Kaptchuk et al. (2008) demonstrated three levels to the placebo response in IBS trials; assessment and observation, a therapeutic ritual, and a supportive patient-practitioner relationship. Three of the seven reviewed studies (Gaylord et al., 2011; Ljótsson 3 et al., 2011; Zomorodi et al., 2014) utilised an active control group (encompassing all three levels) and so would be expected to show a larger placebo response as their control group would have had higher expectancy of improvement than participants in the waitlist control groups of the other studies. This pattern is indeed shown in the data for IBS severity and more clearly for IBS quality of life as shown in Table 8 and 9 and Figure 1 and 2.

Table 8

IBS severity in the control group

Study	Pre intervention	Post intervention	% change post intervention	Follow up	% change follow up
Gaylord et al. (2011)	287 [a]	269 [a]	6.3%	261 [a]	9.1%
Ljótsson 3 et al. (2011)	47.3[b]	41.1[b]	13.1%	39.3[b]	16.9%
Zomorodi et al. (2014)	17.83[c]			16.8[c]	5.8%
Berrill et al. (2014)	221 [a]	206 [a]	6.8%	224 [a]	-1.4%
Ljótsson 1 et al. (2010)	49.6[b]	47.3[b]	4.6%		
Ljótsson 4 et al. (2011)	39.8[b]	40.9[b]	-2.8%		
Zernicke et al. (2013)	249 [a]	230 [a]	7.6%	213.8 [a]	14.1%

[a] =IBS-SSS [b] =GSRS-IBS [c]=unspecified disease intensity measure

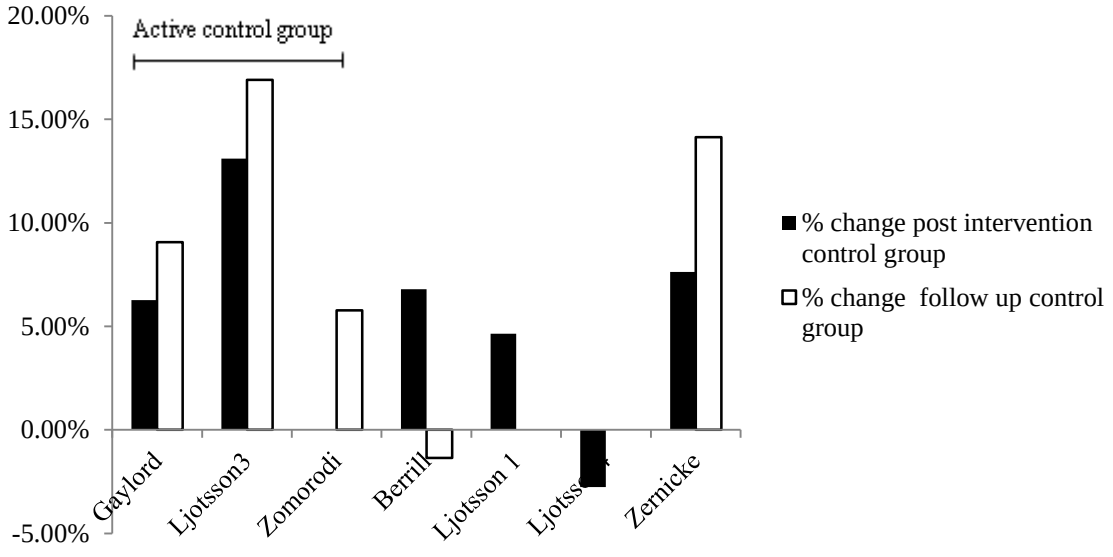

Figure 1. Improvements in IBS symptoms (IBS-SSS) observed in the control groups

Table 9

IBS quality of life in the control group

Study	Pre intervention	Post intervention	% change post intervention	Follow up	% change follow up
Gaylord et al. (2011)	67.4 [b]	70.9 [b]	5.2%	70.5 [b]	4.6%
Ljótsson 3 et al. (2011)	55.5 [b]	65.7 [b]	18.4%	68.7 [b]	23.8%
Zomorodi et al. (2014)					
Berrill et al. (2014)	149 [a]	145 [a]	-2.7%	137 [a]	-8.1%
Ljótsson 1 et al. (2010)	53.8 [b]	52.9 [b]	-1.7%		
Ljótsson 4 et al. (2011)	76.1 [b]	67.4 [b]	-11.4%		
Zernicke et al. (2013)	61.6 [b]	63.1 [b]	2.44%	66.5 [b]	8.0%

[a] =IBDQ [b] =IBS-QoL

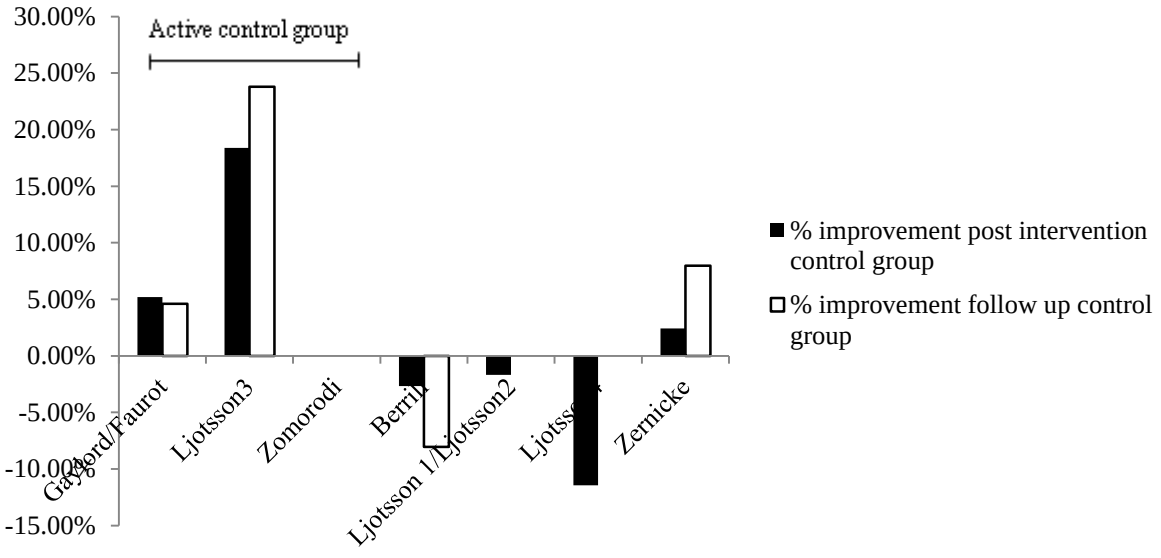

Figure 2. Improvements in health related quality of life (IBS-QoL) observed in the control groups

Reference to the brain-gut axis. Gaylord et al. (2011) reported that "brain-gut interactions are recognised to have a prominent role in modulating gut function" (p.1679) and gave an explanation of brain gut interactions as previously described in the introduction. Zernicke et al. (2013) also mention that "chronic GI symptoms are generated by a combination of intestinal, motor, sensory and central nervous system activity termed the "brain-gut axis"" (p.386) and Zomorodi et al. (2014) made a fleeting reference to the brain-gut axis in their introduction. However Berrill et al. (2014) and the three Swedish research group papers made no reference to the brain-gut axis.

Explanatory theories of IBS. Explanatory theories of IBS propose that changes in the brain-gut axis lead to increased sensitivity of the gut, and changes to the interactions between microflora (bacteria in the gut), the cells lining the gut, and the immune system (Tillisch & Labus, 2011). None of the studies reviewed directly discussed explanatory theories of IBS distinct from discussion of the brain-gut axis.

How is mindfulness linked to the brain-gut axis? Berrill et al. (2014), and the three Swedish research group papers made no reference to the brain-gut axis as it relates to mindfulness, and neither did Zernicke et al. (2013). Gaylord et al. (2011) suggested that mindfulness meditation would influence psychological factors associated with IBS such as heightened perception of intestinal pain, selective attention to gastrointestinal sensations and anxiety about the significance of those sensations. Although they did not express it directly, their implication was that this would then lead to an improvement in gastrointestinal symptoms through brain-gut axis connections. Zomorodi et al. (2014) made similar comments, stating that mindfulness can reduce the brain activity of regions involved in emotion regulation

and pain processing, thereby influencing the brain-gut axis and leading to an improvement in symptoms.

Neuropsychological theories. There was very little discussion of neuropsychological theories in the studies, other than in relation to the brain-gut axis as described above.

Discussion

Summary of findings

The research reviewed will be summarised and discussed in relation to the original findings of Aucoin et al. (2014) and the three aims of this review.

Meta-analysis. Although search criteria allowed inclusion of any functional gastrointestinal disorder, only papers describing trials of IBS of IBS-type symptoms were found and therefore the findings relate only to IBS. Results from the studies indicated that mindfulness-based therapies are effective at reducing IBS symptom severity and improving quality of life. They also suggested that improvements are maintained over the medium term. However the unclear or high risk of bias in many of the studies as assessed by the Cochrane risk of bias assessment led Aucoin et al. (2014) to recommend that the statistically significant effects "be interpreted with some discretion". The seven studies also represented a range of mindfulness-based therapies making comparisons difficult. This review therefore aimed to extend the findings of Aucoin et al. (2014) by answering the following three questions.

1. What are the rationales for offering mindfulness-based therapies to individuals with IBS symptoms and how do the mindfulness-based therapies chosen reflect these? The reviewed studies all aimed to target the primary problems of IBS: symptom severity (abdominal pain/discomfort, alterations in bowel habit and bloating) and reduced health-related quality of life. Secondary problems of comorbid

depression and anxiety were included as co-analyses but the interventions were not designed specifically to target them. Although societal costs such as reduced productivity and loss of work days were widely cited as IBS-related issues, only one study measured the effect of mindfulness-based therapies on this. The studies differed in whether they hypothesised that the mindfulness-based intervention would impact on IBS by improving symptoms (which would then lead to an improvement in quality of life) or conversely would increase quality of life via greater acceptance of symptoms and reduced avoidance which would in turn improve symptoms themselves. Overall the studies provided little information on plausible mechanisms of why their mindfulness-based intervention would impact on IBS. Though several of the studies discussed the brain-gut axis, this was not linked clearly to the mindfulness interventions, or to possible causal mechanisms of action. The rationales given for offering mindfulness-based therapies either were not explicitly discussed, or merely cited observational findings of mindfulness-based therapies leading to improvement of symptoms and quality of life with similar health problems, rather than providing a specific theoretical basis for why mindfulness would lead to improvements in IBS. A variety of mindfulness-based approaches were used in the studies and it is not possible to conclude which choice of approach was most effective. Some studies adapted their protocols specifically for IBS populations whereas others used generic protocols but there was not sufficient data to establish superiority between approaches. Further research is warranted in this area.

2. How do the study designs affect generalisability of findings? External validity was high in terms of Rome-criteria-diagnosed IBS and inclusion of various degrees of psychological disorder, but only one study was from a non-westernised

country. Similarly studies were well designed with measures to demonstrate the impact of mindfulness-based interventions on primary issues of symptoms severity and quality of life, but less well designed to enable conclusions about impact on health-economic factors. Choice of mood/stress measures varied widely but were mostly developed for use with medical populations (for the one measure used that was not, floor effects did not appear to occur in the data) and therefore there can be greater confidence in the data from those measures.

Three studies used active control groups but only two reported efforts to achieve equivalence of interventions on nonspecific factors, and to provide credibility checks to control for expectation of benefit. Participant adherence to the interventions was inconsistently monitored and only one study was able to report data on a relationship between outcomes and adherence to the intervention. Zernicke et al. (2011) reported almost double the amount of improvement in IBS symptoms for those participants who attended a greater number of sessions. Similarly only one study reported monitoring therapists' protocol adherence. This leaves some doubts about generalisability as, without knowing how closely participants' experiences matched the stated protocols, we cannot know how well these interventions will translate to routine practice. If data existed which showed positive outcomes only resulted after close adherence to the specific elements of the protocol, rather than from general effects of attending a mindfulness-like intervention then this could aid the decision making of treatment providers. They would then be able to conclude whether their resources were warranted in being put into an intervention that closely matched the published protocols, or whether they could vary delivery substantially, and still expect positive outcomes.

3. Which conceptual issues should inform future trial designs?

The influence of the placebo effect is one conceptual issue that should inform future trial designs. The three studies in this review that used active control groups, reported greater placebo responses than the studies utilising waitlist or TAU control groups. High levels of placebo response are common in IBS trials (Dorn et al., 2007; Patel et al., 2005; Su et al., 2004) suggesting a large influence of non-specific factors in improvement following interventions. Future trials which utilise sophisticated control group designs matching different elements of the active mindfulness intervention could demonstrate more clearly, which aspects of the placebo effect are the most efficacious and therefore warrant being prioritised in treatment protocols.

Other conceptual issues including possible explanatory theories of IBS, the brain-gut axis and mechanisms of action of mindfulness-based therapies featured little in the reviewed studies. Dysregulation of the brain-gut axis can account for much of the observed symptoms of IBS (Mayer & Tillisch, 2011) and therefore future trials would benefit from being designed to be able to shed some light on whether the positive outcomes observed following mindfulness-based interventions were due to alterations of the brain gut axis, and the mechanisms of this. Current theories of the mechanisms by which mindfulness can influence the brain-gut axis proposes that mindfulness encouraging non-judgemental awareness of physical sensations, cognitions and emotions. This modulates the emotional components of pain processing, reduces catastrophic appraisals of the significance of gastrointestinal symptoms and reduces GI-specific anxiety (Garland et al., 2012).

Efficacy of mindfulness-based therapies for IBS

The meta-analysis conducted by Aucoin et al. (2014) concluded that mindfulness based-therapies for functional gastrointestinal disorders produced

medium effect sizes on both IBS severity and quality of life. Although the scope of this review did not include meta-analytic analysis of the papers, inspection of the data from the nine retrieved papers supported the conclusions of Aucoin et al. (2014). The search conducted for this review retrieved an additional paper to those identified by Aucoin et al. (2014) describing follow up results of an already published study (Gaylord et al., 2011). The additional data from this follow up paper added further evidence of the efficacy of mindfulness-based therapies on symptom severity and quality of life for individuals with IBS (Faurot et al., 2014) however effect sizes could not be calculated due to means only being reported and no standard deviations. The only negative findings were reported in a sample of individuals in remission of IBD who either had high perceived stress levels or IBS symptoms; however subgroup analysis of only those with IBS symptoms did show improvement (Berrill et al, 2011). This suggests that there is a feature of IBS specifically which is amenable to mindfulness-based interventions (for example influencing attention to visceral stimuli), rather than there being a general impact on GI-related health.

A meta-analysis of mindfulness-based therapies for somatisation disorders (Lakhan & Schofield, 2013) included three of the studies included in this review (Gaylord et al., 2011; Ljótsson 1 et al., 2010; Zernicke et al., 2013). They similarly concluded that mindfulness-based therapies for IBS showed medium effect sizes on symptom severity and quality of life although with only three studies (accounting for a combined sample size of 250) these results must be interpreted with caution.

Concordance with literature on mindfulness-based therapies with other populations

The positive results of mindfulness-based therapies with IBS concur with the existing literature on mindfulness-based therapies with other somatic conditions such

as fibromyalgia (Fjorback et al., 2013; Lakhan & Schofield, 2013), chronic pain (Baer, 2003; Chiesa & Serretti, 2011; Grossman et al., 2004; Reiner et al., 2013), cancer (Piet, Würtzen, & Zachariae, 2012; Shennan, Payne, & Fenlon, 2011; Smith, Richardson, Hoffman, & Pilkington, 2005) diabetes (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007; Hartmann et al., 2012), vascular disease (Abbott et al., 2014), Multiple Sclerosis (Simpson et al., 2014), breast cancer (Cramer, Lauche, Paul, & Dobos, 2012), prevention of recurrent depression relapse (Ma & Teasdale, 2004; Teasdale et al., 2000) and current depression or anxiety symptoms (Strauss, Cavanagh, Oliver, & Pettman, 2014).

Clinical implications

There are three main clinical implications that arise from this review; the first that mindfulness-based therapies show promise for positively impacting on severity of symptoms and health-related quality of life for individuals with IBS and should be made more widely available, the second that aspects of the placebo or 'positive care' effect should be harnessed in healthcare interactions for individuals with IBS, and thirdly that information about the brain-gut axis should be more readily explained to patients.

The efficacy data for the effect of mindfulness-based interventions on IBS are only preliminary as they are based on a small number of papers and need replication, but are promising. This suggests that mindfulness-based therapies should be made more widely available for individuals with IBS.

There are also promising findings from the studies using an internet-based protocol (Ljótsson 1 et al., 2010; Ljótsson 2 et al., 2011; Ljótsson 3 et al., 2011; Ljótsson 4 et al., 2011) suggesting that wider provision of mindfulness-based therapies does not necessarily require large resources. However internet delivery

excludes many of the nonspecific effects which should ideally be harnessed. The protocol used in the Ljótsson studies provided some aspects of a positive patient-practitioner relationship using telephone and messaging with practitioners. Use of internet delivery to roll out provision of mindfulness-based therapies would need to be carefully considered for which populations it would be suitable for. In chronic pain studies very high attrition rates are seen with internet delivery methods (which could be a potentially harmful experience for the patient who then feels that they have failed) (Andersson, 2009; Macea, Gajos, Daglia Calil, & Fregni, 2010). However with highly motivated patients, and supportive practitioner relationships involved in other aspects of their care, there may be scope for such low-intensity interventions, but more research is needed on this issue.

Tentative recommendations can also be made to focus on offering mindfulness-based interventions to patients with IBS on a self-referral basis to patients who have already received standard medical care and are still experiencing distressing symptoms, rather than offering it to all patients soon after diagnosis. This recommendation is based on findings from the Swedish research group. Using the same protocol in all three of their studies, much greater improvement were shown when participants chose to self-refer after seeing adverts for the programme (Ljotsson 1 et al., 2010) than when participants were approached at their first meeting with a gastroenterologist shortly after diagnosis (Ljotsson 3 et al., 2011).

Another clinical implication concerns utilisation of the placebo effect. Many of the components of the placebo effect demonstrate aspects of the practitioner-patient relationship that result in positive outcomes and as such can be considered a ‘positive care effect’ (Blease, 2012). All practitioner-patient interactions will contain these aspects to differing extents and therefore efforts should be made to enhance the

key component as much as possible, both in psychological therapies and other healthcare appointments (Enck, Bingel, Schedlowski, & Rief, 2013). In practice this may involve close monitoring of outcomes and improvements (replicating the observer effect), taking time to explain the efficacy and mechanisms of any intervention and likely improvement (replicating expectations of improvement), allowing time during appointments to answer questions and address concerns (replicating attention) and linking patients into supportive IBS networks (replicating social support) (Enck et al., 2013).

The third clinical implication involves explaining the role of the brain-gut axis in IBS to patients. Although this did not explicitly emerge from the studies included in this review, it is a recommendation based on taking an overview of the mechanisms of mindfulness-based therapies discussed in the papers. The function of the brain-gut axis in IBS is well documented (Mayer, 2011; Mulak & Bonaz, 2004; Tanaka et al., 2011; Tillisch et al., 2011) and intuitively experienced in the bodily experience during stress/fear. If patients were provided a clear explanation of the role of the brain-gut axis in IBS, it might serve to increase understanding on the 'functional' nature of the disorder. It can be difficult for many patients diagnosed with functional disorders such as IBS that there is no identifiable physical or structural abnormality to account for their symptoms. This can lead some to feel that they are being told it is 'all in their head' or 'not a real disease' whereas their pain and distress is very real. Explanation of the brain-gut axis could help to provide a biological account of how their very real symptoms can occur without an observable organic disease. It could help to build an integrated mind-body model and perhaps reduce gastro-specific anxiety of symptoms and provide a rationale and motivation for engagement in psychological approached to IBS management.

Research implications

Several research implications arising from this review have already been discussed above, and there are further recommendations which warrant discussion. The first is for further RCTs of mindfulness-based therapies for IBS with larger samples to increase the power of future meta-analyses and increase confidence in the promising results found. This would be aided by consistent use of measures across studies to measure symptom severity and mood/stress.

It would be useful for future studies to collect data on treatment adherence, specifically amount of mindfulness practice completed between sessions and following the intervention. It would be expected that greater duration/frequency of practice would lead to greater/better maintained improvements and further data would allow conclusions to be drawn on the importance/unimportance of such extended practices. However this level of analysis would require large sample sizes in future studies.

It would also be informative for future RCTs to compare and contrast different types of mindfulness-based therapies (for example MBSR vs. MBCT) or dismantling studies to investigate the relative influence of different components of interventions for example number of sessions, presence or absence of a mid-way retreat, use of a generic mindfulness protocol or one specifically designed for IBS.

The currently reviewed studies represented a heterogeneous population of individuals with IBS both in terms of length of time since diagnosis and severity of symptoms (including patients in clinical remission from IBD). It would be important for future studies to investigate which subgroups of individuals with IBS would benefit most from mindfulness-based therapies; those newly diagnosed, or with a long history of IBS; only those that have not responded to other IBS treatments, or as

an adjunct to other successful treatments; and those with, or without comorbid psychological problems?

It would be beneficial for future studies to investigate which factors contributed most strongly to the placebo response, and how they can be utilised to improve patient care in IBS. Whilst in experimental conditions these psychosocial factors may be discounted as 'placebo', their potency demonstrates that they should be enhanced in every patient-practitioner interaction. It would therefore be useful for future studies of mindfulness-based therapies with IBS to focus on how these psycho-social factors can be used to optimise efficacy of treatment.

Limitations

Several issues affect the interpretation of the findings from this review. Caution is needed when interpreting the findings from the study by Zomorodi et al. (2014). Published as an English translation of the original in Farsi, many sentences had ambiguous language. Their published protocol was very unclear, some data were not reported (end of intervention data was omitted and only follow up data reported) and they did not specify the origins of the measures they used. Despite these quality issues the study was included in this review as it was included in the Aucoin et al. (2014) meta-analysis that this review replicated and it was the only study representing a non-westernised sample. The N of the study was very small and so it is likely to have had only a minimal impact on the meta-analysis and it provided some indications that mindfulness-based interventions may have applicability beyond western-based populations.

Another limitation is that a standard quality assessment tool was not used to rate the methodological quality of the included studies as this had already been reported in Aucoin et al. (2014) using the Cochrane risk of bias assessment and

CONSORT checklist for reporting trials of non-pharmacological treatment. This decision was taken as the focus of this review was on expanding the findings of the Aucoin et al. (2014) review in terms of design, methodological and theoretical issues rather than replicating their meta-analysis.

Conclusions

Mindfulness-based therapies for IBS show promising results on reducing symptom severity and improving health-related quality of life. Data were insufficient to make recommendations on which mindfulness-based interventions are likely to be most effective or which subgroups of the IBS populations would benefit most (preliminary findings suggest self-referral to be more appropriate than being offered to all patients). Initial findings suggest that attendance of more than five sessions is associated with greater improvement but this finding is based on only one study and so needs replicating. Interesting questions were raised about the relative importance of non-specific (placebo) effects on the outcome of the interventions and more research is needed to explore this.

References

Abbott, R. A., Whear, R., Rodgers, L. R., Bethel, A., Thompson Coon, J., Kuyken, W., … Dickens, C. (2014). Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *Journal of Psychosomatic Research*, *76*(5), 341–351. doi:10.1016/j.jpsychores.2014.02.012

Adair, J. G. (1984). The Hawthorne effect: A reconsideration of the methodological artifact. *Journal of Applied Psychology*, *69*(2), 334–345. doi:10.1037//0021-9010.69.2.334

Andersson, G. (2009). Using the Internet to provide cognitive behaviour therapy. *Behaviour Research and Therapy*, *47*(3), 175–180. doi:10.1016/j.brat.2009.01.010

Aucoin, M., Lalonde-Parsi, M., & Cooley, K. (2014). Mindfulness-based therapies in the treatment of functional gastrointestinal disorders: A meta-analysis. *Evidence-Based Complementary and Alternative Medicine*, *2014*(140724), 1–11. doi:10.1155/2014/140724

Baer, R. A. (2003). Mindfulness training as a clinical intervention: A conceptual and empirical review. *Clinical Psychology: Science and Practice*, *10*(2), 125–143. doi:10.1093/clipsy.bpg015

Barnett, A. G., van der Pols, J. C., & Dobson, A. J. (2005). Regression to the mean: What it is and how to deal with it. *International Journal of Epidemiology*, *34*(1), 215–220. doi:10.1093/ije/dyh299

Benedetti, F., & Amanzio, M. (2011). The placebo response: how words and rituals change the patient's brain. *Patient Education and Counseling*, *84*(3), 413–419. doi:10.1016/j.pec.2011.04.034

Berrill, J. W., Sadlier, M., Hood, K., & Green, J. T. (2014). Mindfulness-based therapy for inflammatory bowel disease patients with functional abdominal symptoms or high perceived stress levels. *Journal of Crohn's & Colitis*, *8*(9), 945–55. doi:10.1016/j.crohns.2014.01.018

Blease, C. (2012). The principle of parity: The "placebo effect" and physician communication. *Journal of Medical Ethics*, *38*(4), 199–203. doi:10.1136/medethics-2011-100177

Borkovec, T. D., & Nau, S. D. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, *3*(4), 257–260. doi:10.1016/0005-7916(72)90045-6

Brown, K. W., & Ryan, R. M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology*, *84*(4), 822–848. doi:10.1037/0022-3514.84.4.822

Burnett, C.K., & Drossman, D. A. (2004). Irritable bowel syndrome and other functional gastrointestinal disorders. In L. J. Haas (Ed.), *Handbook of primary care psychology* (pp. 411–424). New York, NY: Oxford University Press.

Chang, L. (2004). Review article: Epidemiology and quality of life in functional gastrointestinal disorders. *Alimentary Pharmacology & Therapeutics*, *20*, 31–39. doi:10.1111/j.1365-2036.2004.02183.x

Chiesa, A., & Serretti, A. (2011). Mindfulness-based interventions for chronic pain: A systematic review of the evidence. *Journal of Alternative and Complementary Medicine*, *17*(1), 83–93. doi:10.1089/acm.2009.0546

Cramer, H., Lauche, R., Paul, A., & Dobos, G. (2012). Mindfulness-based stress reduction for breast cancer — a systematic review and meta-analysis. *Current Oncology*, *19*, 343–352. doi:10.3747/co.19.1016

Creed, F., Fernandes, L., Guthrie, E., Palmer, S., Ratcliffe, J., Read, N., … Tomenson, B. (2003). The cost-effectiveness of psychotherapy and paroxetine for severe irritable bowel syndrome. *Gastroenterology*, *124*(2), 303–317. doi:10.1053/gast.2003.50055

Creed, F., Guthrie, E., Ratcliffe, J., Fernandes, L., Rigby, C., Tomenson, B., … Thompson, D. G. (2005). Does psychological treatment help only those patients with severe irritable bowel syndrome who also have a concurrent psychiatric disorder? *Australian and New Zealand Journal of Psychiatry*, *39*, 807–815. doi:10.1080/j.1440-1614.2005.01686.x

Critelli, J. W., & Neumann, K. F. (1984). The placebo: Conceptual analysis of a construct in transition. *American Psychologist*, *39*(1), 32–39. doi:10.1037//0003-066X.39.1.32

Dorn, S. D., Kaptchuk, T. J., Park, J. B., Nguyen, L. T., Canenguez, K., Nam, B. H., … Lembo, a J. (2007). A meta-analysis of the placebo response in complementary and alternative medicine trials of irritable bowel syndrome. *Neurogastroenterology and Motility*, *19*(8), 630–637. doi:10.1111/j.1365-2982.2007.00937.x

Drossman, D. A. (1998). Presidential address : Gastrointestinal illness and the biopsychosocial model. *Psychosomatic Medicine*, *60*, 258–267. doi:0033-3174/98/6003-0258S03.00/0

Drossman, D. A. (1999). Review article: An integrated approach to the irritable bowel syndrome. *Alimentary Pharmacology and Therapeutics*, *13*(s2), 3–14. doi:10.1046/j.1365-2036.1999.0130s2003.x

Drossman, D. A. (2006). The functional gastrointestinal disorders and the Rome III process. *Gastroenterology*, *130*(5), 1377–1390. doi:10.1053/j.gastro.2006.03.008

Drossman, D. A., Creed, F. H., Olden, K. W., Svedlund, J., Toner, B. B., & Whitehead, W. E. (1999). Psychosocial aspects of the functional gastrointestinal disorders. *Gut*, *45*(Supplement 2), ii25–ii30. doi:10.1136/gut.45.2008.ii25

Eippert, F., Finsterbusch, J., Bingel, U., & Büchel, C. (2009). Direct evidence for spinal cord involvement in placebo analgesia. *Science*, *326*, 404. doi:10.1126/science.1180142

Enck, P., Bingel, U., Schedlowski, M., & Rief, W. (2013). The placebo response in medicine: Minimize, maximize or personalize? *Nature Reviews. Drug Discovery*, *12*(3), 191–204. doi:10.1038/nrd3923

Engel, G. L. (1977). The need for a new medical model: A challenge for biomedicine. *Science*, *196*(4286), 130–136. doi:10.1126/science.847460

Farndale, R., & Roberts, L. (2011). Long-term impact of irritable bowel syndrome: A qualitative study. *Primary Health Care Research & Development*, *12*(1), 52–67. doi:10.1017/S1463423610000095

Faurot, K. R., Gaylord, S., Palsson, O. S., Garland, E. L., Mann, J. D., & Whitehead, W. E. (2014). Mindfulness meditation has long-term therapeutic benefits in women with irritable bowel syndrome (IBS): Follow-up results from a randomized controlled trial. *Gastroenterology*, *146*(5), S–124. doi:10.1016/S0016-5085(14)60447-9

Fjorback, L. O., Arendt, M., Ornbøl, E., Walach, H., Rehfeld, E., Schröder, A., & Fink, P. (2013). Mindfulness therapy for somatization disorder and functional somatic syndromes: Randomized trial with one-year follow-up. *Journal of Psychosomatic Research*, *74*(1), 31–40. doi:10.1016/j.jpsychores.2012.09.006

Ford, A. C., Talley, N. J., Schoenfeld, P. S., Quigley, E. M. M., & Moayyedi, P. (2009). Efficacy of antidepressants and psychological therapies in irritable bowel syndrome: Systematic review and meta-analysis. *Gut*, *58*(3), 367–378. doi:10.1136/gut.2008.163162

Frenkel, O. (2008). A phenomenology of the "placebo effect": Taking meaning from the mind to the body. *The Journal of Medicine and Philosophy*, *33*(1), 58–79. doi:10.1093/jmp/jhm005

Garland, E. L., Gaylord, S. A., Palsson, O., Faurot, K., Douglas Mann, J., & Whitehead, W. E. (2012). Therapeutic mechanisms of a mindfulness-based treatment for IBS: Effects on visceral sensitivity, catastrophizing, and affective processing of pain sensations. *Journal of Behavioral Medicine*, *35*(6), 591–602. doi:10.1007/s10865-011-9391-z

Gaylord, S. A., Palsson, O. S., Garland, E. L., Faurot, K. R., Coble, R. S., Mann, J. D., … Whitehead, W. E. (2011). Mindfulness training reduces the severity of irritable bowel syndrome in women: Results of a randomized controlled trial. *The American Journal of Gastroenterology*, *106*(9), 1678–1688. doi:10.1038/ajg.2011.184

Gralnek, I. M., Hays, R. D., Kilbourne, A., Naliboff, B., & Mayer, E. A. (2000). The impact of irritable bowel syndrome on health-related quality of life. *Gastroenterology*, *119*(3), 654–660. doi:10.1053/gast.2000.16484

Gregg, J. A., Callaghan, G. M., Hayes, S. C., & Glenn-Lawson, J. L. (2007). Improving diabetes self-management through acceptance, mindfulness, and values: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *75*(2), 336–343. doi:10.1037/0022-006X.75.2.336

Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research*, *57*(1), 35–43. doi:10.1016/S0022-3999(03)00573-7

Guthrie, E., Creed, F., Dawson, D., & Tomenson, B. (1993). A randomised controlled trial of psychotherapy in patients with refractory irritable bowel syndrome. *The British Journal of Psychiatry*, *163*(3), 315–321. doi:10.1192/bjp.163.3.315

Håkanson, C. (2014). Everyday life, healthcare, and self-care management among people with irritable bowel syndrome: An integrative review of qualitative research. *Gastroenterology Nursing*, *37*(3), 217–225. doi:10.1097/SGA.0000000000000048

Hartmann, M., Kopf, S., Kircher, C., Faude-Lang, V., Djuric, Z., Augstein, F., … Nawroth, P. P. (2012). Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients: Design and first results of a randomized controlled trial (the Heidelberger Diabetes and Stress-study). *Diabetes Care*, *35*(5), 945–947. doi:10.2337/dc11-1343

Hayes, S. C., Strosahl, K. D., & Wilson, K. G. (1999). *Acceptance and commitment therapy: An experiential approach to behavior change*. New York, NY: Guilford Press.

Hróbjartsson, A., & Gøtzsche, P. C. (2010). Placebo interventions for all clinical conditions. *The Cochrane Database of Systematic Reviews*, *2010*(1). doi:10.1002/14651858.CD003974.pub3

Hungin, A. P. S., Whorwell, P. J., Tack, J., & Mearin, F. (2003). The prevalence, patterns and impact of irritable bowel syndrome : An international survey of 40 000 subjects. *Alimentary Pharmacology and Therapeutics*, *17*, 643–650. doi:10.1046/j.0269-2813.2003.01456.x

Jakobsson, U. E., Ringstrom, G., Sjövall, H., & Simrén, M. (2013). How patients with long-term experience of living with irritable bowel syndrome manage illness in daily life: A qualitative study. *European Journal of Gastroenterology & Hepatology*, *25*(12), 1478–1483. doi:10.1097/MEG.0b013e328365abd3

Kabat-Zinn, J. (1990). *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain and illness*. New York, NY: Dell Publishing.

Kabat-Zinn, J., Lipworth, L., & Burney, R. (1985). The clinical use of mindfulness meditation for the self-regulation of chronic pain. *Journal of Behavioral Medicine*, *8*(2), 163–190. doi:10.1007/BF00845519

Kabat-Zinn, J., Lipworth, L., Burney, R., & Sellers, W. (1986). Four-year follow-up of a meditation-based program for the self-regulation of chronic pain: Treatment outcomes and compliance. *The Clinical Journal of Pain*, *2*(3), 159–174. doi:00002508-198602030-00004

Kaptchuk, T. J., Friedlander, E., Kelley, J. M., Sanchez, M. N., Kokkotou, E., Singer, J. P., … Lembo, A. J. (2010). Placebos without deception: A randomized controlled trial in irritable bowel syndrome. *PloS One*, *5*(12), 1–7. doi:10.1371/journal.pone.0015591

Kaptchuk, T. J., Kelley, J. M., Conboy, L. A., Davis, R. B., Kerr, C. E., Jacobson, E. E., … Lembo, A. J. (2008). Components of placebo effect: Randomised controlled trial in patients with irritable bowel syndrome. *British Medical Journal*, *336*(7651), 999–1003. doi:10.1136/bmj.39524.439618.25

Lakhan, S. E., & Schofield, K. L. (2013). Mindfulness-based therapies in the treatment of somatization disorders: A systematic review and meta-analysis. *PloS One*, *8*(8), 1–13. doi:10.1371/journal.pone.0071834

Linde, K., Witt, C. M., Streng, A., Weidenhammer, W., Wagenpfeil, S., Brinkhaus, B., … Melchart, D. (2007). The impact of patient expectations on outcomes in four randomized controlled trials of acupuncture in patients with chronic pain. *Pain*, *128*, 264–271. doi:10.1016/j.pain.2006.12.006

Ljótsson, B., Andersson, G., Andersson, E., Hedman, E., Lindfors, P., Andréewitch, S., … Lindefors, N. (2011). Acceptability, effectiveness, and cost-effectiveness of internet-based exposure treatment for irritable bowel syndrome in a clinical sample: A randomized controlled trial. *BMC Gastroenterology*, *11*(110), 1–13. doi:10.1186/1471-230X-11-110

Ljótsson, B., Andréewitch, S., Hedman, E., Rück, C., Andersson, G., & Lindefors, N. (2010). Exposure and mindfulness based therapy for irritable bowel syndrome-An open pilot study. *Journal of Behavior Therapy and Experimental Psychiatry*, *41*(3), 185–190. doi:10.1016/j.jbtep.2010.01.001

Ljótsson, B., Falk, L., Vesterlund, A. W., Hedman, E., Lindfors, P., Ruck, C., … Andersson, G. (2010). Internet-delivered exposure and mindfulness based therapy for irritable bowel syndrome - A randomized controlled trial. *Behaviour Research and Therapy*, *48*, 531–539. doi:10.1016/j.brat.2010.03.003

Ljótsson, B., Hedman, E., Andersson, E., Hesser, H., Lindfors, P., Hursti, T., … Andersson, G. (2011). Internet-delivered exposure-based treatment vs. stress management for irritable bowel syndrome: A randomized trial. *The American Journal of Gastroenterology*, *106*(8), 1481–1491. doi:10.1038/ajg.2011.139

Ljótsson, B., Hedman, E., Lindfors, P., Hursti, T., Lindefors, N., Andersson, G., & Ruck, C. (2011). Long-term follow-up of internet-delivered exposure and mindfulness based treatment for irritable bowel syndrome. *Behaviour Research and Therapy*, *49*(1), 58–61. doi:10.1016/j.brat.2010.10.006

Longstreth, G. F., Thompson, W. G., Chey, W. D., Houghton, L. A., Mearin, F., & Spiller, R. C. (2006). Functional bowel disorders. *Gastroenterology*, *130*(5), 1480–1491. doi:10.1053/j.gastro.2005.11.061

Ma, S. H., & Teasdale, J. D. (2004). Mindfulness-based cognitive therapy for depression: Replication and exploration of differential relapse prevention effects. *Journal of Consulting and Clinical Psychology*, *72*(1), 31–40. doi:10.1037/0022-006X.72.1.31

Macea, D. D., Gajos, K., Daglia Calil, Y. A., & Fregni, F. (2010). The efficacy of Web-based cognitive behavioral interventions for chronic pain: A systematic review and meta-analysis. *The Journal of Pain*, *11*(10), 917–929. doi:10.1016/j.jpain.2010.06.005

Mayer, E. A. (2011). Gut feelings: The emerging biology of gut-brain communication. *Nature Reviews. Neuroscience*, *12*(8), 453–466. doi:10.1038/nrn3071

Mayer, E. A., & Tillisch, K. (2011). The brain-gut axis in abdominal pain syndromes. *Annual Review of Medicine*, *62*, 381–396. doi:10.1146/annurev-med-012309-103958

Mearin, F., Badía, X., Balboa, A., Baró, E., Caldwell, E., Cucala, M., … Talley, J. (2001). Irritable bowel syndrome prevalence varies enormously depending on the employed diagnostic criteria: Comparison of Rome II versus previous criteria in a general

population. *Scandinavian Journal of Gastroenterology*, *36*(11), 1155–1161. doi:10.1080/00365520152584770

Meissner, K. (2011). The placebo effect and the autonomic nervous system: Evidence for an intimate relationship. *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences*, *366*, 1808–1817. doi:10.1098/rstb.2010.0403

Mönnikes, H., Tebbe, J. J., Hildebrandt, M., Arck, P., Osmanoglou, E., Rose, M., … Heymann-Mönnikes, I. (2001). Role of stress in functional gastrointestinal disorders. *Digestive Diseases*, *19*(3), 201–211. doi:10.1159/000050681

Mulak, A., & Bonaz, B. (2004). Irritable bowel syndrome: A model of the brain-gut interactions. *Medical Science Monitor*. Retrieved from http://www.scopus.com/inward/record.url?eid=2-s2.0-1942470635&partnerID=tZOtx3y1

Nyenhuis, D. L., Yamamoto, C., Lucheta, T., Terrien, A., & Parmentier, A. (1999). Adult and geriatric normative data and validation of the profile of mood states. *Journal of Clinical Psychology*, *55*(1), 79–86. doi:10.1002/(SICI)1097-4679(199901)55:1<79::AID-JCLP8>3.0.CO;2-7

Pajak, R., Lackner, J., & Kamboj, S. K. (2013). A systematic review of minimal-contact psychological treatments for symptom management in irritable bowel syndrome. *Journal of Psychosomatic Research*, *75*(2), 103–112. doi:10.1016/j.jpsychores.2013.05.007

Palsson, O. S., & Drossman, D. A. (2005). Psychiatric and psychological dysfunction in irritable bowel syndrome and the role of psychological treatments. *Gastroenterology Clinics of North America*, *34*(2), 281–303. doi:10.1016/j.gtc.2005.02.004

Palsson, O. S., Turner, M. J., Johnson, D. A., Burnett, C. K., & Whitehead, W. E. (2002). Hypnosis treatment for severe irritable bowel syndrome investigation of mechanism and effects on symptoms. *Digestive Diseases and Sciences*, *47*(11), 2605–2614. doi:10.1023/A:1020545017390

Patel, S. M., Stason, W. B., Legedza, A., Ock, S. M., Kaptchuk, T. J., Conboy, L., … Lembo, A. J. (2005). The placebo effect in irritable bowel syndrome trials: A meta-analysis. *Neurogastroenterology and Motility*, *17*(3), 332–340. doi:10.1111/j.1365-2982.2005.00650.x

Piet, J., Würtzen, H., & Zachariae, R. (2012). The effect of mindfulness-based therapy on symptoms of anxiety and depression in adult cancer patients and survivors: A systematic review and meta-analysis. *Journal of Consulting and Clinical Psychology*, *80*(6), 1007–1020. doi:10.1037/a0028329

Placebo. (n.d.). "placebo, n.". Retrieved from http://www.oed.com/view/Entry/144868?redirectedFrom=placebo

Reiner, K., Tibi, L., & Lipsitz, J. D. (2013). Do mindfulness-based interventions reduce pain intensity? A critical review of the literature. *Pain Medicine*, *14*(2), 230–242. doi:10.1111/pme.12006

Rønnevig, M., Vandvik, P. O., & Bergbom, I. (2009). Patients' experiences of living with irritable bowel syndrome. *Journal of Advanced Nursing*, *65*(8), 1676–1685. doi:10.1111/j.1365-2648.2009.05030.x

Segal, Z. L., Williams, J. M. G., & Teasdale, J. D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. New York, NY: Guildford Publications.

Seminowicz, D. A., Labus, J. S., Bueller, J. A., Tillisch, K., Naliboff, B. D., Bushnell, M. C., & Mayer, E. A. (2010). Regional gray matter density changes in brains of patients with irritable bowel syndrome. *Gastroenterology*, *139*(1), 48–57. doi:10.1053/j.gastro.2010.03.049

Shennan, C., Payne, S., & Fenlon, D. (2011). What is the evidence for the use of mindfulness-based interventions in cancer care ? A review. *Psycho-Oncology*, *20*, 681–697. doi:10.1002/pon.1819

Simpson, R., Booth, J., Lawrence, M., Byrne, S., Mair, F., & Mercer, S. (2014). Mindfulness based interventions in multiple sclerosis-a systematic review. *BMC Neurology*, *14*(15), 1–9. doi:10.1186/1471-2377-14-15

Smith, J. E., Richardson, J., Hoffman, C., & Pilkington, K. (2005). Mindfulness-based stress reduction as supportive therapy in cancer care: Systematic review. *Journal of Advanced Nursing*, *52*(3), 315–327. doi:10.1111/j.1365-2648.2005.03592.x

Spiller, R., Aziz, Q., Creed, F., Emmanuel, A., Houghton, L., Hungin, P., … Whorwell, P. (2007). Guidelines on the irritable bowel syndrome: Mechanisms and practical management. *Gut*, *56*(12), 1770–1798. doi:10.1136/gut.2007.119446

Stewart-Williams, S., & Podd, J. (2004). The placebo effect: Dissolving the expectancy versus conditioning debate. *Psychological Bulletin*, *130*(2), 324–340. doi:10.1037/0033-2909.130.2.324

Strauss, C., Cavanagh, K., Oliver, A., & Pettman, D. (2014). Mindfulness-based interventions for people diagnosed with a current episode of an anxiety or depressive disorder: A meta-analysis of randomised controlled trials. *PloS One*, *9*(4), 1–13. doi:10.1371/journal.pone.0096110

Su, C., Lichtenstein, G. R., Krok, K., Brensinger, C. M., & Lewis, J. D. (2004). A meta-analysis of the placebo rates of remission and response in clinical trials of active crohn's disease. *Gastroenterology*, *126*(5), 1257–1269. doi:10.1053/j.gastro.2004.01.024

Tanaka, Y., Kanazawa, M., Fukudo, S., & Drossman, D. A. (2011). Biopsychosocial model of irritable bowel syndrome. *Journal of Neurogastroenterology and Motility*, *17*(2), 131–139. doi:10.5056/jnm.2011.17.2.131

Teasdale, J. D., Segal, Z. V., Williams, J. M. G., Ridgeway, V. A., Soulsby, J. M., & Lau, M. A. (2000). Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *Journal of Consulting and Clinical Psychology*, *68*(4), 615–623. doi:10.1037//0022-006X.68.4.615

Tillisch, K., & Labus, J. S. (2011). Advances in imaging the brain-gut axis: Functional gastrointestinal disorders. *Gastroenterology*, *140*(2), 407–411. doi:10.1053/j.gastro.2010.12.014

Tillisch, K., Mayer, E. A., & Labus, J. S. (2011). Quantitative meta-analysis identifies brain regions activated during rectal distension in irritable bowel syndrome. *Gastroenterology*, *140*(1), 91–100. doi:10.1053/j.gastro.2010.07.053

Timmer, A., Preiss, J., Motschall, E., Rücker, G., Jantschek, G., & Moser, G. (2011). Psychological interventions for treatment of inflammatory bowel disease. *Cochrane Database of Systemaic Reviews*, *2011*(2). doi:10.1002/14651858.CD006913.pub2

Webb, A. N., Kukuruzovic, R., Catto-Smith, A. G., & Sawyer, S. M. (2008). Hypnotherapy for treatment of irritable bowel syndrome. *Cochrane Database of Systematic Reviews*, *2007*(4). doi:10.1002/14651858.CD005110.pub2.

Whitehead, W. E., Palsson, O., & Jones, K. R. (2002). Systematic review of the comorbidity of irritable bowel syndrome with other disorders: What are the causes and implications? *Gastroenterology*, *122*(4), 1140–1156. doi:10.1053/gast.2002.32392

Zeidan, F., Martucci, K. T., Kraft, R. A., Gordon, N. S., McHaffie, J. G., & Coghill, R. C. (2011). Brain mechanisms supporting the modulation of pain by mindfulness meditation. *The Journal of Neuroscience*, *31*(14), 5540–5548. doi:10.1523/JNEUROSCI.5791-10.2011

Zernicke, K. A., Campbell, T. S., Blustein, P. K., Fung, T. S., Johnson, J. A., Bacon, S. L., & Carlson, L. E. (2013). Mindfulness-based stress reduction for the treatment of irritable bowel syndrome symptoms: A randomized wait-list controlled trial. *International Journal of Behavioral Medicine*, *20*(3), 385–396. doi:10.1007/s12529-012-9241-6

Zijdenbos, I., de Wit, N., van der Heijden, G., Rubin, G., & Quartero, A. (2009). Psychological treatments for the management of irritable bowel syndrome. *Cochrane Database of Systematic Reviews*, *2009*(1). doi:10.1002/14651858.CD006442.pub2.

Zomorodi, S., Abdi, S., & Tabatabaee, S. K. R. (2014). Comparison of long-term effects of cognitive-behavioral therapy versus mindfulness-based therapy on reduction of symptoms among patients suffering from irritable bowel syndrome. *Gastroenterology and Hepatology from Bed to Bench*, *7*(2), 118–124. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017567/

Part 2: Empirical Paper

Exploratory study of mindfulness for inpatients with chronic gastrointestinal pain: does it reduce pain related distress and increase confidence in pain self-management?

Abstract

Aims. To evaluate whether a guided self-help mindfulness course reduced pain-related distress and improved quality of life for inpatients with complex gastrointestinal pain and to investigate how useful and applicable participants experienced the course to be as well as the challenges and barriers they faced in taking part.

Method. A mixed methods approach was used combining multiple single case design. Graphical analysis assessed changes in pain intensity and distress across multiple time points and pre-post analysis of changes in psychological distress, self-efficacy, pain acceptance and mindfulness were analysed for reliable and clinically significant levels of change. Interviews before and after participation in the course were qualitatively analysed using thematic analysis.

Results. Only four of the 15 participants completed the course within the time of the study. 'Completers' demonstrated reductions in pain distress over time as well as reliable and clinically significant change on most measures except for pain acceptance. The six participants who continued with the course described experiencing the course as useful, even when in intense pain. All participants described some challenges and the nine participants who discontinue the course described barriers to completing due to recurring illness, time taken up by pain and illness management and external distractions.

Conclusions. Initial findings demonstrate the potential of using guided self-help mindfulness with inpatients. A briefer version of resources would increase its acceptability and further research could evaluate its potential with wider groups. The significant challenges and barriers facing patients with chronic and complex gastrointestinal pain require consideration of which inpatients will benefit most.

Introduction

Chronic Pain

Pain has been defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey et al., 1979, p. 250). Chronic pain is commonly classed as any persistent non-cancer pain that persists for three months or more (Turk & Okifuji, 2001). Many people are affected by chronic pain, with a recent survey reporting that it affects 31-37% of adults in the UK (The Heath and Social Care Information Centre, 2012), more commonly women and older age groups. Available treatments are not wholly effective at eliminating chronic pain, leaving many people distressed and disabled (Turk, 2002). People with chronic pain often experience depression (Bair, Robinson, Katon, & Kroenke, 2003; Miller & Cano, 2009) and twice the rate of anxiety disorders compared to the healthy population (McWilliams, Cox, & Enns, 2003). Pain is a subjective experience (Merskey et al., 1979). It cannot be measured directly, only through an individual's self-report or behaviour (recently fMRI-detected activation in certain brain areas are nearly as accurate as behaviour in assessing pain, although this is not yet clinically applicable) (Brodersen et al., 2012; J. E. Brown, Chatterjee, Younger, & Mackey, 2011).

Pain experiences are best described using a biopsychosocial model which includes the influences of psychological and social factors (Gatchel, 2005) built on gate control theory (Melzack & Wall, 1965). The conscious experience of pain is built up from signals arising from the interplay between peripheral and visceral nociceptors (bottom-up processing) and central contextual and emotional information (top-down processing) (Turk & Gatchel, 2002). This means that pain is not purely a result of physical stimulation, but is heavily influenced by emotional

and other processing in the brain which can act to predispose someone to experience pain, amplify or suppress the severity of pain signals or perpetuate the experience of pain (Gatchel, Peng, Peters, Fuchs, & Turk, 2007).

Many psychological processes can impact on sensations of pain: attention, interpretation and beliefs, as it is adaptive, from an evolutionary perspective, to use all possible information to make sense of a new pain, and previous experiences are important (Linton & Shaw, 2011). One of the functions of pain is to demand attention (Eccleston & Crombez, 1999) so that the individual mobilises escape and protective responses to minimise injury. This can be modulated by other pressing demands on attention (for instance when survival is at stake) which can inhibit pain temporarily due to endogenous opioids (Lester & Fanselow, 1985). More often, attention is dominated by pain or by the expectation of pain (hypervigilance) (Eccleston & Crombez, 1999). Interpretation of pain also has an impact on processing, as demonstrated by the finding that patients with Irritable Bowel Syndrome (IBS) who believed that their symptoms were associated with serious pathology reported more intense symptoms and used fewer adaptive coping strategies (Drossman et al., 1999). Pain-related beliefs can be understood as providing shortcuts to interpretation, often drawing more on fears than on actual risk, which can then lead to unhelpful pain-related behaviours (e.g. "hurt is harm" leading to avoidance behaviours). Beliefs can also inform descending influences which amplify pain or fail to inhibit it (Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012).

Brain-gut axis and gastrointestinal pain

Gastrointestinal pain encompasses any pain located in gut, intestines, colon or rectum. Processing of gastrointestinal pain differs from that of musculoskeletal

pain due to reciprocal processing between the enteric nervous system (ENS) and the central nervous system (CNS) named the brain-gut axis. The brain-gut axis describes a continuous feedback loop between sensory neurons of the ENS (including the gut, intestines, colon and rectum) and motor responses generated in the CNS (Burnett, C.K., & Drossman, 2004). Nerve signals from the ENS differ from those from our skin, for example, as they do not usually enter conscious perception, but are part of the autonomic nervous system, and are generated by different stimuli (torsion, stretch and distension) rather than by high levels of heat, cold or pressure. However in certain circumstances, changes to the brain-gut axis lead to hypersensitivity so that normally unperceived signals from the gut become perceived as pain or discomfort which is posited to be one of the explanations for the experience of pain without observable tissue damage in Functional Gastrointestinal Disorders (FGIDs) (Mayer & Tillisch, 2011).

Psychological interventions with pain

As psychological factors are an important component of the experience of pain, intervening at the psychological level should have the potential to improve an individual's experience of pain. The psychological intervention most widely investigated for effectiveness in pain management is Cognitive Behavioural Therapy (CBT).

CBT. The CBT approach to chronic pain management includes both behavioural and cognitive components. The behavioural components focus on identifying and changing unhelpful pain-related behaviours (such as restricting activity to avoid or minimise pain) which can otherwise exacerbate the pain problem through further physical deterioration and lack of opportunity for positive experiences. The cognitive components focus on challenging unhelpful beliefs about

pain and styles of processing pain-related thoughts such as catastrophizing. A recent Cochrane meta-analysis found there was evidence for CBT having a small beneficial effect on improving pain, minimal effects on improving disability but larger effects in improving mood (Williams, Eccleston, & Morley, 2012).

Mindfulness interventions for chronic pain. As previously described, emotional reactivity to pain can increase the distress it causes (Gatchel et al., 2007). Mindfulness based approaches aim to reduce this distress by increasing acceptance (not resignation) towards chronic pain and thereby reducing unhelpful attempts to avoid or control pain when that is not possible. The individual can then focus on other experiences in the environment and their own valued activities (Burch & Penman, 2013).

Mindfulness has been described as focussing attention on the experiences of the current moment in an open, curious and accepting way, without judging or reacting to them (Kabat-Zinn, 1990). It is a skill inherent in all humans, but individuals possess it to a greater or lesser degree (K. W. Brown & Ryan, 2003).

Origins. Mindfulness practices originated in Eastern traditions including Buddhism over 2000 years ago. Western cultures began to adopt the central principles of present-moment awareness and non-judgement of experiences more widely in the 1970s.

Structured mindfulness programmes. The first use of mindfulness practices in a structured way were described by Jon Kabat-Zinn who developed Mindfulness Based Stress Reduction (MBSR) (Kabat-Zinn, Lipworth, Burney, & Sellers, 1986). MBSR was developed for individuals with chronic health problems (most experienced pain) and aimed to help them cope more effectively with their distress. Group participants attended two and a half hour sessions weekly for eight weeks, a

full day retreat between weeks six and seven and were encouraged to practise for a minimum of 45 minutes personal meditation daily at home. Three main techniques were taught in the MBSR programme. The 'body scan' meditation instructs the individual to sequentially focus their attention on different areas of their body, trying to notice any sensations as purely and uncritically as they can, without adding judgements or labels. The 'sitting meditation' instructs individuals to focus mindfully on the physical sensations of breathing, and to try to bring non-judgemental awareness to the natural stream of consciousness that all individuals continuously experience. 'Hatha yoga' practices comprise the final elements involving gentle stretches, breathing exercises and encouragement of postures that strengthen and relax the body.

A second widespread structured mindfulness programme was later developed by Mark Williams and others in the UK for recovered recurrently depressed patients to prevent depressive relapse (Segal, Williams, & Teasdale, 2002). This approach combined mindfulness practices with techniques from CBT to form Mindfulness Based Cognitive Therapy (MBCT). Being based on earlier MBSR it shared many features, with similar length and duration of the programme and similar meditations including 'the body scan', 'mindful movement' and different length 'sitting meditations'.

Efficacy of mindfulness programmes. Early studies of MBSR with outpatients reported positive improvements both for pain ratings and physical symptoms (Kabat-Zinn, Lipworth, & Burney, 1985), which were maintained four years later for physical and psychological symptom improvement (Kabat-Zinn et al., 1986). Recent neuroimaging studies showed changes in brain regions related to pain-

processing in individuals after repeated mindfulness practice (Zeidan et al., 2011) suggesting mindfulness has an effect at a neural level.

Meta-analyses of mindfulness-based interventions report reductions in pain intensity with effect sizes around 0.5 (Baer, 2003; Grossman, Niemann, Schmidt, & Walach, 2004; Reiner, Tibi, & Lipsitz, 2013). Another meta-analysis with more stringent measures of inclusion criteria reported a lack of evidence for direct effects of mindfulness on reducing pain intensity but strong evidence for non-specific effects on reduction of pain symptoms, improvement of depressive symptoms and improvements in coping with pain (Chiesa & Serretti, 2011). The majority of studies into the use of mindfulness with chronic pain patients have focussed on musculoskeletal pain. However, two systematic reviews have reported on the efficacy of mindfulness-based interventions in improving gastrointestinal pain and related symptoms of Irritable Bowel Syndrome (IBS) and Functional Gastrointestinal Disorders (FGIDs) (Aucoin, Lalonde-Parsi, & Cooley, 2014; Lakhan & Schofield, 2013).

Both MBSR and MBCT are designed to be delivered to groups of participants in outpatient settings and therefore represent patients well enough to travel and commit to an eight week group. However many individuals with chronic pain may be unable to attend such a structured programme due to unpredictability of their health status, frequent hospital admissions and access issues. A method of delivery which could be more flexible may therefore be beneficial. One study demonstrated the feasibility of providing mindfulness instruction via audio tapes to individuals receiving chemotherapy for cancer and found positive outcomes on measures of mood and quality of life (Altschuler, Rosenbaum, Gordon, Canales, & Avins, 2012).

Chronic pain in inpatient settings

A recent national patient survey of 64,000 people admitted to NHS hospitals reported good pain management to be one of the highest concerns of patients, and satisfaction with pain control was below expected standards (Care Quality Commission, 2012). Provision of pain services to inpatients relies largely on analgesic pain management and most formal psychological interventions are only available to outpatients. To date there have not been any published accounts of attempts to provide a mindfulness programme flexibly to inpatients which can then be continued following discharge home.

Gastrointestinal pain in inpatient settings. Chronic gastrointestinal pain can be extremely difficult to manage with traditional analgesia as the common side effects of the most potent analgesics (opioids) can severely affect gastrointestinal functioning. Many individuals with chronic gastrointestinal pain are often unable to tolerate stronger painkillers and therefore have to cope with high levels of residual pain. Individuals with gastrointestinal pain are also likely to require frequent lengthy hospital admissions due to difficulties with feeding and nutrition (many are fed either directly by a tube into their gut or into their veins) and consequently frequent infections. They represent a severe and complex subset of hospital patients who may experience many more frequent and extended hospitalisations. When not hospitalised, multiple outpatient hospital appointments and extended daily health regimens take up significant portions of individuals' time and energy. These patients therefore differ from those recruited to most existing studies of mindfulness for ill health or chronic pain who are usually at a more stable period in their illness and able to attend outpatient mindfulness groups regularly. Although this poses significant challenges to participation, this group is a subset of chronic pain patients

who may benefit most from having access to a mindfulness-based intervention within the hospital setting, as they may find it very difficult to attend outpatient groups.

Research questions

The aims of this study therefore are to assess the feasibility of providing a mindfulness-based intervention to inpatients with gastrointestinal pain and answer the following hypotheses:

1. Can an individual mindfulness intervention for inpatients with gastrointestinal pain reduce pain-related distress, improve quality of life, and increase confidence in pain self-management?

2. How useful and applicable do inpatients with gastrointestinal pain find MBSR methods?

Methods

Setting

The study took place across two specialist wards at an inner city University teaching hospital admitting patients with chronic and complex gastrointestinal pain. The primary ward specialised in patients with "gastrointestinal failure" and often admitted patients for lengthy hospital stays with an average duration of six weeks, with some lasting for several months. Another doctoral study investigating staff attitudes towards pain management occurred during the same time period.

Participants

Participants for the study were patients admitted to the two identified wards between August 2014 and February 2015 who were experiencing long-term

gastrointestinal pain as well as many comorbid difficulties including infections and feeding difficulties.

Inclusion and exclusion criteria. Inclusion criteria were: age 18 years or older, gastrointestinal pain experienced for more than three months, and able to understand English. Exclusion criteria were: previous experience of a mindfulness programme, severe cognitive impairment, or profound hearing difficulties.

Ethical approval. Ethical approval was obtained from the National Research Ethics Service Committee London - City Road and Hampstead on 1st July 2014 (Appendix 1).

Procedure

Recruitment. Recruitment took place between August 2014 and February 2015. In August 2014 the researcher met with nursing staff on the wards to discuss the rationale for the study and agree on a protocol for recruitment. Potential participants were identified by senior nursing staff on each of the wards and discussed with the researcher weekly. If the participants met the inclusion criteria then nursing staff would approach the patient, describe the study, offer a patient information sheet, and ask for verbal consent for the patient to be visited by the researcher. The researcher met with the patient to discuss the study further and confirm that the eligibility criteria were met and answer any questions. Participants were given a minimum of 24 hours to consider taking part in the study before the researcher returned to obtain written consent.

Data collection. Participants who consented to take part completed initial baseline measures in person with the researcher and recorded an interview about their chronic pain. Pain intensity, distress and qualitative feedback on the intervention was recorded following completion of each section of the eight-part

mindfulness course either in person if the participant remained in hospital, or by telephone if they had been discharged home. Following completion of the programme participants repeated the initial baseline measures and recorded a further interview about their chronic pain and experience of the mindfulness programme either in person or by telephone. Participants who did not complete the programme recorded an interview about their experience of the programme, their decision not to complete it and the challenges and barriers they faced when trying to follow the programme. All data and audio files were stored securely on password-protected, university computers.

Mindfulness programme. The treatment intervention consisted of a published self-taught mindfulness programme 'Mindfulness for Health: A practical guide to relieving pain, reducing stress and restoring wellbeing' (Burch & Penman, 2013), guided and supported by the researcher. This programme was selected as the treatment programme had been demonstrated to have positive results on mental wellbeing and coping with pain when delivered in a group format (C. A. Brown & Jones, 2013; Cusens, Duggan, Thorne, & Burch, 2010).

The materials consisted of a book which provided background information on mindfulness, chronic pain and the scientific basis and rationale for using a mindfulness approach with chronic pain, as well as providing many personal vignettes of individual's experiences of chronic pain and mindfulness. The rationale for choosing this book included the accessible nature of its content which presupposed no existing knowledge of mindfulness techniques. It was also one of the few widely available self-directed mindfulness programmes specifically intended for chronic pain populations rather than general populations. It therefore took into account necessary adaptations readers with chronic pain may need to make to their

mindfulness practice. Following the preliminary background chapters, the book is split into eight parts introducing a new element of the programme in each section accompanied by a new mindfulness meditation (audio recorded and provided to the participants on an mp3 player). As well as introducing the new meditation, each section also discusses the rationale for each type of meditation, provides personal examples of previous users benefitting from the practices, and recommends additional 'habit releaser' activities to further develop mindfulness skills e.g. spending time with nature or using mindfulness when making a hot drink. Later sections also introduced ideas around pacing activities including self-monitoring. Participants were encouraged by the researcher in weekly contacts to progress through the sections of the programme weekly and to listen to specified mindfulness meditation a minimum of once daily.

Design

The design of a study should be chosen that best answers the research questions proposed (Barker, Pistrang, & Elliott, 2002). This study posed two research questions, with each being suitable for a different approach and so a mixed-methods design was chosen incorporating both quantitative and qualitative methods. The quantitative data would be used to assess the efficacy of the intervention, and the qualitative data would be used to assess usefulness and applicability of the intervention. This follows a 'partially mixed concurrent equal status design' (Leech & Onwuegbuzie, 2009), as the two methods of data collection are undertaken concurrently and each method is given equal status. Due to the sparseness of existing literature and research with this population, this was designed as an exploratory study. A multiple single case design was chosen to address the first research question, with repeated measures collected from each participant as s/he progressed

through the programme. Due to the complex nature and variety of conditions the participants experienced, multiple external factors could have impacted on the quantitative outcome of the programme and so each participant acted as his/her own control. In order to address the second research question, a qualitative approach was chosen to be able to reflect the richness and individual nature of the data from each participant.

Measures

Time points at which each measure was taken is shown in Table 1.

Table 1

Measurement time points

Time point	**Measures administrated**
Baseline	PI, PD, HADS, PSEQ, CPAQ, FFMQ, PrePI
Programme	PI, PD, FMP, WQF
End point	PI, PD, HADS, PSEQ, CPAQ, FFMQ, PostPI/DOI

Note: PI=Pain Intensity Rating; PD= Pain Distress Rating; HADS= Hospital Anxiety and Depression Scale; PSEQ=Pain Self Efficacy Questionnaire; CPAQ=Chronic Pain Acceptance Questionnaire; FFMQ=Five Factor Mindfulness Questionnaire; FMP=Frequency of Mindfulness Practice; WQF=Weekly Qualitative Feedback; PreP=Pre-Programme Interview; PostPI/DOI= Post-Programme Interview/Drop Out Interview.

Pain intensity and pain distress. A Numerical Rating Scale (NRS) was used which asked participants to rate their pain on an 11 point scale (from 0 to 10) which asked "how intense is the pain on average in the last week" with 0 being anchored with a label of "no pain" and 10 being anchored with the label "extreme pain". Participants either circled the appropriate number on the numbered line using pen and paper, or verbally reported it to the researcher who recorded it. A similar NRS was used for pain distress ratings, also on an 11 point scale (from 0 to 10) which

asked: “how distressing is the pain on average in the last week”. The scale was anchored with 0 being labelled “not distressing at all” and 10 being anchored with the label “extremely distressing”. Again participants circled the appropriate number using pen and paper, or verbally reported it to a researcher who recorded it. Eleven point NRS have been found to be equally reliable and valid for pain ratings as Visual Analogue Scales (VAS), 101 point numerical rating scales and 11 point box scales for both chronic and acute pain (Jensen, Karoly, & Braver, 1986; Jensen, Karoly, O’Riordan, Bland, & Burns, 1989). A NRS was chosen as studies have found it is preferred by individuals over a VAS (Price, Patel, Robinson, & Staud, 2008). Internal consistency cannot be used for these measures as they are single item measures. Zautra, Johnson, and Davis (2005) reported a two-week test-retest reliability of .69 for pain intensity on a 101 point NRS, no estimates of reliability for pain distress were found and so a .69 estimate of reliability was adopted following the same adoption by Morley, Williams and Hussain (2008).

Frequency of mindfulness practice. The frequency with which participants listened to the mindfulness meditations was recorded for each section of the programme completed, as a measure of programme adherence. This was entered on to the ‘weekly feedback sheet’ (Appendix 2) by circling the appropriate number for frequency and writing the average length of each practice.

Weekly qualitative feedback. The ‘weekly feedback sheet’ ended with three questions inviting participants to provide qualitative feedback, the first about the pain: “this week, how did the pain make you feel emotionally”, and the others inviting reflection on the mindfulness programme: “what went well” and “what didn’t go well”. Participants either wrote their responses on the sheets or answered verbally, their responses recorded verbatim by the researcher.

Psychological distress. The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a 14 item questionnaire composed of two seven-item subscales, the HADS-A and HADS-D, intended to measure levels of anxiety or depression. This was selected in preference to other measures of anxiety and depression as it does not contain items capturing somatic elements of distress which would otherwise be likely to inflate scores in a chronic pain sample. For each of the 14 statements respondents are requested to indicate which of four verbal descriptions best fits the truthfulness of that statement for them. Although many studies have confirmed the two-factor structure (Bjelland, Dahl, Haug, & Neckelmann, 2002) a recent review of 50 studies found only half confirmed a two factor structure and concluded that the HADS is more suitable to provide a single measure of distress (Cosco, Doyle, Ward, & McGee, 2012). It has shown good psychometric properties within health populations with a test-retest reliability of r=.72 and Cronbach's α=.89-.93 (Zigmond & Snaith, 1983) and good convergent validity with correlations between the HADS and other questionnaires of psychological distress ranging from .49 to .83 (Bjelland et al., 2002).

Self-efficacy. The Pain Self Efficacy Questionnaire (PSEQ) (Nicholas, 1989) is a 10 item scale that attempts to capture a measure of an individual's confidence in being able to perform specific behaviours despite pain, rated on a numerical scale from 0 "not at all confident" to 6 "completely confident". Scores range from 0 to 60 with higher scores representing stronger self-efficacy beliefs. The PSEQ has been shown to have good test-retest reliability and a high internal consistency (Cronbach's α=.92), and validity (Nicholas, 2007).

Acceptance. The Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken, Vowles, & Eccleston, 2004) is a 20 item measure included to provide a

rating of acceptance of pain. It was adapted through factor analysis from an original version (Geiser, 1992) resulting in two factors (Pain Willingness and Activity Engagement). Factor stability and construct validity has been demonstrated (McCracken et al., 2004) as well as good internal consistency (Cronbach's α between 0.79 and 0.87) (Nicholas & Asghari, 2006).

Mindfulness. The Five Facet Mindfulness Questionnaire (FFMQ) (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) is a 39 item questionnaire which has been developed from five mindfulness questionnaires using exploratory factor analysis. It proposes five facets: Observe, Describe, Nonjudging of Inner Experience, Acting with Awareness, and Nonreactivity to Inner Experience, that together form a single second-order factor: overall mindfulness. The FFMQ has been shown to have good internal consistency (Cronbach's α between 0.72 and 0.92) and good construct validity (Baer et al., 2008).

Interviews.

Pre-programme interview. Before starting the mindfulness programme, all participants were interviewed regarding their chronic pain and expectations of the programme. The interview schedule was developed to encourage participants' reflections on the current status of their chronic pain, how they related to it and how they visualised it (Appendix 3). The schedules were used as a guide to the interview and alternative or follow-up questions used where appropriate.

Post-programme interview. All participants who completed the mindfulness programme were again interviewed using the interview schedule from the pre-programme interview. This was chosen to enable comparisons of participants' descriptions of their pain, relationship to pain and visualisation of pain. An additional interview schedule was developed based on elements of the Change

Interview (Elliott, Slatick, & Urman, 2001), including questions exploring change and attributions of changes as well as questions focussed on gathering experiential data of the programme and thoughts of usefulness/applicability of the programme (Appendix 4).

Drop-out interview. Participants who were unable to complete the mindfulness programme were interviewed to ascertain their reasons for dropping out, any challenges or barriers that led them to drop out, and whether they recommended any adaptations to the programme (Appendix 5).

Analysis

Quantitative analysis. All quantitative data were entered into statistical analysis software (IBM SPSS Statistics version 22). Repeated weekly measures were displayed graphically following guidelines by Morley and Adams (1991) and analysed visually. Pre/post questionnaire data were analysed for each individual for both reliable change and clinically significant change (Jacobson & Truax, 1991). Reliable change describes changes in individuals' scores that are large enough to not merely be due to measurement error. Clinically significant change describes changes in individuals' scores that both show reliable change and change of magnitude that is clinically relevant (and not trivial). Clinical significance can be defined as moving outside the range of scores of a clinical population (criterion a) or within the range of scores of a normative population (criterion c) or halfway between (criterion b). Reliable change criteria were calculated for each measure using published reliability coefficients. As there are no available statistics representing a normative population, means and standard deviations from relevant clinical populations were used (see Table 2). Following Jacobson and Truax (1991), criterion a was used for clinical significance (participant's scores needed to move to beyond 1.96 standard deviations

from the clinical norm to be classified as clinically significant change). Data were entered into a Microsoft Excel calculator to compute statistics and generate graphs (Morley & Dowzer, 2014). For ratings of pain intensity and pain distress, reliability estimates were not used as these rely on an assumption that pain scores will remain stable over time and so any variation is due to error. In chronic pain however, it is expected that pain will vary over time, particularly in the two-week window used for test-retest reliability estimates. Therefore the criteria for clinically significant change was a 30% reduction in pain scores from baseline, a degree of change considered clinically relevant within chronic pain populations (Dworkin et al., 2005).

Table 2

Reliable change statistics for all measures

Measure	**Published clinical population**	**Clinical population mean**	**Clinical population SD**	**Reliability coefficient**
HADS	(Morley, Williams & Hussain, 2008)	20.85	7.2	α=.89-.93
PSEQ	(Morley, Williams & Hussain, 2008)	22.66	10.56	α=.92
CPAQ	(McCracken et al., 2004)	70.5	19.0	α=.79
FFMQ	(Schütze, Rees, Preece, & Schütze, 2010)	125.08	31.43	α=.78

HADS= Hospital Anxiety and Depression Scale, PSEQ= Pain Self-Efficacy Questionnaire, CPAQ= Chronic Pain Acceptance Questionnaire, FFMQ= Five Factor Mindfulness Questionnaire

Qualitative Analysis. A pragmatic approach was adopted towards qualitative analysis and the methods chosen to best answer the second research question

(Pistrang & Barker, 2012). As the study was a feasibility project trialling mindfulness with an inpatient gastrointestinal pain population for the first time, the qualitative data were collected to enable evaluation of the programme, recommendations for adaptions before expanding the intervention more widely across the hospital, and to gain insight into participants' experiences of the course. The interview schedule used for data collection therefore focused on specific aspects of participants' experiences rather than an overview of their experience. Thematic Analysis (TA) was selected to analyse the data. TA is a systematic and transparent method of qualitative analysis which enables patterns of meaning to be identified and analysed in a data set (Joffe, 2012).

TA is a flexible qualitative method suitable for research from different epistemological positions (Braun & Clarke, 2006). A critical realist stance was adopted for this research which assumed that although data can tell us more about reality, interpretation is necessary to access the underlying structures (Willig, 2013). Therefore a degree of subjectivity is inherent in the creation of knowledge (Madill, Jordan, & Shirley, 2000). This position was suited to the analysis of participant transcripts to identify and contextualise the reality of their experience engaging with the mindfulness programme, which are also likely shaped by particular contexts and understandings such as the role of being a patient and living with a chronic illness.

TA was selected for its flexibility in allowing both an inductive (bottom-up approach led by the content of the data) and a deductive (top-down approach which uses ideas or topics brought by the researcher to interpret the data) approach to analysis (Braun & Clarke, 2012). A primarily deductive approach was used in order to address the second research question. Transcripts were analysed according to three domains which reflected the questions asked at interview: hopes and expectations of

the mindfulness course, positive and negative aspects of the course, and challenges, barriers and suggestions for improvements. This approach was chosen as the primary aim of the qualitative analysis was to gain evaluative data on the programme to inform future use and focussed primarily on the manifest content of the data.

The six stage procedure described by Braun and Clarke (2006) was followed. All recordings of pre and post interviews were transcribed verbatim and any personal identifiable information removed, and all written weekly feedback was typed and collated. This was performed by the researcher to help facilitate early familiarisation with the data. All data items were re-read and initial comments annotated on the transcripts. On the following reading of the data, initial codes were noted as any items of text which appeared to describe (either explicitly or latently) an idea or concept relevant to the research question. A code refers to the "most basic segment or element of the raw data" (Braun & Clark, 2006, p.19). Themes were then constructed from these initial codes by clustering together codes which the researcher interpreted to be linked conceptually. This led to an initial thematic map. The entire data set was then re-read to review the initial tentative themes against the raw data and any recoding/changes to themes made, to try and ensure the themes were heterogeneous and that the codes within the themes were homogenous. Once the amended thematic map closely fit the data in terms of adequately describing the elements of the research question apparent in the data, themes were defined and named and extracts of raw data selected which clearly illustrate incidences of the themes in participants' responses.

The researcher kept an awareness that she was an active agent in the research process (Braun & Clarke, 2012), and constructed themes from the available data so personal ideas and assumptions would necessarily impact on the analysis. Therefore

prior to data analysis and throughout coding the researcher made notes of their implicit assumptions and thoughts on the data to help clarify any biases in interpretation. An example transcript was independently coded by a peer researcher and any differences in coding were discussed and code/theme definitions more accurately defined.

Personal context

I am a 26 year old heterosexual white British woman and I have lived in England all my life. I am a Trainee Clinical Psychologist at UCL and have worked in the area of mental health for six years, with two six month placements in Health Psychology settings. I have always been in good health and have never experienced chronic pain, and therefore will have a different lens of interpretation on the data than someone with a personal experience of chronic pain or chronic illness. My experiences of inpatient hospital settings are predominantly in a professional context rather than as a patient or relative and so my understanding of patient-health professional interactions will similarly be influenced by this context.

Results

Participant recruitment took place between August 2014 and March 2015. The two identified gastrointestinal failure wards comprised 90 patient beds. Across the eight month recruitment period 68 potential participants were identified through discussions with nursing and medical staff. Of these, 17 did not meet inclusion criteria, 23 declined to participate and 13 were discharged from the ward before consent could be gained. In total 15 participants gave written consent and completed baseline measures.

Participant characteristics

Of the 15 participants who took part 73% were female and 80% were white British. The mean age of the sample was 32.3 (SD =9.9; range 21-52; median 29 years) and the average years of education was 13.5 (SD= 2.3; range 10-19; median 13 years). The primary diagnoses related to gastrointestinal pain were Crohn's disease (20%), ulcerative colitis (7%), gastroparesis (20%), and pancreatitis (7%). No diagnosis had been proposed for two participants (13%). The median time since onset of chronic pain was seven years. All were prescribed medication for pain and the majority were prescribed opioids (87%). Half the participants reported current diagnoses of depression (47%) and a third were prescribed antidepressants.

Attrition

Only one participant remained on the ward for the full duration of the mindfulness course. Due to the complex nature of the health difficulties participants faced, many found they were unable to complete the course. Three participants were discharged shortly after entering the study and dropped out before completing week one of the course. For one participant (P8), his chronic pain stopped shortly after discharge from hospital after successful surgery and so he did not begin the course. P2 was unable to engage with the mindfulness course since she became very unwell during transfer home and was readmitted to her local hospital for several weeks, while her father was diagnosed with cancer. P9 dropped out before completing week one as she found it very difficult to cope with how unwell she felt once discharged home and was readmitted to hospital several times.

Of the 12 participants who began the mindfulness course, half dropped out before completion. For three participants this was due to illness and frequent readmissions to hospital (P6 after four months trying to complete the first two

weeks; P12 after three months completing half of the course; P15 after three months completing week one). A further two participants dropped out part way through, reporting that they were not finding the course helpful (P10 after two months completing half of the course; P14 after two months completing three weeks). Another participant (P11) completed week one while an inpatient, but on discharge was unable to continue as her daughter became suddenly unwell and needed frequent visits to specialist hospitals. T-tests demonstrated no statistical differences at baseline on any measure between the six participants who continued with the course and the nine who either did not start or dropped out (see Appendix 6).

Of the six participants who continued with the course, only four were able to complete it within the time frame of the study. Most participants found it very difficult to complete each weekly section of the course within seven days because of unexpected illness and extended periods of time attending outpatient appointments, completing their daily health regimes and other external pressures on their time and energy. Therefore two participants were still continuing with the course when data collection ended (P7 after six months had progressed through five weeks; P13 after three months had progressed through one week). This resulted in four participants completing all eight weeks of the mindfulness course.

Figure 1 displays the flow of participants through the study including attrition rates at each stage and the final data available for analysis. Of the 13 participants for whom ending measures were available and an end interview conducted: four were ‘completers’, two were ‘incomplete’, four were ‘drop-outs’ and three were ‘non-starters’. The two missing data were both ‘dropouts’ who were uncontactable.

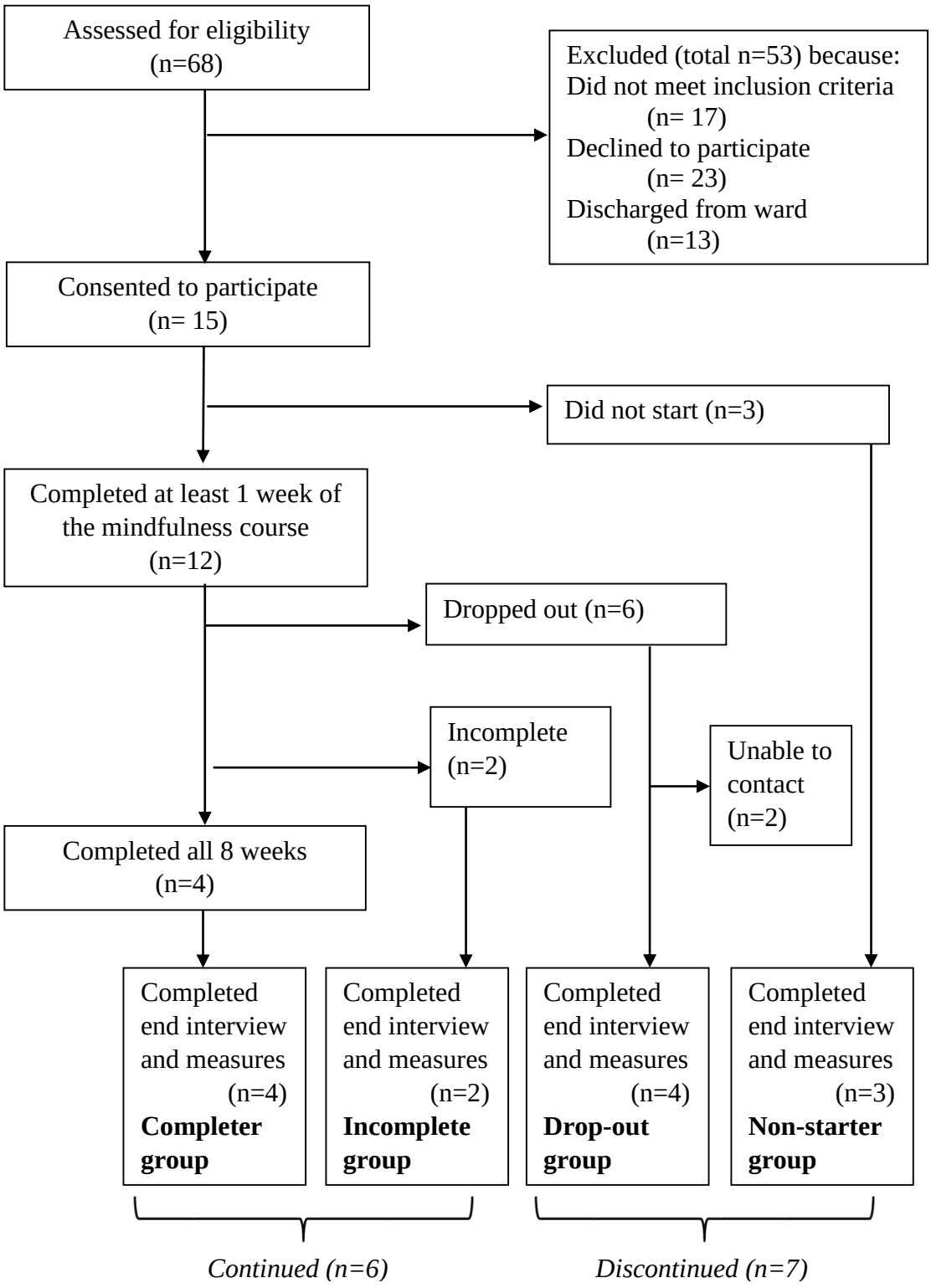

Figure 1. Participant flow

Quantitative analysis

The quantitative data were analysed to address the first research question: can an individual mindfulness intervention for inpatients with gastrointestinal pain reduce pain-related distress, improve quality of life, and increase confidence in pain self-management? Group level statistical analyses of baseline-endpoint measures were not possible as the small sample size meant that there was not enough power to detect an effect (risk of type II error too high). Statistical analysis of baseline-endpoint data was calculated per participant using reliable change and clinically significant change criteria, so that each participant acted as his/her own control.

Reliable change index (RCI) and clinically significant change (CSC). Table 3 and Figure 2-5 show the 'completer' group participants' mean scores for each measure at baseline and endpoint (pain intensity and pain distress were also measured weekly and are discussed separately). The RCI for each measure was calculated and where the observed change from baseline to endpoint was greater than the RCI (and therefore unlikely to be due to measurement error) is indicated in Table 3. CSC criteria were also calculated and where these criteria are met are indicated in Table 3. Of the 24 baseline-endpoint observations, 14 met CSC criteria. Due to a statistical quirk, no participants demonstrated reliable change that was not also clinically significant, in part due to the stringent measures of RCI, which, given the large SD in the samples, required a substantial baseline-endpoint change to meet the reliable change criteria, and therefore were also large enough to meet the CSC criteria. RCI for pain ratings were not calculated and clinical significance defined as a reduction in pain scores from baseline of >30%.

Weekly pain ratings. Assessing change between baseline and endpoint only captures an overall change and cannot describe the trajectory of change for

participants. Ratings of pain intensity and pain distress were collected following completion of each week of the course and are represented graphically for each participant who completed four or more weeks of the course (see Figure 6 and 7).

Pain intensity ratings were not intended as a primary outcome measure of this study as mindfulness does not aim to reduce pain itself (although this sometimes occurs) but aims to reduce the distress that pain causes. However, pain intensity scores were collected as the context of pain distress ratings and because it may have helped participants to distinguish the two in their ratings.

Table 3

Mean scores for each participant who completed the mindfulness course at baseline and endpoint with reliable change and clinically significant change interpretation

Measure	**P1**	**P3**	**P4**	**P5**
Pain intensity				
Baseline	10	6	8	6
Endpoint	0	5	7	0
RCI	CSC	NC	NC	CSC
Pain distress				
Baseline	10	6	7	5
Endpoint	0	4	5	0
RCI	CSC	CSC	CSC	CSC
HADS				
Baseline	22	17	20	6
Endpoint	6	11	16	8
RCI	RC, CSC	RC, CSC	NC	NC
PSEQ				
Baseline	12	16	15	41
Endpoint	33	27	30	33
RCI	RC, CSC	RC, CSC	RC, CSC	NC
CPAQ				
Baseline	17	53	46	64
Endpoint	35	60	60	72
RCI	NC	NC	NC	NC
FFMQ				
Baseline	118	120	112	138
Endpoint	144	135	134	140
RCI	RC, CSC	RC, CSC	RC, CSC	NC

HADS= Hospital Anxiety and Depression Scale; PSEQ= Pain Self Efficacy Questionnaire; CPAQ= Chronic Pain Acceptance Questionnaire; FFMQ= Five Factor Mindfulness Questionnaire; RCI= Reliable Change Index; RC= Reliable Change at the 95% confidence interval; CSC= Clinically Significant Change; NC= No Change.

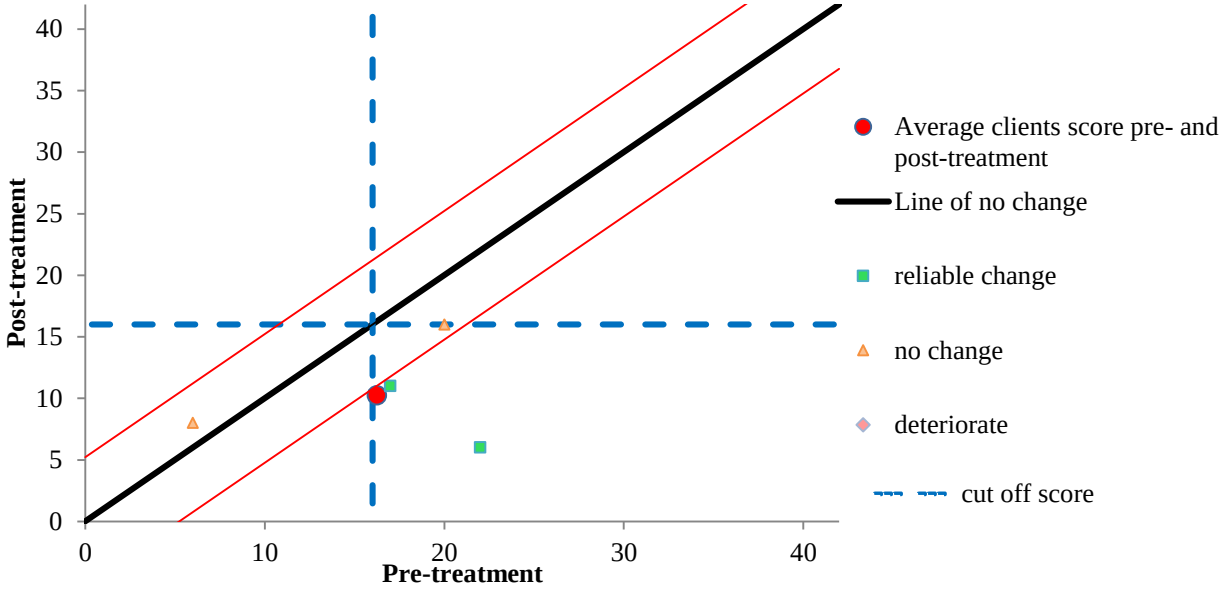

Figure 2 Plot of HADS scores pre and post treatment for completer group, with reliable change margins and clinical cut offs demonstrated

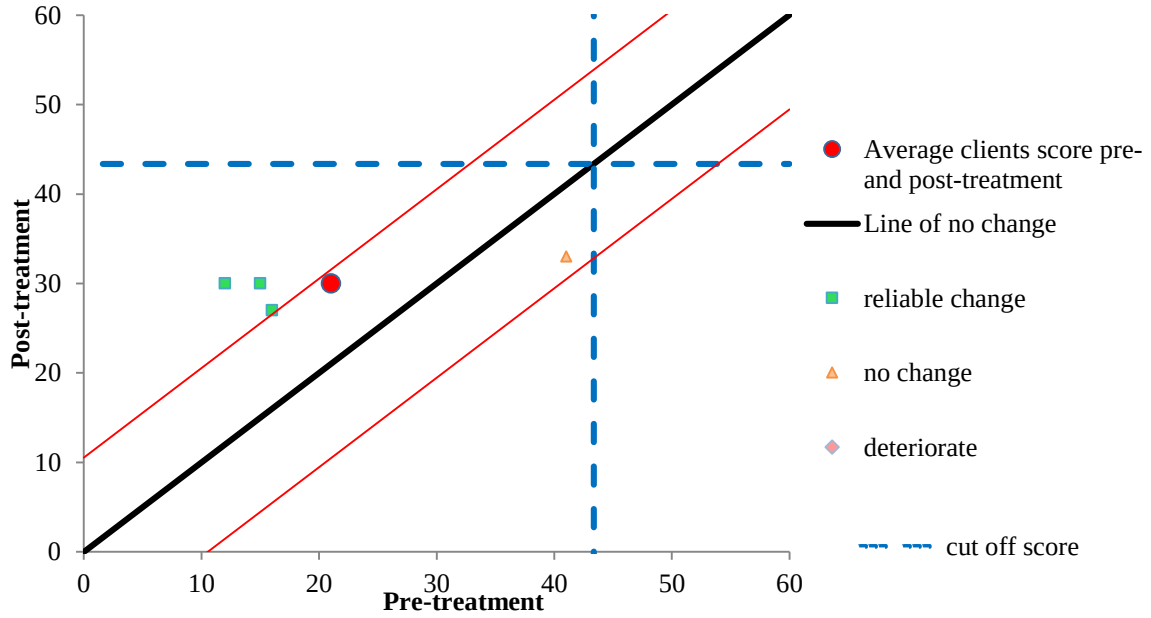

Figure 3 Plot of PSEQ scores pre and post treatment for completer group, with reliable change margins and clinical cut offs demonstrated

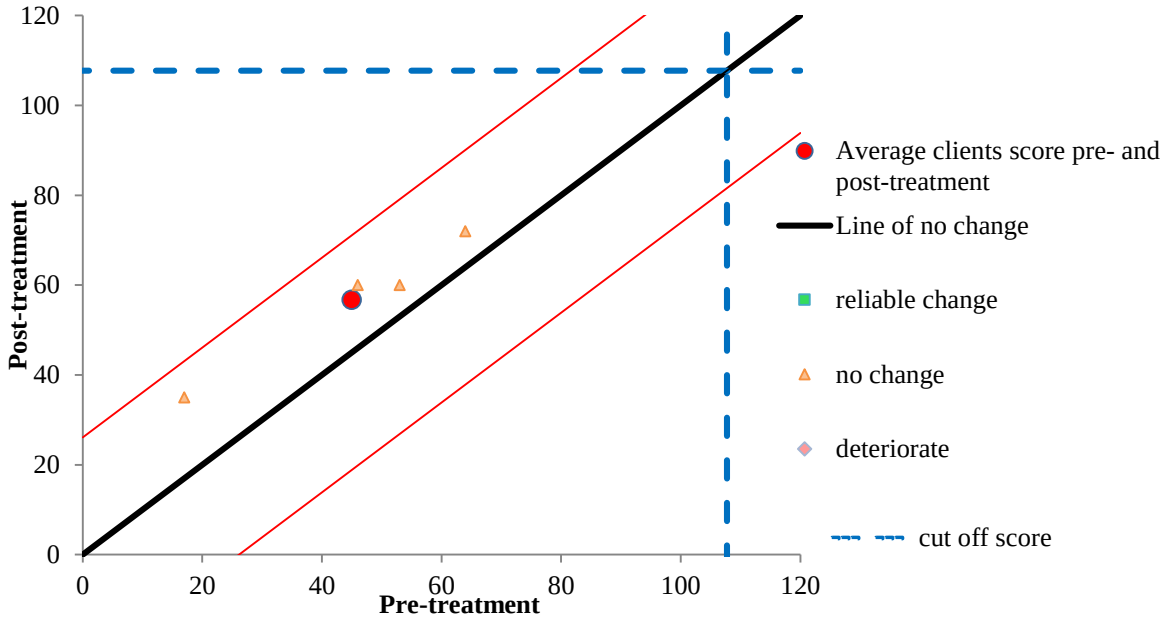

Figure 4 Plot of CPAQ scores pre and post treatment for completer group, with reliable change margins and clinical cut offs demonstrated

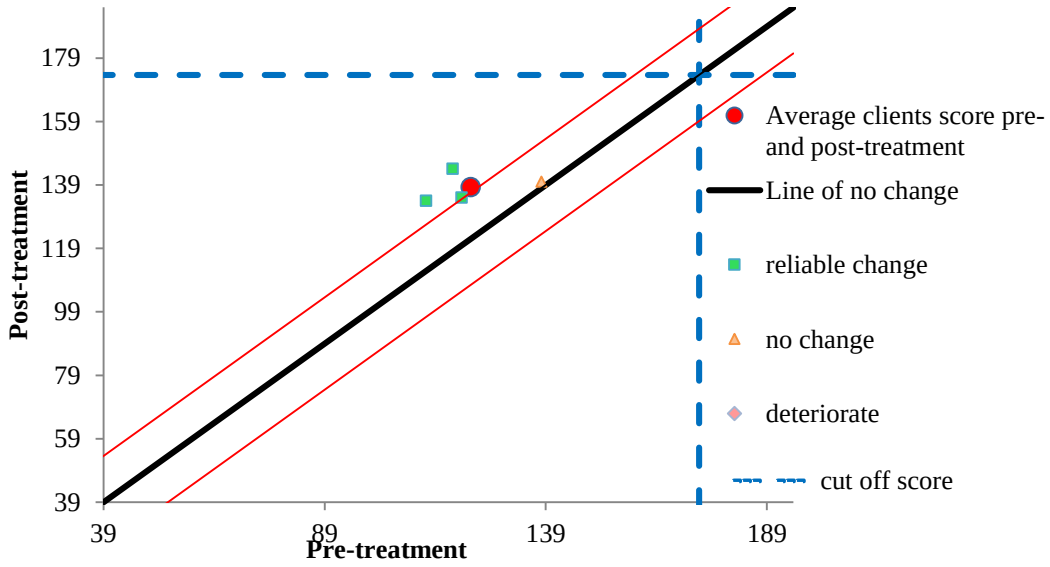

Figure 5 Plot of FFMQ scores pre and post treatment for completer group, with reliable change margins and clinical cut offs demonstrated

Visual analysis of the graphs for P1 demonstrate the most marked changes in pain distress across the time frame of the study, reducing steadily from the maximum 10/10 pain distress rating at baseline to 0/10 by week four and remaining at 0/10 until the end. The graphs for pain intensity for P1 closely matches that for pain distress with only the ratings at week one differing (5/10 for pain intensity and 8/10 for pain distress).

Weekly pain intensity ratings for P3 appear stable across the nine timepoints with a peak corresponding with week five. P3's pain distress scores show greater variation with an equivalent peak at week five but more pronounced troughs at week one and seven and an overall reduction in pain distress over time.

Weekly pain scores for P4 show greater differences, with pain intensity ratings generally being higher than pain distress (range 6.5-9 for pain intensity and 4-8 for pain distress). What can also be seen from the graphs for P4 are that changes in pain ratings over the weeks were consistent in one direction as for P1, but both increased and decreased over time. The peak at week six coincides with P4 having a procedure under general anaesthetic which caused a spike in pain and difficulties practising the meditations.

The pain graphs for P5 again show close resemblance to each other and following initial decreases up to week four, oscillate between ratings of 0/10 and 4/10 until the end. The peaks at weeks five and seven represent 'flare-ups' of his Crohn's disease.

P10 dropped out of the study after week four due to increasing pain and finding the mindfulness unhelpful. Visual analysis of the pain rating graphs shows that whilst pain intensity remained generally high across this time period, pain

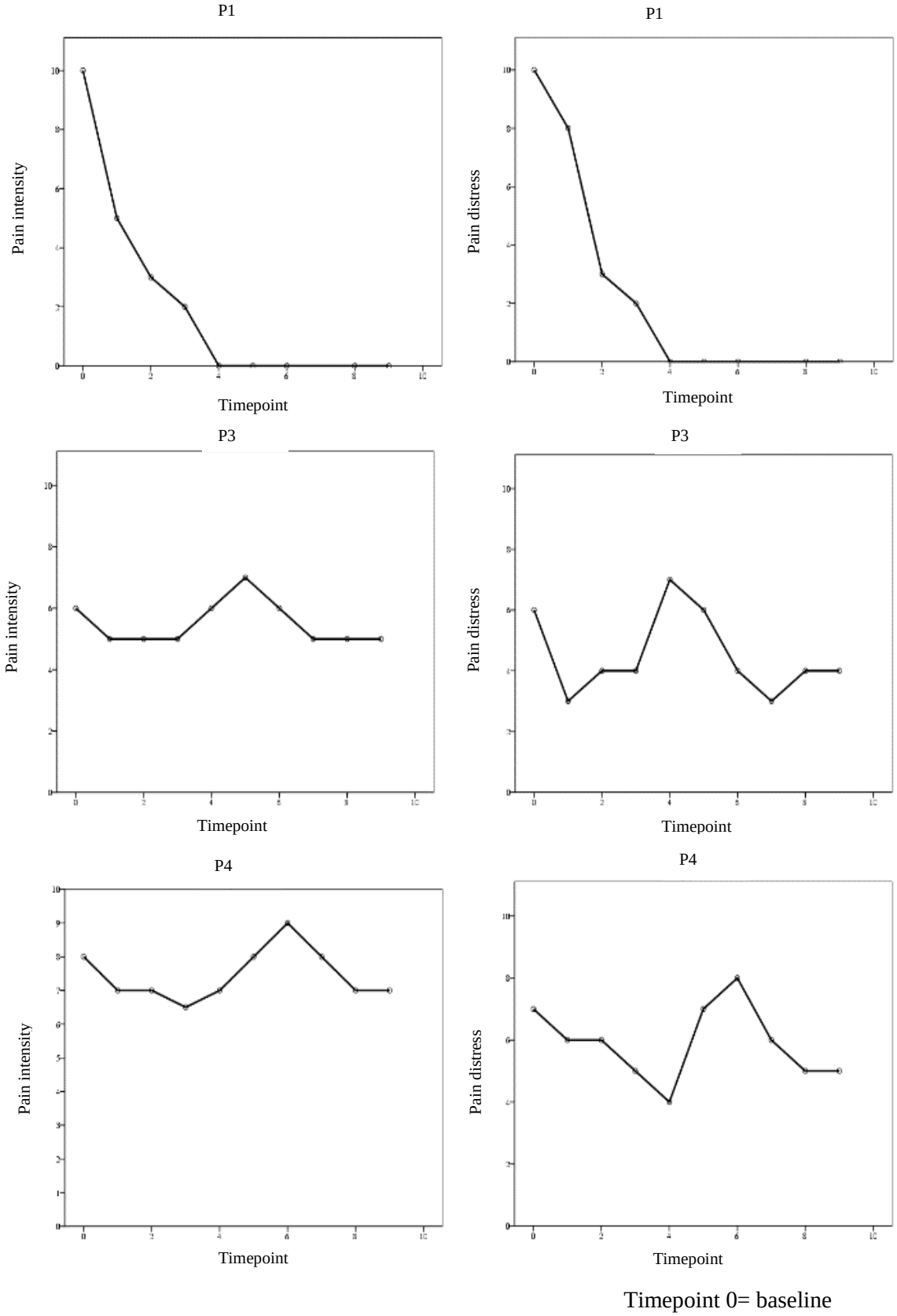

Figure 6 Weekly ratings of pain intensity and distress

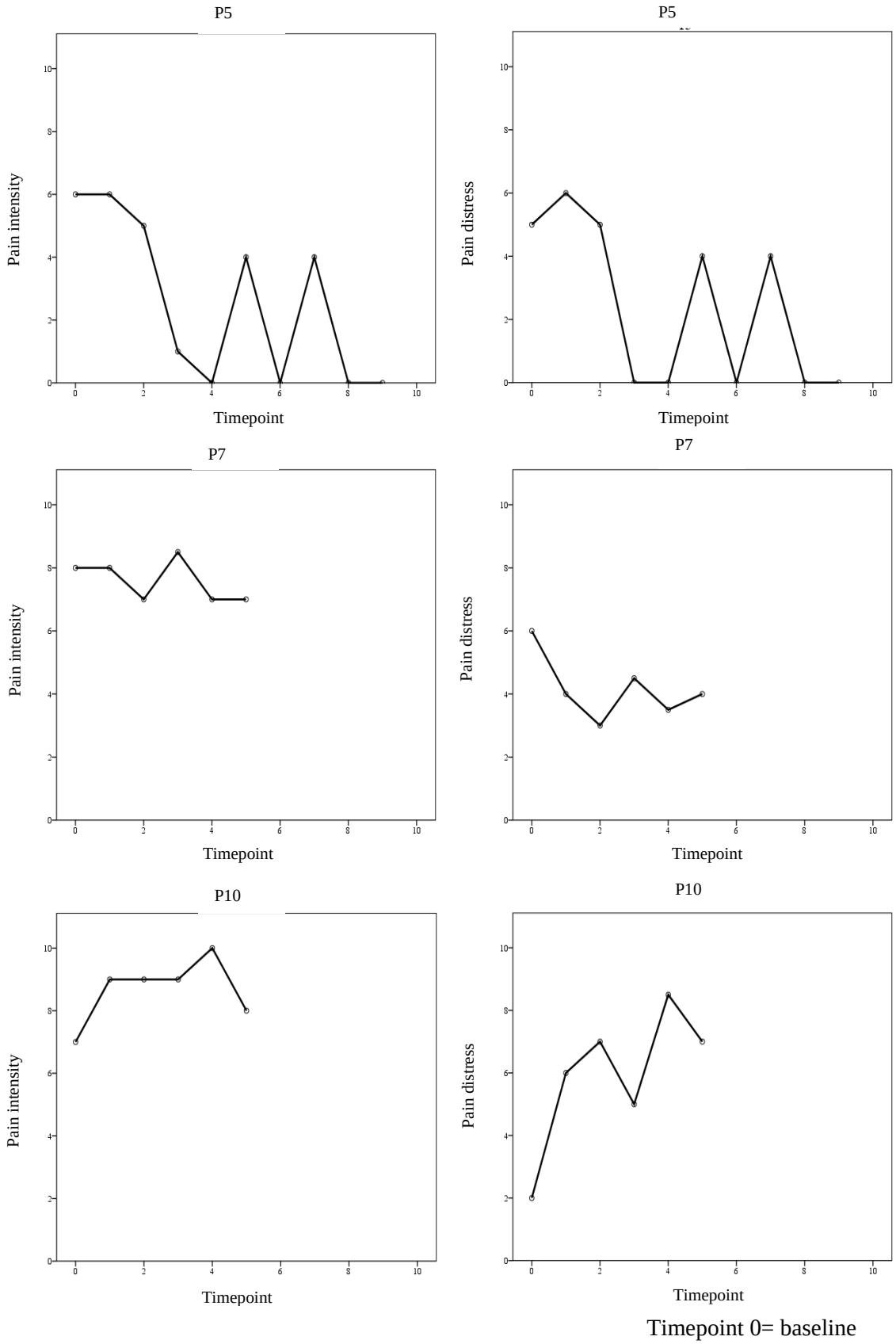

Figure 7 Weekly ratings of pain intensity and distress

distress ratings increased. Anecdotal comments from P10 across the weeks described increasing problems with her feed (she was fed through a tube into her intestines) and uncertainty about the cause of the problems. This uncertainty may account for the increased distress recorded, while the pain intensity remained constant.

Qualitative analysis

All 15 participants were interviewed before beginning the mindfulness course and 13 were contactable to interview following the course. In addition eight participants provided brief written feedback after completing each week of the course. These qualitative data were analysed together in order to answer the second research questions: how useful and applicable do inpatients with gastrointestinal pain find MBSR methods? Brief descriptions of each participant's pain characteristics are detailed in Table 4.

Sections of the data where participants described their pain were not coded as they did not address the research question. Data were categorised under two broad headings (usefulness and applicability) and within these categories a general thematic analysis was undertaken (see Appendix 7 for an annotated example). Ten themes were found within three domains (see Table 5). Each theme is discussed with extracts from participants' transcribed interviews and weekly written feedback. Data from all participants were analysed together but attention will be drawn to the differences between those that continued with the course (completer and incomplete groups n=6) and those that discontinued (non starter and drop out groups n=7). To enable clarity those that continued with the course will be designated C after their participant number and those that discontinued will be designated D.

Table 4

Participant pain characteristics

P	Gender	Age	Cause of gastrointestinal pain	Pain years	Completion status
1C	female	28	Gastroparesis as a complication of type 1 diabetes	4	Completer
3C	female	52	Gastroparesis	13	Completer
4C	female	21	Pancreatitis, chronic pain syndrome and fibromyalgia	17	Completer
5C	male	26	Crohn's disease	16	Completer
7C	female	44	Gastroparesis due to connective tissue disease, fibromyalgia and neuropathic pain	20	Incomplete
13C	female	34	Gastrointestinal dysfunction due to spina bifida	34	Incomplete
6D	male	46	Ulcerative colitis leading to most of the bowel being removed	11	Drop out
10D	female	21	Addison’s disease leading to gastroparesis	1	Drop out
11D	female	25	Crohn's disease	10	Drop out
12D	female	20	Unknown	1	Drop out
14D	male	29	Unknown	7	Drop out
15D	female	41	Tuberculosis in stomach	0.33	Drop out
2D	female	41	Crohn's disease	6	Non starter
8D	male	24	Spinal cord injury leading to intestinal dysfunction	4	Non starter
9D	female	32	Blunt liver trauma subsequent to surgery for gallstones	0.33	Non starter

Table 5

Categories, domains, themes and sources

Category	Domain	*Theme*	Number of sources
Usefulness	1) Hopes and expectations of the mindfulness course	*a*) *Reducing pain*	4
		b) Increasing coping with pain	12
		c) Relaxation	8
		d) Low expectations	3
	2) Outcomes/finding of the experience of doing the course	*e*) *Results from the course and what is different now*	7
		f) When the techniques are useful	4
		g) Positive aspects of the course	7
		h) Negative aspects of the course	7
Applicability	3) Difficulties engaging with mindfulness/lack of fit with illness	*i*) *Challenges of using mindfulness*	5
		j) Barriers to starting or completing the course	7
		k) Suggestions of how it could be adapted	8

1) Hopes and expectations of the mindfulness course. Themes in this domain are focussed on what the expectations for the course were (reported both before starting the course and in retrospect at the end interview) and related primarily to interview questions on hopes for the course. Examples of all four themes within this domain were reported equally by participants that continued with the course and those that discontinued and therefore will be presented together.

a) Reducing pain. The aims of the mindfulness course were not to reduce pain intensity and this was explicitly discussed with participants before consent was gained. Despite this, several participants stated that they hoped the course would reduce their pain. Each participant usually qualified this hope with awareness that that might not be possible:

P3C: *I don't know whether it can have any effect on the actual physical symptoms of my pain, that would be wonderful, I'm not sure on that*

P9D: *the ultimate goal is to not be in pain, um, but I know that this can't cure me 100%*

Although only a few participants explicitly mentioned this, I believe many more held this hope as several commented after dropping out of the course that it had not helped reduce their pain, implying that they had originally held this expectation.

b) Increasing coping with pain. The vast majority of the data describing participants' expectations and hopes for the mindfulness course concerned increasing coping with pain:

P3C: *to be able to cope with it, maybe cope with it better, I feel I cope with it quite well [sniff], because I've had it for so long*

P11D: *just maybe a different way of, yet again, try and cope with pain because it's something I am going to have for the rest of my life*

P14D: *If it can help with enduring the pain and just, what's the word I'm looking for, deal with it basically*

For many participants, increase coping with pain meant being able to cope with lower doses of medication, or to be able to delay needing the next dose:

P2D: *I'm on so many different medications and I thought if there's some sort of way that I can do things slightly differently it might be better*

P11D: *that's what I'd like to get out of it really, just try and get down off of such high medication with different coping techniques because I cope terribly with withdrawals*

P13C: *so just maybe how to live with it and, because I don't, I don't like taking too many pain killers, um, because I always worry about my brain, like, when I'm older, and I don't want my brain going to mush*

Some aspects of 'coping with pain' seemed to refer to not being so depressed by pain, or less preoccupied by it. Another interpretation is that 'coping with pain' reflects ideas of individuals' responsibility for remaining in pain, that once medicine has done all it can for the patient, they just have to 'learn to live with it'.

P3C: *I hate it when doctors say I'm a complex patient, I don't want to be a complex patient I really don't*

P4C: *when you're in the situation you don't have a choice…you can't fall to pieces*

P8D: *I've had doctors tell me…"unfortunately you've just got to live with it"*

c) Relaxation. Participants also described relaxation as a key hope for what mindfulness could offer and linked increase stress/anxiety with heightened pain:

P1C: *I wanted to get a sense of, um, like relaxation because I was very anxious and, um, I just wanted to just like feel less anxious and less worried if I did get pain*

P12D: *be more relaxed in myself, more comfortable because I get very tense and very worried and I think that just makes everything worse as well*

P9D: *maybe because I'm so stressed that's why I'm feeling the pain more*

P14D: *Because the pain is there, there's nothing I can do about it, but thinking about it and stressing about it makes it worse, if there's any way I can take my mind off it, I'm willing to embrace that*

d) Low expectations. Counter to the main emphasis with the theme of hopes and expectations of the mindfulness course, several participants reported honestly that they were fairly sceptical about the course and held low expectations, partially due to past history of trying techniques that they did not find helpful:

P1C: *I know it sounds a bit horrible in a way but I wasn't really expecting it to do mind-blowing things*

P4C: *this isn't me being a pessimistic just a realist, I don't, I don't go in with any high, with any high expectations because a) I don't really know what to expect, and b) I don't want to expect anything and that shadow or prevent me from seeing or following something else that comes up*

P8D: *I don't really know really, to be honest, I've had, you know, when you've had something for so long and you've had so many people try and change it and alter it for you and nothing works… if you want my honest opinion I don't think it will do anything but I'm willing to try it, I'm willing to try it*

2) Outcomes/finding of the experience of doing the course. Themes in this domain focussed on the experience of doing the mindfulness course, including outcomes from the course and when they found it useful. Themes on the positive and negative aspects of the course closely followed the questions about what they liked and did not like about the book, tracks and each section of the course. Most of the data that contributed to this domain originated from those participants who continued with the course. Although some who discontinued the course also contributed, this

domain is best illustrated by the participants who continued as they experienced more of the interventions and were better able to describe which elements they found useful.

e) Results from the course and what is different now. This theme captured the descriptions participants gave of how they found the mindfulness course had had an effect; what the outcome of taking part was and how things had changed due to participating in the study. Of the four participants who completed the whole eight weeks of the course, three described it as an overall positive experience and one found it partially positive:

P1C: *it's been a really good experience so far… it's really helped me blossom in a way… I'm kind of sad that it's come to an end*

P4C: *overall a very positive one [experience]*

P5C: *I think it was a bit helpful, yeah, yeah I think it was a bit helpful*

P3C: *Sometimes it worked quite well and at other times it didn't work at all well*

P7C: *if I'd been able to get further, I think it would definitely have been a good experience*

Many participants reported finding it increased relaxation and helped to feel less anxious when in pain:

P1C: *I find it really relaxing, if I'm feeling sick I just remember the breathing exercises and it really does calm me down*

P3C: *the relaxation part of it worked really well as I ended up falling asleep each time, which is a bonus when the pain has woken you up so managed to use it to get back to sleep*

P5C: *the things it was saying, like telling you to relax and stuff was just making your mind more relaxed*

f) When the techniques are useful. As well as discussing how they had found the mindfulness course had had an effect, the four 'completers' also detailed when they found the techniques to be useful:

P1C: *when I get pain, um, or when I've just vomited, that's when I use it*

P3C: *when I was having my line, when I was having my lines done recently I tried to use it then because I was in an awful lot of pain*

P3C: *I've found I've called on it more in the acute setting than I have for the day to day stuff*

P4C: *I find that I do the breathing one, um, that's my main, my main weapon before I then ask for a dose of oxynorm [oxycodone]*

P5C: *I was in too much pain so I was just waiting; I relaxed for a couple of hours to see if it would go away*

g) Positive aspects of the course. As well as describing the overall usefulness of the mindfulness course, participants also specified which aspects they found were particularly positive. Repeated mention was made of the first two weeks' meditation; 'the body scan' and 'the breathing anchor'. Many participants reported finding these useful and positive as they were very straightforward, and could be used even when in a lot of pain, and week three's 'mindful movement' was also singled out as particularly positive:

P1C: *I know I use it a lot, the first one, the body scan was the best one that I use… I find it really relaxing*

P3C: *they were easier for me to do and I found them much more beneficial than the latter thing*

P4C: *I really enjoyed especially the first two, especially the first two, so the bodyscan and the um eh breathing anchor… They're really really really simple ones that you can [do] even when you're in absolute agony*

P4C: *despite not being able to move freely at all, I have loved the mindful movement meditation. I have learned to focus on the positive feelings of the movements I can do and that in a way has started to override the negative feelings of pain and discomfort. This has become easier and easier to do and more automatic. It's meant that I don't fear movement anymore and feel I have more control.*

There was also mention that the book was clear and concise and gave straightforward instructions that could be easily followed:

P1C: *it's got instructions and it tells you what to do it's just sort of does it step by step with you*

P4C: *it was another way of reinforcing what the- , what the meditations were in giving you a foundation to build on when you were listening to them, so for the for the more challenging ones it wasn't something completely new that you were having to try*

P7C: *I liked the case studies in the book.*

One participant found the case vignettes in the book particularly interesting:

P7C: *reading the case studies, the different examples, um that I found very helpful in the book*

Another positive aspect of the course that was repeatedly reported was the repetitive nature of the practice and how the knowledge and skills were built up gradually, week by week.

P1C: *each one teaches you something different and I just found as you combine them and bring them like next one and then the next one, as you build them up, it makes a bigger picture*

P4C: *that got better and easier with time as I got more practice*

P5C: *repeating it so many times made it easier to understand and remember*

h) Negative aspects of the course. As well as describing positive aspects of the course participants also identified the less useful or less applicable elements. These included burden on time:

P3C: *I think when it's new and you're doing a new programme you're very much looking at it the whole time and it just in certain ways it was like becoming a bit of a pain in the backside at times "oh god I haven't done that this week, I best read that"*

Mention was also made several times of the sections of the book covering ideas of pacing were sometimes difficult, unhelpful or too time consuming. As the book was not written specifically for inpatient use, the pacing recommendations assumed you were in your own home and this made it difficult to adapt for some participants:

P3C: *I am finding it harder to do some of the exercises e.g. pacing as hospital is such an artificial environment*

P4C: *The idea of keeping a 'pacing' diary made me feel stressed and burdened. I am good at pacing and can do it automatically. I don't want to pay it any special attention. Facing and thinking about it reminds me in a constant and unhelpful way that I am ill and cannot do all the things I would like to do.*

One participant also found the reading level of the book fairly complex, and another that the book sections were overly long:

P5C: *it was a bit complicated, yeah, the words*

P7C: *some of them [the chapters] were like, in some cases, really like substantially long, just too much to take in*

3) Difficulties engaging with mindfulness/lack of fit with illness. This domain focussed on the questions participants were asked about how the course may be adapted in light of their experience, and the factors that made continuation difficult. It captured some of the difficulties common to many people trying to learn a new strategy, but also the specific challenges for this patient group.

i*) *Challenges of using mindfulness. The first theme, challenges of using mindfulness, described the difficulties participants experienced when doing the course, but that did not stop them from being able to engage with it and therefore are provided by those that continued with the course. These included consistently falling asleep during meditations, initially finding it difficult, distractions within a hospital environment, and burdens on time:

P3C: *I think in some ways it would be easier if it were all in hospital or it would be easier if it were all at home, it was difficult switching backwards and forwards between the two*

P4C: *for most of the others, for at least a couple of weeks or so, I had to really focus on the person's voice giving the instructions, and I was focussing so much on the instructions that actually doing the, eh, the kind of positive side of doing the meditation was getting lost in translation because I wasn't focussing on doing that part, I was focussing on trying to listen and focus on what was being said*

P5C: *I found it ok, at first I didn't find it ok so I had to keep going back but then I found it ok after*

P3C: *because of how my illness is and what I have to fit in in a day to manage my illness I found [it was] adding in more and more things [to fit in]*

P13C: *it was frustrating that I wasn't able to do more, lots of things getting in the way…like the medications and the nurses in the day just getting in the way, and like kind of just outside life as well got in the way*

j) Barriers to starting or completing the course. Whilst the challenges made it difficult for participants to progress through the course, they did not stop them completely. There were however several barriers that prevented participants from starting the course or led them to drop out, not because they were not finding it helpful or thought that it might have a positive benefit, but because they were unable to find a way that it could fit into their life and their illness at the time. As they prevented them from completing the course, all the barriers were reported by participants who discontinued. The most significant barrier appeared to be due to illness, usually related to the condition that resulted in chronic pain:

P2D: *I was taken ill on the way home and then I was in and out of hospital for the next couple of months...which made it too difficult because I'd go in, be too sick and not be able to do it*

P9D: *I wasn't expecting to be so poorly, I wasn't expecting my illness to be as consuming as it was*

P14D: *I had spaces in between when I was too unwell and couldn't do it*

P15D: *Everything, everything's got in the way to be honest and it's all down to my health, it's all down to the diagnosis, the tablets, can't tolerate the tablets*

This was also the case for P12D, who though unable to complete an ending interview reported that the reason she had to dropout was due to being unwell back in hospital needing surgery. Closely related to the impact of illness were the barriers of frequently being readmitted to hospital:

> **P2D:** *the most stressful thing was the being in and out of hospital because every time I was feeling like I was kind of getting back to being able to cope and do things then it felt like I was going backwards with that, kind of getting knocked down again with that, so I'd say that one, being in and out of hospital one was probably the worst, um, yeh, it was dreadful*
>
> **P6D:** *unfortunately when I came out of hospital last time there wasn't a week went past that I wasn't up here one or two days a week and that took it out of me so the next day I'd be in bed and I was just so tired all the time*
>
> **P9D:** *when I came out of hospital I had multiple rebound trips to my local hospital*

Another frequently cited barrier to being able to use the mindfulness course was lack of time, both generally and because of demands on time from illness regimes:

> **P9D:** *I couldn't give anybody any length of time; I couldn't even give myself time*
>
> **P10D:** [I'd] *end up spending the whole day, essentially, trying to meditate*

k) Suggestions of how it could be adapted. Of the participants who continued with the mindfulness course, many had suggestions of how the course could be improved or adapted for patients with gastrointestinal pain. One suggestion was for the course to be delivered all in one location as it was difficult to transition between hospital and home:

P3C: *in an ideal world it would be eight weeks in hospital*

P13C: *when you're in hospital, you actually, you get bored so you'd be more focussed to do it as well, whereas when you're back at home, as well as sort of dealing with your own pain and health issues, life gets in the way*

Another suggestion was to simplify the material in the book or to change the format of the book to make it easier to follow when unwell:

P4C: *I would try and make it even less complex, because, I mean it's really good having other people's experiences in there but on my, um, on my days when I wasn't feeling too good, I found, I found that difficult, sometimes difficult to get past, and I'd get lost*

P5C: *language I think more simpler*

P7C: *I think it would be easier to listen to something rather than try to read it yourself*

In terms of adaptations of the course specifically to meet the needs of patients with gastrointestinal pain, one participant in particular emphasised the need to tailor the course individually to each patient, rather than as a block course:

P3C: *with these, sort of like, the the little package that, um, we're trying to do with this mindfulness thing is that I think for the us strange patients who've got gut problems I don't think it's unfortunately going to be a thing that we can just pick off the shelf …I say tailoring it to somebody to how they actually need it, that's how I see it progressing…if I left it just as it was, I wouldn't get an awful lot from it*

Another participant recommended including case study vignettes from patients with gastrointestinal pain in the book as well:

P7C: *it would be quite good maybe to have someone, maybe with gastro pain or people that have long term chronic illnesses*

Discussion

The effectiveness and acceptability of a guided self-help mindfulness course for chronic gastrointestinal pain was evaluated with 15 inpatient participants. A multiple single case design was used to assess change in pain ratings over time, in addition to baseline and endpoint quantitative outcome measures. Qualitative interviews were used to evaluate the course's usefulness and acceptability with this population. First the findings will be summarised and then discussed within the context of the wider literature. Following this the strengths and limitations of the study and clinical and scientific implications will be discussed.

Summary of findings

1. Can an individual mindfulness intervention for inpatients with gastrointestinal pain reduce pain-related distress, improve quality of life, and increase confidence in pain self-management?

Pain distress ratings reduced over the period of the intervention by a clinically significant amount from baseline to endpoint for all four participants who completed the mindfulness course. Pain distress and pain intensity ratings were closely associated for some participants, but for others pain distress ratings decreased whilst pain intensity remained relatively constant. Participants who had completed it reported that the mindfulness course was "*a really good experience*" (P1C) and straightforward enough to be used when acutely unwell "*you could do it even when you were really poorly; you didn't have to be at the top of your game in order to interact with it and do it*" (P4C).

With regard to improved quality of life, measures of psychological distress decreased for the majority of 'completers'. Participants reported that some negative emotions became less frequent "*I'm not so anxious, I'm not so, um, worried, um, as what I'd used to be*" (P1C) whilst others reported that negative emotions still occurred but were less distressing "*they're not so sharp and painful*" (P4C)

Confidence in doing things despite pain increased following the intervention with three 'completers' reaching reliable and clinically significant improvement. No changes were observed in pain acceptance. Mindfulness skills increased across the course with clinically significant improvements for three out of four 'completers'.

2. *How useful and applicable do inpatients with gastrointestinal pain find MBSR methods?*

Prior to beginning the mindfulness course, most participants hoped that it would help them to cope with pain whilst a smaller number also hoped it would reduce pain intensity (contrary to descriptions of the study). Several participants had low expectations of the course due to previous disappointing experiences. Those who continued reported that, overall, doing the course was a positive experience and several of those that dropped out or were unable to start said that they would like to be able to engage with mindfulness in the future. Overwhelmingly the earlier sections of the course (body scan and breathing anchor meditations) were described as being useful, easy to follow and most used by those who completed all sections of the course. Participants differed in being able to use the mindfulness techniques during intense pain, or finding it too difficult. Overall the book and audio tracks were found useful and applicable but for a minority of participants the book was too long or complex. Some participants also commented that finding time to practise mindfulness was a burden with the complex regimes required of their illnesses. This

was cited both as a challenge by those who continued and as a barrier by those who discontinued.

Three fifths of the sample discontinued the course. Only two of these nine participants reported dropping out due to finding the mindfulness course unhelpful. The remainder reported barriers to completion related to their illness and healthcare and to external stresses. Participants who continued with the course made suggestions for how it could be adapted to improve the fit for inpatient chronic gastrointestinal pain patients including: introducing the course during an extended inpatient admission, reducing the complexity of the book and producing an audio version; and tailoring the course for each patient, with clinician contact.

In summary, the data from the four 'completers suggests that a guided self-help mindfulness course shows potential benefits for inpatients with gastro intestinal pain although with such a small number completed, these results must be taken with caution. The challenges and barriers faced by this population of chronic and complex gastrointestinal pain patients are significant and so adaptations to standard MBSR delivery are needed.

Wider context

The current study investigated only a small sample of heterogeneous gastrointestinal pain patients and results cannot be generalised to the wider chronic pain/chronic illness populations. However the findings were in line with previous reports of positive outcomes following mindfulness interventions including the original accounts of MBSR with outpatients with pain and illness (Kabat-Zinn et al., 1985). Although reductions in pain intensity were not an aim of the present study, clinically significant improvements occurred for two of the four 'completers', as has been reported in recent meta analyses (Baer, 2003; Grossman et al., 2004; Reiner et

al., 2013). Another meta-analysis (Chiesa & Serretti, 2011) reported strong benefits of mindfulness on depressive symptoms (as found in this study) and on coping with pain (demonstrated in this study through measures of increased confidence in doing activities despite the pain and qualitative reports of increased abilities to use relaxation to cope with pain). Patients with gastrointestinal pain frequently have multiple additional medical and psychological difficulties and the initial positive results in this study may have resulted from improvement in these factors. Mindfulness interventions have shown promising effects on improving depressive symptoms and quality of life for patients with fibromyalgia (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Sephton et al., 2007), improving symptoms and abdominal pain in IBS (Gaylord et al., 2011) and ameliorating depression, anxiety and fatigue in patients with multiple sclerosis (Grossman et al., 2010).

Measures of acceptance of chronic pain did not increase reliably for any of the four 'completers'. This may be due to participants' initial baseline scores being considerably lower than the mean of the clinical population with which they were compared. Although it was the most similar published data set in terms of sample characteristics, the majority of that population reported back pain, and were not currently under treatment. Participants in this study were in active inpatient treatment for gastrointestinal problems, including infections, procedures and pain management. Another possible account is that changes to pain acceptance may not be sensitive over the short term, and longer term practice with mindfulness may demonstrate later increases in acceptance.

Qualitative findings. Participants' responses during the semi-structured interviews revealed useful practical information about their expectations of mindfulness, the outcomes and the challenges they faced.

When participants spoke of wanting to increase their abilities to 'cope with the pain', one interpretation was that they had internalised the expectations of 'western medicine' that it was their *responsibility* to 'cope with the pain'. Within the traditional working model of most healthcare interactions there is an assumption that illness and pain are acute and temporary. Following from ideas proposed by Foucault, since the birth of modern medicine the disease entity has been objectified and separated from the person (Foucault, 1963) and has a mechanical manifestation and solution. This model does not fit well with chronic pain and illness as often a 'fix' or 'cure' is not possible. From the clinicians' perspective, concepts of responsibility for health and illness are shifted away from the medical practitioner and placed back on the patient (Eccleston, Williams, & Stainton Rogers, 1997).

One of the significant challenges/barriers participants reported when trying to engage with the mindfulness course was difficulties finding time. During weekly feedback, participants repeatedly reported being unable to complete that week's mindfulness practice and to progress. They frequently reported frustration about the limits imposed on them by pain and illness and the needs and responsibilities of their lives 'outside'. For many participants, being ill and in pain was a fulltime 'career', both literally in terms of hours spent in hospital, attending outpatient appointments, taking medication, enteral feeds and visits from district nurses, and symbolically in terms of the amount of emotional time and energy taken by living with pain and illness. The majority of participants spoke of how this left little time for their 'real' life, families, work, friends, goals, desires and interests. These findings fit with other qualitative accounts from patients living with chronic pain and illness including individuals with IBS who described constantly living on the borderline between

wellbeing and illness (Delmar et al., 2005) and time constraints being one of the main barriers to self-management of pain (Bair et al., 2009).

Plausible mechanisms. As a feasibility study, the results reported here cannot demonstrate causal relationships between practice of mindfulness and reduced distress of gastrointestinal pain. However the promising findings can be discussed against several proposed mechanisms which attempt to account for similar findings in research of larger, controlled studies.

Following completion of the course, increases in mindfulness as measured by the FFMQ were observed; unfortunately, the sample size was too small to test for associations with the other improvements. Studies of MBSR for patients with IBS demonstrated significant correlations between increases in mindfulness scores and decreases in gastro-specific anxiety after eight weeks of MBSR, maintained at six month follow up (Kearney, McDermott, Martinez, & Simpson, 2011). Further research could investigate whether decreases in anxiety (and specifically gastro-specific anxiety) is a mediating factor between increases in mindfulness skills and reductions in gastrointestinal pain.

The majority of participants who continued with the course reported feeling more relaxed as an outcome from practising the mindfulness. Anxiety and fear amplify pain (Keefe, Rumble, Scipio, Giordano, & Perri, 2004) and greater activation of limbic (emotion processing) areas of the brain is found in chronic compared to acute pain (Apkarian, Hashmi, & Baliki, 2011). Therefore, if relaxation can reduce anxiety and fear, pain may also decrease. One participant particularly illustrated the powerful impact of anxiety on the distress of being in pain "*if I'm feeling sick I just remember the breathing exercises and it really does calm me down*" (P1C). She found the straightforward meditations in the mindfulness course

helped to break the vicious cycle of pain and anxiety. This finding was also demonstrated in a qualitative study of older adults' experiences of using mindfulness for back pain (Morone, Lynch, Greco, Tindle, & Weiner, 2008).

Several imaging studies have investigated the neural correlates between mindfulness practice and reduced distress indicating that changes occur at a neural level. Changes in anticipatory processing in the dorsolateral prefrontal cortex and somatosensory cortices indicated improved regulation of the emotional responses to pain which related to improved mental health following mindfulness training for patients with chronic pain (C. A. Brown & Jones, 2013) rather than being related to reduced pain experience. Anticipatory anxiety about pain increases the perceived intensity of identical stimuli (Ploghaus et al., 2001). Meditation has been shown to reduce the anticipation and negative appraisal of pain and this has been associated with differential activation of the midcingulate cortex and medial prefrontal cortex (C. A. Brown & Jones, 2010).

Distraction is sometimes reported to be an effective coping strategy for managing pain (Buhle, Stevens, Friedman, & Wager, 2012). Mindfulness training instructs individuals to focus on sensations rather than distract from them and is reported to be effective. It is argued that it is not whether we attend to pain sensations that impacts on brain processing so much as how we attend to them (Buhle & Wager, 2010) with the emphasis in mindfulness practices to resist evaluating the sensations, and merely notice that they are there.

Strengths and limitations

This study represented the first attempt to deliver guided self-help mindfulness to inpatients with painful gastrointestinal illness. Use of a small sample and multiple single case design and qualitative methods allowed in depth analysis of

each participant's experience. It also enabled data to be gathered about the challenges and barriers facing inpatients with gastrointestinal pain attempting to develop mindfulness skills. This is a chronically ill population with pain that faces unique challenges besides chronic pain, such as enteral feeding and associated frequent infections. The severity and complexity of the condition s many participants were experience meant that this population differed from the standard chronic pain samples recruited to most studies of psychological approaches to pain management which require attendance at outpatient appointments as a minimum. Most of the current population who experience repeated admissions to hospital would not be able to participate in research in outpatient settings.

The small sample used does not enable generalisation, nor modelling of the impact of external variables on the trajectories of pain distress, quality of life and confidence managing pain. Recruitment took place while participants were inpatients on specialist gastrointestinal wards, and throughout the period of study many had changes to medication, medical procedures, recurrent infections, and social changes that may have impacted on the results.

Recruitment of participants was difficult to achieve on the busy hospital wards. The recruitment procedure required nursing or medical staff to identify potential participants. Several potential participants commented that they had been in hospital for many weeks and would have found it useful to begin the mindfulness course sooner. Although recruitment discussions were held with nursing staff weekly, most 'referrals' were biased towards patients who were requesting high levels of opioid medication and were nearing discharge, and were therefore a concern for staff, while patients whose pain was well controlled by medication were less likely to be 'referred'.

Attrition accounted for a large proportion of the sample. This was anticipated as participants were unwell. Loss of participants reduced the total number of 'completers' below the eight originally intended for analysis. As already discussed, most research into chronic pain does not recruit from populations with multiple and complex pain presentations with repeated hospital stays. The high attrition rates in this study could be attributed to the severe and complex nature of the health problems participants were facing. Although it resulted in only a small number completing and provided end data for analysis, seven of the nine participants were interviewed and provided valuable data on feasibility.

Implications

Clinical. This study relates directly to clinical practice and several implications have emerged. This study emerged out of a comprehensive review of pain management methods at a major university teaching hospital and a working group is already in place to be able to take forward the findings from this study. A guided self-help mindfulness course was feasible and found to be useful and applicable to participants who completed the course, but requires further adaptations. This provides preliminary evidence that mindfulness should be developed further as an intervention for some inpatients with gastrointestinal pain, in addition to their medical care.

There are current debates about the degree to which extended practice with mindfulness is necessary for positive outcomes (Carmody & Baer, 2008, 2009; Vettese, Toneatto, Stea, Nguyen, & Wang, 2009). Given the challenges on time reported by participants and the near universal reports that the initial two meditations were the most useful and frequently used, it could be argued that development of a briefer version of the materials currently used would be of benefit.

Introducing brief mindfulness materials and guided meditations to inpatients may provide a time-efficient method of pain management for individuals. Many participants described difficulties fitting in practices at home alongside all the distractions of being unwell. This population often experience extended inpatient admissions and there are few opportunities for them to fill their time and manage their conditions. An audio 'podcast' introducing mindfulness and the bodyscan and breathing anchor meditations could be made accessible to patients via their bedside entertainment systems. Nursing/medical staff or peer support volunteers could raise awareness of these resources and be available to discuss their use with patients to help manage anxiety, prepare for procedures and educate patients about non-medical approaches to pain management that are available to them in the future if needed. Further evaluation is necessary to investigate the efficacy of this approach, and to establish cost-effectiveness. It would also need to be thought about carefully for which inpatients would benefit from being introduced to mindfulness and not merely presented as a panacea to all.

Use of relaxation tapes/resources is widespread in pain management settings and yet several participants who demonstrated improvements following the mindfulness course reported that previous attempts with other relaxation resources were unsuccessful. Specific elements of the mindfulness course that were described as helpful compared to standard relaxation was the addition of the book providing psychoeducational information about pain and providing an extended rationale for using mindfulness to aid living with pain. This step appeared to be important in building motivation to persist with the practices, something which is likely to be reduced if a patient is offered a relaxation CD without additional guidance. There is extensive support for the efficacy and effectiveness of guided self-help or 'minimal-

contact' interventions with chronic pain, chronic illness and IBS (Ahl, Mikocka-Walus, Gordon, & Andrews, 2013; Beatty & Lambert, 2013; Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Matcham et al., 2014) with outcomes comparative to therapist delivered interventions (Pajak, Lackner, & Kamboj, 2013). In addition the meditations were adapted for individuals in pain, one participant reported that she had always struggled with taking deep breaths when previously instructed to relax, but found the mindfulness instruction of observing breaths much easier to use and much more effective.

Another clinical implication emerging from this study is the high rate of attrition of participants being unable to begin/complete the course. In clinical use this could be reduced by developing a briefer version as discussed. It may also be the case that this will be most effective when patients are able to practise and develop the skills whilst on the ward for an extended period, and may be less useful if presented shortly before discharge.

Scientific. This study demonstrated the potential usefulness of guided self-help with inpatients with gastrointestinal pain but further research is needed due to the high rate of drop out in this study, and the positive findings relating to only four 'completers'. The next step would be to use this data to inform a larger study to confirm the present findings. It would be important for future expansions of this research to include a follow-up period of not less than six months to capture the effects of ongoing mindfulness practice. Previous studies of MBSR for IBS found that non-significant improvements in quality of life and gastro-specific anxiety reported at the end of the course became significantly improved after six months (Kearney et al., 2011). Further investigation of the importance of the frequency and duration of mindfulness practice would also be fruitful. As burden on time was

reported to be one of the particular challenges of this group in engaging with the course, reducing practice requirements could increase the acceptability of the programme.

The qualitative components of the current feasibility study were strongly influenced by the needs of the quantitative analysis and were restricted to evaluating the course. Following a larger trial of guided self-help mindfulness for patients with gastrointestinal pain, an exploratory and deductive qualitative investigation of individuals' experiences of using mindfulness, including over the longer term, would provide valuable information on how individuals assimilate ongoing mindfulness practice into their pain management regimes and what they ascribe the long term impact of mindfulness to be.

Conclusions

A guided self-help mindfulness course for inpatients with gastrointestinal pain and illness shows potential to reduce pain-related distress, improve quality of life and increase confidence in pain self-management following completion. Despite significant challenges and barriers to participation for this patient group, those who were able to complete the course reported an overall positive experience, increases in relaxation and decreases in pain-related anxiety. Pain distress ratings reduced for all participants who completed the course and for some pain intensity also reduced. Clinical implications include developing a briefer version of the course to provide on patient bedside entertainment systems for general use by a wider group of patients. This feasibility study provides proof of concept for further RCTs in this area to enable greater generalisations and exploration of causal mechanisms.

References

Ahl, A., Mikocka-Walus, A., Gordon, A., & Andrews, J. M. (2013). Are self-administered or minimal therapist contact psychotherapies an effective treatment for irritable bowel syndrome (IBS): A systematic review. *Journal of Psychosomatic Research*, *75*(2), 113–120. doi:10.1016/j.jpsychores.2013.04.008

Altschuler, A., Rosenbaum, E., Gordon, P., Canales, S., & Avins, A. L. (2012). Audio recordings of mindfulness-based stress reduction training to improve cancer patients' mood and quality of life--a pilot feasibility study. *Supportive Care in Cancer*, *20*(6), 1291–1297. doi:10.1007/s00520-011-1216-7

Apkarian, V. A., Hashmi, J. A., & Baliki, M. N. (2011). Pain and the brain: Specificity and plasticity of the brain in clinical chronic pain. *Pain*, *152*(SUPPL.3), S49–S64. doi:10.1016/j.pain.2010.11.010

Aucoin, M., Lalonde-Parsi, M., & Cooley, K. (2014). Mindfulness-based therapies in the treatment of functional gastrointestinal disorders: A meta-analysis. *Evidence-Based Complementary and Alternative Medicine*, *2014*(140724), 1–11. doi:10.1155/2014/140724

Baer, R. A. (2003). Mindfulness training as a clinical intervention: A conceptual and empirical review. *Clinical Psychology: Science and Practice*, *10*(2), 125–143. doi:10.1093/clipsy.bpg015

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment*, *13*(1), 27–45. doi:10.1177/1073191105283504

Baer, R. A., Smith, G. T., Lykins, E., Button, D., Krietemeyer, J., Sauer, S., … Williams, J. M. G. (2008). Construct validity of the five facet mindfulness questionnaire in meditating and nonmeditating samples. *Assessment*, *15*(3), 329–342. doi:10.1177/1073191107313003

Bair, M. J., Matthias, M. S., Nyland, K. A., Huffman, M. A., Stubbs, D. L., Kroenke, K., & Damush, T. M. (2009). Barriers and facilitators to chronic pain self-management: A qualitative study of primary care patients with comorbid musculoskeletal pain and depression. *Pain Medicine*, *10*(7), 1280–1290. doi:10.1111/j.1526-4637.2009.00707.x

Bair, M. J., Robinson, R. L., Katon, W., & Kroenke, K. (2003). Depression and pain comorbidity. *Archives of International Medicine*, *163*, 2433–2445. doi:10.1097/ALN.0b013e31822ec185

Barker, C., Pistrang, N., & Elliott, R. (2002). *Research methods in clinical psychology: An introduction for students and practitioners*.

Beatty, L., & Lambert, S. (2013). A systematic review of internet- based self- help therapeutic interventions to improve distress and disease- control among adults

with chronic health conditions. *Clinical Psychology Review, 33*, 609– 622. doi:10.1016/j.cpr.2013.03.004

Bender, J. L., Radhakrishnan, A., Diorio, C., Englesakis, M., & Jadad, A. R. (2011). Can pain be managed through the Internet? A systematic review of randomized controlled trials. *Pain, 152*(8), 1740–1750. doi:10.1016/j.pain.2011.02.012

Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale: An updated literature review. *Journal of Psychosomatic Research*, *52*(2), 69–77. doi:10.1016/S0022-3999(01)00296-3

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. doi:10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2012). Thematic analysis. In H. (Ed); Cooper, P. M. (Ed); Camic, D. L. (Ed); Long, A. T. (Ed); Panter, D. (Ed); Rindskopf, & K. J. (Ed) Sher (Eds.), *APA handbook of research methods in psychology, Vol 2: Research designs: Quantitative, qualitative, neuropsychological, and biological.* (Vol. 2, pp. 57–71). Washington DC: American Psychological Association. doi:10.1037/13620-004

Brodersen, K. H., Wiech, K., Lomakina, E. I., Lin, C. S., Buhmann, J. M., Bingel, U., … Tracey, I. (2012). Decoding the perception of pain from fMRI using multivariate pattern analysis. *NeuroImage*, *63*(3), 1162–1170. doi:10.1016/j.neuroimage.2012.08.035

Brown, C. A., & Jones, A. K. P. (2010). Meditation experience predicts less negative appraisal of pain: electrophysiological evidence for the involvement of anticipatory neural responses. *Pain*, *150*(3), 428–438. doi:10.1016/j.pain.2010.04.017

Brown, C. A., & Jones, A. K. P. (2013). Psychobiological correlates of improved mental health in patients with musculoskeletal pain after a mindfulness-based pain management program. *The Clinical Journal of Pain*, *29*(3), 233–244. doi:10.1097/AJP.0b013e31824c5d9f

Brown, J. E., Chatterjee, N., Younger, J., & Mackey, S. (2011). Towards a physiology-based measure of pain: Patterns of human brain activity distinguish painful from non-painful thermal stimulation. *PLoS ONE*, *6*(9), 2–9. doi:10.1371/journal.pone.0024124

Brown, K. W., & Ryan, R. M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology*, *84*(4), 822–848. doi:10.1037/0022-3514.84.4.822

Buhle, J. T., Stevens, B. L., Friedman, J. J., & Wager, T. D. (2012). Distraction and placebo: Two separate routes to pain control. *Psychological Science*, *23*(3), 246–253. doi:10.1177/0956797611427919

Buhle, J. T., & Wager, T. D. (2010). Does meditation training lead to enduring changes in the anticipation and experience of pain? *Pain*, *150*(3), 382–383. doi:10.1016/j.pain.2010.05.004

Burch, V., & Penman, D. (2013). *Mindfulness for health: A practical guide to relieving pain, reducing stress and restoring wellbeing.* London, England: Piatkus.

Burnett, C.K., & Drossman, D. A. (2004). Irritable bowel syndrome and other functional gastrointestinal disorders. In L. J. Haas (Ed.), *Handbook of primary care psychology* (pp. 411–424). New York, NY: Oxford University Press.

Carmody, J., & Baer, R. A. (2008). Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of Behavioral Medicine*, *31*(1), 23–33. doi:10.1007/s10865-007-9130-7

Carmody, J., & Baer, R. A. (2009). How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *Journal of Clinical Psychology*, *65*(6), 627–638. doi:10.1002/jclp.20555

Chiesa, A., & Serretti, A. (2011). Mindfulness-based interventions for chronic pain: A systematic review of the evidence. *Journal of Alternative and Complementary Medicine*, *17*(1), 83–93. doi:10.1089/acm.2009.0546

Cosco, T. D., Doyle, F., Ward, M., & McGee, H. (2012). Latent structure of the Hospital Anxiety And Depression Scale: A 10-year systematic review. *Journal of Psychosomatic Research*, *72*(3), 180–184. doi:10.1016/j.jpsychores.2011.06.008

Crombez, G., Eccleston, C., Van Damme, S., Vlaeyen, J. W., & Karoly, P. (2012). Fear-avoidance model of chronic pain: The next generation. *Clinical Journal of Pain*, *28*(6), 475–483. doi:10.1097/AJP.0b013e3182385392

Cusens, B., Duggan, G. B., Thorne, K., & Burch, V. (2010). Evaluation of the Breathworks pain management programme : Effects on well-being and multiple measures of mindfulness. *Clinical Psychology and Psychotherapy*, *17*, 63–78. doi:10.1002/cpp.653

Delmar, C., Bøje, T., Dylmer, D., Forup, L., Jakobsen, C., Majbritt, M., … Pedersen, B. D. (2005). Achieving harmony with oneself : Life with a chronic illness. *Scandinavian Journal of Caring Sciences*, *19*, 204–212. doi:10.1111/j.1471-6712.2005.00334.x

Drossman, D. A., Creed, F. H., Olden, K. W., Svedlund, J., Toner, B. B., & Whitehead, W. E. (1999). Psychosocial aspects of the functional gastrointestinal disorders. *Gut*, *45*(Supplement 2), ii25–ii30. doi:10.1136/gut.45.2008.ii25

Dworkin, R. H., Turk, D. C., Farrar, J. T., Haythornthwaite, J. A., Jensen, M. P., Katz, N. P., … Witter, J. (2005). Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*, *113*(1-2), 9–19. doi:10.1016/j.pain.2004.09.012

Eccleston, C., & Crombez, G. (1999). Pain demands attention: A cognitive-affective model of the interruptive function of pain. *Psychological Bulletin*, *125*(3), 356–366. doi:10.1037/0033-2909.125.3.356

Eccleston, C., Williams, A. C. de C., & Stainton Rogers, W. (1997). Patients' and professionals' understandings of the casues of chronic pain: Blame, responsibility and identity protection. *Social Sciences and Medicine*, *45*(5), 699–709. doi:10.1016/S0277-9536(96)00404-2

Elliott, R., Slatick, E., & Urman, M. (2001). Qualitative change process research on psychotherapy: Alternative strategies. In J. Frommer & D. L. Rennie (Eds.), *Qualitative psychotherapy research - methods and methodology* (pp. 69 – 111). Lengerich, Germany: Pabst.

Foucault, M. (1963). *The birth of the clinic: An archeology of medical perception*. London, England: Tavistock.

Gatchel, R. J. (2005). *Clinical essentials of pain management*. Washington DC: American Psychological Association.

Gatchel, R. J., Peng, Y. B., Peters, M. L., Fuchs, P. N., & Turk, D. C. (2007). The biopsychosocial approach to chronic pain: Scientific advances and future directions. *Psychological Bulletin*, *133*(4), 581–624. doi:10.1037/0033-2909.133.4.581

Gaylord, S. A., Palsson, O. S., Garland, E. L., Faurot, K. R., Coble, R. S., Mann, J. D., … Whitehead, W. E. (2011). Mindfulness training reduces the severity of irritable bowel syndrome in women: Results of a randomized controlled trial. *The American Journal of Gastroenterology*, *106*(9), 1678–1688. doi:10.1038/ajg.2011.184

Geiser, D. S. (1992). *A comparison of acceptance-focussed and control-focussed psychological treatments in a chronic pain treatment center (Unpublished doctoral dissertation)*. University of Nevada, Reno.

Grossman, P., Kappos, L., Gensicke, H., D'Souza, M., Mohr, D. C., Penner, I. K., & Steiner, C. (2010). MS quality of life, depression, and fatigue improve after mindfulness training: A randomized trial. *Neurology*, *75*(13), 1141–1149. doi:10.1212/WNL.0b013e3181f4d80d

Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits. A meta-analysis. *Journal of Psychosomatic Research*, *57*(1), 35–43. doi:10.1016/S0022-3999(03)00573-7

Grossman, P., Tiefenthaler-Gilmer, U., Raysz, A., & Kesper, U. (2007). Mindfulness training as an intervention for fibromyalgia: Evidence of postintervention and 3-year follow-up benefits in well-being. *Psychotherapy and Psychosomatics*, *76*(4), 226–233. doi:10.1159/000101501

Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, *59*(1), 12–19. doi:10.1037/0022-006X.59.1.12

Jensen, M. P., Karoly, P., & Braver, S. (1986). The measurement of clinical pain intensity: A comparison of six methods. *Pain*, *27*(1), 117–126. doi:10.1016/0304-3959(86)90228-9

Jensen, M. P., Karoly, P., O'Riordan, E. F., Bland, F., & Burns, R. S. (1989). The subjective experience of acute pain: An assessment of the utility of 10 indices. *The Clinical Journal of Pain*, *5*(2), 153–159. doi:10.1097/00002508-198906000-00005

Joffe, H. (2012). Thematic analysis. In D. Harper & A. R. Thompson (Eds.), *Qualitative research methods in mental health and psychotherapy: A guide for students and practitioners* (pp. 209–223). Chichester, England: John Wiley & Sons, Ltd. doi:10.1002/9781119973249.ch15

Kabat-Zinn, J. (1990). *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain and illness*. New York, NY: Dell Publishing.

Kabat-Zinn, J., Lipworth, L., & Burney, R. (1985). The clinical use of mindfulness meditation for the self-regulation of chronic pain. *Journal of Behavioral Medicine*, *8*(2), 163–190. doi:10.1007/BF00845519

Kabat-Zinn, J., Lipworth, L., Burney, R., & Sellers, W. (1986). Four-year follow-up of a meditation-based program for the self-regulation of chronic pain: Treatment outcomes and compliance. *The Clinical Journal of Pain*, *2*(3), 159–174. doi:00002508-198602030-00004

Kearney, D. J., McDermott, K., Martinez, M., & Simpson, T. L. (2011). Association of participation in a mindfulness programme with bowel symptoms, gastrointestinal symptom-specific anxiety and quality of life. *Alimentary Pharmacology and Therapeutics*, *34*(3), 363–373. doi:10.1111/j.1365-2036.2011.04731.x

Keefe, F. J., Rumble, M. E., Scipio, C. D., Giordano, L. A., & Perri, L. M. (2004). Psychological aspects of persistent pain: Current state of the science. *The Journal of Pain*, *5*(4), 195–211. doi:10.1016/j.jpain.2004.02.576

Lakhan, S. E., & Schofield, K. L. (2013). Mindfulness-based therapies in the treatment of somatization disorders: A systematic review and meta-analysis. *PloS One*, *8*(8), 1–13. doi:10.1371/journal.pone.0071834

Leech, N. L., & Onwuegbuzie, A. J. (2009). A typology of mixed methods research designs. *Quality and Quantity*, *43*(2), 265–275. doi:10.1007/s11135-007-9105-3

Lester, L. S., & Fanselow, M. S. (1985). Exposure to cat produces opioid analgesia in rats. *Behavioral Neuroscience*, *99*(4), 756–759. doi:10.1037//0735-7044.99.4.756

Linton, S. J., & Shaw, W. S. (2011). Impact of psychological factors in the experience of pain. *Physical Therapy*, *91*(5), 700–711. doi:10.2522/ptj.20100330

Madill, A., Jordan, A., & Shirley, C. (2000). Objectivity and reliability in qualitative analysis: Realist, contextualist and radical constructionist epistomologies. *British Journal of Psychology*, *91*, 1–20. doi:10.1348/000712600161646

Matcham, F., Rayner, L., Hutton, J., Monk, a., Steel, C., & Hotopf, M. (2014). Self-help interventions for symptoms of depression, anxiety and psychological distress in patients with physical illnesses: A systematic review and meta-analysis. *Clinical Psychology Review*, *34*(2), 141–157. doi:10.1016/j.cpr.2014.01.005

Mayer, E. A., & Tillisch, K. (2011). The brain-gut axis in abdominal pain syndromes. *Annual Review of Medicine*, *62*, 381–396. doi:10.1146/annurev-med-012309-103958

McCracken, L. M., Vowles, K. E., & Eccleston, C. (2004). Acceptance of chronic pain: Component analysis and a revised assessment method. *Pain*, *107*, 159–166. doi:10.1016/j.pain.2003.10.012

McWilliams, L. A., Cox, B. J., & Enns, M. W. (2003). Mood and anxiety disorders associated with chronic pain: An examination in a nationally representative sample. *Pain*, *106*, 127–133. doi:10.1016/S0304-3959(03)00301-4

Melzack, R., & Wall, P. (1965). Pain mechanisms: A new theory. *Science*, *150*, 971–979.

Merskey, H., Albe-Fessard, D. G., Bonica, J. J., Carmon, A., Dubner, R., Kerr, F. W. L., … Sunderland, S. (1979). Pain terms: A list with definitions and notes on usage. *Pain*, *6*(3), 249–252. doi:10.1016/0304-3959(79)90046-0

Miller, L. R., & Cano, A. (2009). Comorbid chronic pain and depression: Who is at risk? *Journal of Pain*, *10*(6), 619–627. doi:10.1016/j.jpain.2008.12.007

Morley, S., & Adams, M. (1991). Graphical analysis of single-case time series data. *The British Journal of Clinical Psychology*, *30*, 97–115. doi:10.1111/j.2044-8260.1991.tb00926.x

Morley, S., & Dowzer, C. N. (2014). Manual for the Leeds reliable change indicator: Simple Excel applications for the analysis of individual patient and group data.

Leeds, England: University of Leeds. Retrieved from http://www.leeds.ac.uk/lihs/psychiatry/dclin/rcic.html

Morley, S., Williams, A. C. de C., & Hussain, S. (2008). Estimating the clinical effectiveness of cognitive behavioural therapy in the clinic: Evaluation of a CBT informed pain management programme. *Pain*, *137*(3), 670–680. doi:10.1016/j.pain.2008.02.025

Morone, N. E., Lynch, C. S., Greco, C. M., Tindle, H. A., & Weiner, D. K. (2008). "I felt like a new person." The effects of mindfulness meditation on older adults with chronic pain: Qualitative narrative analysis of diary entries. *The Journal of Pain*, *9*(9), 841–848. doi:10.1016/j.jpain.2008.04.003

Nicholas, M. K. (1989). Self-efficacy and chronic pain. In *Annual Conference of the British Psychological Society*. St. Andrews, Scotland.

Nicholas, M. K. (2007). The pain self-efficacy questionnaire: Taking pain into account. *European Journal of Pain*, *11*(2), 153–163. doi:10.1016/j.ejpain.2005.12.008

Nicholas, M. K., & Asghari, A. (2006). Investigating acceptance in adjustment to chronic pain: Is acceptance broader than we thought? *Pain*, *124*(3), 269–279. doi:10.1016/j.pain.2006.04.032

Pajak, R., Lackner, J., & Kamboj, S. K. (2013). A systematic review of minimal-contact psychological treatments for symptom management in irritable bowel syndrome. *Journal of Psychosomatic Research*, *75*(2), 103–112. doi:10.1016/j.jpsychores.2013.05.007

Pistrang, N., & Barker, C. (2012). Varieties of qualitative research: A pragmatic approach to selecting methods. In H. (Ed); Cooper, P. M. (Ed); Camic, D. L. (Ed); Long, A. T. (Ed); Panter, D. (Ed); Rindskopf, & K. J. (Ed) Sher (Eds.), *APA handbook of research methods in psychology, Vol 2: Research designs: Quantitative, qualitative, neuropsychological, and biological.* (Vol. 2, pp. 5–18). Washington DC: American Psychological Association. doi:10.1037/13620-001

Ploghaus, A., Narain, C., Beckmann, C. F., Clare, S., Bantick, S., Wise, R., … Tracey, I. (2001). Exacerbation of pain by anxiety is associated with activity in a hippocampal network. *The Journal of Neuroscience*, *21*(24), 9896–9903. doi:21/24/9896 [pii]

Price, D. D., Patel, R., Robinson, M. E., & Staud, R. (2008). Characteristics of electronic visual analogue and numerical scales for ratings of experimental pain in healthy subjects and fibromyalgia patients. *Pain*, *140*(1), 158–166. doi:10.1016/j.pain.2008.07.028

Reiner, K., Tibi, L., & Lipsitz, J. D. (2013). Do mindfulness-based interventions reduce pain intensity? A critical review of the literature. *Pain Medicine*, *14*(2), 230–242. doi:10.1111/pme.12006

Schütze, R., Rees, C., Preece, M., & Schütze, M. (2010). Low mindfulness predicts pain catastrophizing in a fear-avoidance model of chronic pain. *Pain*, *148*(1), 120–127. doi:10.1016/j.pain.2009.10.030

Segal, Z. L., Williams, J. M. G., & Teasdale, J. D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. New York, NY: Guildford Publications.

Sephton, S. E., Salmon, P., Weissbecker, I., Ulmer, C., Floyd, A., Hoover, K., & Studts, J. L. (2007). Mindfulness meditation alleviates depressive symptoms in women with fibromyalgia: Results of a randomized clinical trial. *Arthritis and Rheumatism*, *57*(1), 77–85. doi:10.1002/art.22478

The Heath and Social Care Information Centre. (2012). Health Survey for England 2011, Chapter 9: Chronic Pain. Retrieved from http://www.hscic.gov.uk/catalogue/PUB09300

Turk, D. C. (2002). Clinical effectiveness and cost-effectiveness of treatments for patients with chronic pain. *The Clinical Journal of Pain*, *18*, 355–365. doi:10.1097/00002508-200211000-00003

Turk, D. C., & Gatchel, R. J. (Eds.). (2002). *Psychological approaches to pain management: A practitioner's handbook* (2nd ed.). New York, NY: Guilford.

Turk, D. C., & Okifuji, A. (2001). Pain terms and taxonomies. In D. Loeser, S. H. Butler, & J. J. Chapman (Eds.), *Bonica's pain management* (3rd ed., pp. 17–25). Philadelphia, PA: Lippincott Williams & Wilkins.

Vettese, L. C., Toneatto, T., Stea, J. N., Nguyen, L., & Wang, J. J. (2009). Do mindfulness meditation participants do their homework? And does it make a difference? A review of the empirical evidence. *Journal of Cognitive Psychotherapy*, *23*(3), 198–225. doi:10.1891/0889-8391.23.3.198

Williams, A. C. de C., Eccleston, C., & Morley, S. (2012). Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database of Systematic Reviews*, *2012*(11). doi:10.1002/14651858.CD007407.pub3.

Willig, C. (2013). *Introducing qualitative research in psychology* (3rd ed.). Maidenhead, England: Open University Press.

Zautra, A. J., Johnson, L. M., & Davis, M. C. (2005). Positive affect as a source of resilience for women in chronic pain. *Journal of Consulting and Clinical Psychology*, *73*(2), 212–220. doi:10.1037/0022-006X.73.2.212

Zeidan, F., Martucci, K. T., Kraft, R. A., Gordon, N. S., McHaffie, J. G., & Coghill, R. C. (2011). Brain mechanisms supporting the modulation of pain by mindfulness meditation. *The Journal of Neuroscience*, *31*(14), 5540–5548. doi:10.1523/JNEUROSCI.5791-10.2011

Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica, 67*(6), 361–370. doi:10.1111/j.1600-0447.1983.tb09716.x

Part 3: Critical Appraisal

Critical appraisal

Previous experiences

Prior to embarking on clinical training, my previous experience and personal interests oriented me towards health psychology. My choice to study psychology as an undergraduate was influenced by the appeal that as an area of enquiry, psychology employed both reductionist, evidence based scientific methods similar to medical sciences, as well as interpretative higher level understandings of the human condition and contextual influences. Within health psychology, I found the interface between medical sciences of disease process, and social sciences of what it is to be human, a fascinating area of study. Clinical psychologists, as scientists schooled in both disciplines, are well placed to be able to bring together methods from both perspectives. It was within this context that I sought to conduct my major research project within health psychology and which influenced my choice of mixed methodology.

Choice of approach (mixed methods)

Choosing a mixed methods approach was primarily led by the research questions but also fit with my epistemological stance which I would describe as critical realist. Similar to my view of the strengths of psychology in drawing on both quantitative and qualitative traditions, I believe that research in psychology should produce data that both brings us closer to the reality of the human brain and behaviour, but that also recognises that we are restricted in our understanding of that reality as it is perceived and interpreted through our own brains and behaviour.

Challenges on wards

When choosing this topic of research I was aware from the outset that conducting research in a busy inpatient hospital environment would mean that I

would be working with the whole staff team in an indirect way, even though the focus of my research questions was with patients. With knowledge of both my personal experience working as a healthcare assistant on an inpatient ward, and of psychological theories of systems and group dynamics, I was aware that I would need to present myself as non-threatening and non-blaming towards the staff teams, especially as I was reliant on their support to identify potential participants. I drew on systemic models of increasing levels of context influencing individuals' experience. For example, each nurse on the ward would have her/his own personal beliefs, attitudes and experiences towards pain management. This would also be influenced by the beliefs, attitudes and experiences of their immediate contexts. This in turn would be influenced by the context of the whole hospital (which at this time had embarked on improving pain management for its inpatients including rolling out educational programmes for nurses), which in turn would be influenced by the wider societal context of increasing demands and expectations on nurses, despite reduced resources.

My experience on the ward mainly consisted of interactions with the nursing staff rather than other health professionals as they were the 'gatekeepers' to potential participants and kindly supported my research. I quickly learnt which staff were interested and intrigued by the research, saw its potential for patient and staff benefit, and were willing to identify possible participants. There were also staff who appeared less interested or dismissive of the research or viewed my request for participants as 'one more thing' they were expected to do on top of an already large list of demands on their time. It could be easy at times to slip into a position of judging these staff members as wanting to avoid work or enjoying the power they had over me (when in most of their work the power was viewed as being held by the

doctors). However, when viewed in the context of the many layers of pressures and expectations they were under, their reactions were much more understandable.

Recruitment challenges

This research project took place in the context of a hospital trust who were committed to improving the experiences of patients with pain whilst in hospital and had set up a working group to assess the situation and implement solutions. The gastrointestinal failure wards were identified as an area where a lot of patients had significant levels of pain, often difficult to manage pharmacologically. When invited to propose a research project within these wards we expected to have few difficulties recruiting patients. Staff reported that across the 90 beds on the two wards, many patients had extended hospital stays and there would be little issue in recruiting the desired eight participants and implement the eight week intervention.

Following eight months of recruitment, 15 participants had consented to take part but by the end of data collection only four had completed the intervention and only one of these had been an inpatient for the whole programme. This resulted in a change of focus of parts of the research project, particularly the qualitative component. The original intention had been to gather data on participants experiences of the mindfulness intervention following completion and analyse for common themes. As only four participants could provide this data, the focus of the qualitative analysis was widened to include the experiences of participants who had been unable to complete the programme, and to analyse the common themes that arose in relation to this.

As is often the case when conducting research, it can be disappointing when your data collection does not match up to your hopes. In this case however, the necessary change provided rich and interesting data about the barriers and challenges

participants faced when trying to complete the course. Before conducting the research I had underestimated difficulties this population faced. I had known intellectually but had not appreciated the full impact this would have. Through conducting the research I was able to gather a much richer understanding.

Dual roles and tension in research

The process of completing the doctoral training in clinical psychology is one of inhabiting dual roles; the clinician and the researcher. Whilst being an avid consumer of research in clinical psychology, prior to training I envisaged myself primarily as a clinician rather than a researcher. This was mainly due to an assumption that research is something that is done 'at a distance' from those it concerns; that research is done 'to' clients whereas therapy is done 'with' clients. Using a single-case design for my research allowed me to challenge my assumptions and experience; conducting research much closer to current clinical health psychology practice.

Although a single case design and qualitative analysis allowed me to inhabit the role of a researcher quite similar to my working preferences as a clinician, I still found there was an inherent tension between the two roles at times. In certain circumstances the skills of an objective researcher were more important. This was evident when conducting the semi-structured interviews and reminding myself to take a curious, not-knowing stance and not feel the need to 'jump in' and support the participant. Many participants' descriptions of their pain and the impact it had on their lives was highly emotive and the skills of a clinician were important to be able to hear the emotive content, manage the emotions it arose in myself, and respond to the emotions that arose for the participant in a respectful and validating way. I found that I had to be constantly aware of balancing the need to be empathic towards the

participants and respond in an ethical way to their distress, as well as trying not to lead the participant to describe their experiences in the ways I was making sense of them. To manage this tension I maintained a reflective component to my research diary and thought about how I managed similar situations in my clinical work.

I found it helpful to think of the research interviews as similar to clinical assessment sessions. In an assessment I would both aim to facilitate a good therapeutic alliance, by sensitively responding to clients' distress and experiences, whilst also aiming to gather data. I would try to hold several different hypotheses in mind at once, asking clarifying questions and checking with clients on their understanding not to impose my own assumptions. I also sought peer supervision with other trainees who experienced similar tensions between their two roles and shared ideas of how best to manage.

Impact of the researcher on the research

When conducting the qualitative aspects of this research project, I was aware that it is not possible for a researcher to be entirely objective and my interpretations of the data will necessarily be influenced by my own contexts, thoughts and assumptions. However, it was only on reflecting on the research as a whole that I considered the impact that my own contexts, thoughts and assumptions may have had on the raw data generated even before it was analysed and interpreted. When I listened to audio recordings of the interviews and re-read the transcripts I noticed the highly personal and emotive accounts many participants gave of their experience of living with chronic pain and experience of a mindfulness intervention. At the time I had not thought this unusual as my previous interactions with patients in health psychology settings as a clinician had been very similar. However, on reflection, I wondered whether patients had been able to give such personal accounts because I

was a psychologist, and whether they would have given different accounts had the research been conducted by a doctor or nurse.

Impact of the research on the researcher

My assumptions prior to clinical training were that clinical and research roles were very distinct and that by focussing time on conducting research, one had to sacrifice time spent in clinical roles. What this research project has taught me is that there are several ways in which the role of researcher can be complementary to the role of a clinician, whilst still producing valuable data. This knowledge was mostly gained from my experience of using a single case design. By having a small number of participants, I was able to personally deliver the intervention in every case and chart their progress throughout. At the analysis stage I was also able to stay with the richness and idiosyncratic nature of each participant's data, whereas this would not have been possible with larger scale group level analyses. I found that single case design research is compatible with ongoing clinical work and hope to continue conducting this type of research once qualified; something I had never previously anticipated.

Conclusions

Before completing this research project I already knew that I wanted to focus on the area of clinical health psychology once qualified. I had not expected to also want to continue conducting research in this area. The challenge of high levels of attrition provided an alternative focus for parts of the qualitative analysis which I believe adds to the richness and usefulness of the data. I look forward to facing more of these challenges in the future.

Appendix 1: Ethical approval letter

NHS
Health Research Authority

NRES Committee London - City Road & Hampstead
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421339

01 July 2014

Ms Amanda C de C Williams
Reader in Clinical Health Psychology
University College London
Research Dept of Clinical, Educational & Health Psychology
University College London
WC1E 7HB

Dear Ms Williams

Study title:	**Exploratory study of mindfulness for in patients with chronic gastrointestinal pain: does it reduce pain related distress and increase confidence in pain self-management?**
REC reference:	**14/LO/0683**
Protocol number:	**N/A**
IRAS project ID:	**145220**

Thank you for your letter of 20 June 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Tina Cavaliere, nrescommittee.london-cityroadandhampstead@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

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

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. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the 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).

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 completed 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. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper		17 June 2014
Covering letter on headed paper		04 April 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		26 July 2014
GP/consultant information sheets or letters	1	17 June 2014
Non-validated questionnaire [FFMQ]	1	04 April 2014
Non-validated questionnaire [CPAQ]	1	04 April 2014
Other [Student Rebecca Ellis CV]		04 April 2014
Other [Interview Schedule Start]	1	04 April 2014
Other [Email - Insurance Confirmed]		09 April 2014
Other [Interview Schedule End]	1	04 April 2014
Other [Gareth Drake CV]		04 April 2014
Participant consent form	2	17 June 2014
Participant information sheet (PIS)	2	17 June 2014
REC Application Form	145220/592	04 April 2014
Referee's report or other scientific critique report		09 October 2013
Research protocol or project proposal	1	04 April 2014
Summary CV for Chief Investigator (CI)		04 April 2014
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	1	04 April 2014
Validated questionnaire [Weekly Feedback]	1	04 April 2014
Validated questionnaire [HADS]	1	04 April 2014
Validated questionnaire [PSEQ]	1	04 April 2014

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.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/LO/0683	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Pp Mr Hari Jayaram
Vice Chair

Email:nrescommittee.london-cityroadandhampstead@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Suzanne Emerton*
jrostudentresearch@ucl.ac.uk

Appendix 2: Weekly feedback questionnaire

Weekly Feedback

How intense was the pain on average over the last week?

No pain Extreme pain

0 1 2 3 4 5 6 7 8 9 10

How distressing was the pain on average over the last week?

Not distressing at all Extremely distressing

0 1 2 3 4 5 6 7 8 9 10

This week, how has the pain made you feel emotionally?

……
……
……
……
……
……
……

How many times have you used mindfulness this week?

0 1 2 3 4 5 6 7 8 9 10+

For how long on average each time? ……..minutes

What went well?

……
……
……
……
……

What didn't go well?

……
……
……
……
……

Appendix 3: Pre-intervention interview schedule

Interview Schedule Start

How would you describe your pain?

How long have you been in pain?

Is there an explanation or a diagnosis the doctors have suggested for the cause of the pain?

How do you relate to your pain?

Has your relationship to the pain changed over time?

Do you ever visualise your pain? If you did what would it look like? (size, colour, shape etc.)

What would be your hopes for the mindfulness course?

Appendix 4: Post-intervention interview schedule

Interview Schedule End

What was your experience of using the mindfulness exercises?

What did you like/what was helpful about the mindfulness exercises?

Was there anything you didn't like/wasn't helpful about the mindfulness exercises?

What did you like/what was helpful about the reading?

Was there anything you didn't like/wasn't helpful about the reading?

How are you doing now? What changes, if any, have you noticed in yourself since starting the mindfulness?

In general, what do you attribute these changes to? What do you think might have brought them about? (both from mindfulness or outside)

Was there anything missing from the mindfulness course?

Were there any ways in which you adapted/changed the course?

What has it been like for you to be involved in this research?

Do you have any suggestions for us, regarding the research or the mindfulness itself?

Appendix 5: Drop-out/non-starter interview schedule

Interview Schedule non-starter/drop-out

What were the main reasons for you wanting to start doing the mindfulness course?

What were the main reasons for you not to be able to start/finish?

Which things got in the way?

How could the course be changed/adapted that would have made it easier/more suitable?

Would there be a better time/what would need to be different in the future for it to be possible for you to do the mindfulness course?

Appendix 6: t-tests of demographic variables comparing participants who did not start/dropped out and participants that continued with the course

Group Statistics

	CompletionStatus	N	Mean	Std. Deviation	Std. Error Mean
BaselineHADScomposite	Completer/incomplete	6	16.50	6.921	2.825
	Non-starter/dropout	9	22.56	10.584	3.528
BaselinePSEQ	Completer/incomplete	6	19.83	11.583	4.729
	Non-starter/dropout	9	17.44	14.046	4.682
BaselineFFMQtotal	Completer/incomplete	6	120.00	17.754	7.248
	Non-starter/dropout	9	117.56	26.857	8.952
BaselineCPAQtotal	Completer/incomplete	6	47.33	20.373	8.317
	Non-starter/dropout	9	38.22	22.438	7.479
Baselinepainintensity	Completer/incomplete	6	6.50	3.450	1.408
	Non-starter/dropout	9	7.50	1.118	.373
Baselinepaindistress	Completer/incomplete	6	5.83	3.251	1.327
	Non-starter/dropout	9	6.83	2.424	.808

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
BaselineHADScomposite	Equal variances assumed	.820	.382	-1.229	13	**.241**
	Equal variances not assumed			-1.340	12.998	**.203**
BaselinePSEQ	Equal variances assumed	.570	.464	.345	13	**.736**
	Equal variances not assumed			.359	12.250	**.726**
BaselineFFMQtotal	Equal variances assumed	.740	.405	.195	13	**.848**
	Equal variances not assumed			.212	12.993	**.835**
BaselineCPAQtotal	Equal variances assumed	.042	.841	.798	13	**.439**
	Equal variances not assumed			.815	11.611	**.432**
Baselinepainintensity	Equal variances assumed	3.285	.093	-.821	13	**.427**
	Equal variances not assumed			-.686	5.707	**.519**
Baselinepaindistress	Equal variances assumed	.009	.927	-.685	13	**.506**
	Equal variances not assumed			-.644	8.651	**.536**

Appendix 7:

P4 End interview

What was your experience of using the mindfulness exercise over the last nine weeks?

Umm, overall a very positive one. I came in being quite sceptical because my mum is very very very into mindfulness and she'd gone she'd gone from being, beforehand if I'd had any negative emotions then she'd be talking me through whereas when she started mindfulness she started "oh well just let it go it's not important" which I felt was dismissive, but now I know what she means because you learn what, well, you don't let go of them, um, but you, relearn and resort them if that makes sense? So the really really negative ones, um, you, they you learn to dull, dull their edge so they're not so sharp and painful, they're still obviously still painful but they're not sharp and don't stay there for long periods of time, yeh

Outcome-positive experience

Hopes-low expectations

Outcome-reduced negative emotions

So overall very good one? So what did you like about the mindfulness exercises?

Um, I liked that they were simple, easy to remember so you didn't have to keep the referring to the book. I found one confusing that may have been because that week I'd had a general anaesthetic [laughs]

Positive-straightforward

Negative- confusing

Which week was that? Do you remember which?

That was umm, I can't remember which week but I remember it was the open heart one and still now, I think that was week 5, it was either week five or week six, round about that area, um and I just found it and still do find it confusing, I don't understand it, um but all the others I really enjoyed especially the first two, especially the first two, so the bodyscan and the um eh breathing anchor

Positive- body scan

Positive- breathing anchor

Yeh, and what is it about those two that you preferred to the others?

They're really really really simple ones that you can even when you're in absolute agony and when you are in that kind of place, literally it sounds strange but other, but when I've talked about this with other people who are ill, are in the same kind of experience they find that the world just goes, it kind of loses all its colour, it's as if your non essential organs and things, kind of not shut down, but you don't notice them anymore, so the world loses its colour and becomes darker and dimmer, I mean kind of visually as well as emotionally, um so when you're in that kind of pain where there isn't, you literally don't, it's so overwhelming that it seeped into absolutely everything, it can be or is, that can be but is, very difficult to be able to draw out a meditation or anything at all that isn't related to how much pain you're in. So those two are so simple, and are so basic, you can um, you can use them, and you can draw on them even when you're right down in the darkest depths of being in pain

Positive-straightforward

Positive- can be used in pain

Yeh

Then they're just there and can snap into action whereas the others you have to, at least for the moment, this might be because I haven't done them for everyday for eight weeks, so I might find that they take on the same qualities as, but those two in particular I can rely on to switch in automatically when I start doing them almost without realising, if that makes sense?

Usefulness- when pain is bad

Appendix 8: Patient information sheet

University College London Hospitals NHS
NHS Foundation Trust

Research Department of Clinical,
Educational and Health Psychology
University College London
Gower Street
London
WC1E 6BT

Telephone: 020 7676 2000
Website: www.ucl.ac.uk

[redacted]
www.uclh.nhs.uk

Project ID: **14/0190**

Study of the effects of mindfulness on pain-related distress for hospital inpatients (student study)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is conducting this study?
This study is being conducted by Rebecca Ellis and Gareth Drake, Trainee Clinical Psychologists employed by the NHS, and will form part of an academic qualification (Doctorate in Clinical Psychology).

What is the study trying to find out?
Mindfulness is a mental state achieved by focusing one's awareness on the present moment, while calmly acknowledging and accepting one's feelings, thoughts, and bodily sensations and is used as a therapeutic technique. This study aims to look into the effect of mindfulness on the distress of chronic pain for people when they are in hospital. Published studies suggest that mindfulness groups can help reduce pain, pain distress and improve abdominal symptoms and quality of life for people with chronic pain in the community, but it has not been tried with people in hospital.

You have been invited to take part because you are an inpatient on this ward and you have been identified as having significant pain.

What will I be asked to do?
If you consent to take part in this study I will ask you to do three things:

1. The first is to complete some questionnaires about your pain, how much it impacts on your life and your thoughts about pain. These will take approximately 30 minutes to complete and will be paper and pen based. We will also ask you some questions about your experience of pain on the ward. We would like to audio record this conversation, but can if you prefer make notes.

2. We will meet every other week for up to 8 weeks for around 30 minutes. We will lend you a book about mindfulness and an mp3 player with mindfulness tracks on it. Each time we meet we will introduce a new mindfulness meditation, discuss how it can be most helpful, and we can practise it together. We will then leave you with a music player with a recording of the mindfulness meditation on it for you to practice with each day. Each meditation is about 10 minutes long. An example of a meditation is called 'The Body Scan' and involves you lying or sitting down whilst your attention is directed towards different parts of your body to observe what sensations you can feel in each part. We will also ask you to keep a record of how often you use the mindfulness exercises, this should take about 5 minutes each week.

3. At the end of the 8 weeks we will ask you to complete the same questionnaires as at the beginning and we will also ask you about your experience of the mindfulness programme. We would like to audio record this conversation, but can if you prefer make notes.

What data will be collected?
The data collected will include basic personal information (e.g. age, gender, and ethnicity) and your responses to the questionnaires. All data collected will be anonymised so that you cannot be identified from it and it will be kept strictly confidential. University College London (UCL) will be responsible for the safety and security of this data. Some anonymised direct quotes may be included in the final publication.

What are the risks of taking part?
We do not expect there to be any risks of taking part in this study and do not expect there to be an increase in pain. It is possible that by engaging with mindfulness and increasing your awareness of thoughts, feelings and bodily sensations, you may become distressed. Other people with chronic pain who have used these techniques find that any distress soon reduces and results in longer term acceptance of pain and reduced distress. If you do become distressed you can ask to speak with one of the researchers (Rebecca Ellis, contact details at the end of this sheet) who is a third year doctoral Clinical Psychology Trainee with experience in working with people who are distressed. There may be some mild intrusion/inconvenience when the researchers ask to meet with you each fortnight.

What are the possible benefits of taking part?
We hope that the mindfulness programme will help you with your pain, although this cannot be guaranteed. The information we get from this study may help us to treat future patients with abdominal pain better. You may benefit from being able to access a psychological intervention which many studies have reported result in reduced distress of chronic pain, stress and depression. You will also be given the opportunity for interaction with people outside of your medical team. You may learn skills which you can continue to use when the study has finished and so continue to benefit in the longer term.

What will happen if I don't carry on with the study?
If you choose to withdraw from the study before the end, all identifiable data will be withdrawn. Data which is not identifiable to the research team may be retained.

What happens when the study ends?
When the study finishes, you will be able to carry on with the mindfulness exercises yourself for as long as you wish (we can provide you with the mp3 files), however we will ask you to return the book and mp3 player.

What will happen to the results of the research study?
Following the study, the researchers will feedback the results to staff and patient on the ward at an informal meeting. If you are no longer present on the ward, you will be given the opportunity to attend this meeting or to be sent an information sheet summarising the findings. The results of this study will be written up as part of a Doctorate in Clinical Psychology thesis. It is also intended that they will be published in a scientific journal and some anonymised direct quotes may be used (you will not be identifiable in either of these).

Who is organising and funding the study?
This study is organised and funded by University College London.

Who has reviewed this study?
This study will be reviewed by University College London Hospital NHS Trust Research Committee and the NRES London – City Road and Hampstead Research Ethics Committee.

What if there is a problem?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your researcher if you would like more information on this and contact details are at the end of this sheet.

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your researcher, please make the claim in writing to Amanda Williams who is the Chief Investigator for the research and is based at University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Contact for further information
If you would like any more information, you can ask to talk to me whenever I am on the ward or you can contact me on: [redacted]

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Student Researcher
Rebecca Ellis
Trainee Clinical Psychologist
Research Department of Clinical,
Educational and Health Psychology
University College London
WC1E 7HB
02076791608

Chief investigator
Dr Amanda C de C Williams
Reader in Clinical Health Psychology
Research Department of Clinical,
Educational and Health Psychology
University College London
WC1E 7HB
02076791608

Patient Advice and Liaison Service
[redacted]

Sponsor representative
Susanne Emerton
R&D (1st Floor, Maple House)
Resenheim Wing
Ground Floor
25 Grafton Way
London
WC1E 6DB
Tel: 0207 447 7430

Appendix 9: Patient consent form

University College London Hospitals NHS
NHS Foundation Trust

Research Department of Clinical,
Educational as Health Psychology
University College London
Gower Street
London
WC1E 6BT

Telephone: 020 7676 2000
Website: www.ucl.ac.uk

[redacted]

www.uclh.nhs.uk

UCLH Project ID number: 14/0190
Patient Identification Number for this study:

CONSENT FORM

Title of project: Study into the effects of mindfulness on pain-related distress for hospital inpatients (student study)

Name of Academic Supervisor/ Chief Investigator: Dr Amanda Williams
Name of student researchers: Rebecca Ellis and Gareth Drake

Please initial box

1. I confirm that I have read and understood the information sheet dated 17/06/14 (version 2) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I have had sufficient time to consider whether or not want to be included in the study ☐
3. 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. ☐
4. I understand that sections of any of my medical notes may be looked at by responsible individuals or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
5. I understand that anonymised direct quotes may be used and that the interviews may be audio recorded. ☐
6. I agree to take part in the above study. ☐

Continued on next page/

1 form for Patient;
1 to be kept as part of the study documentation,
1 to be kept with hospital notes

University College London Hospitals NHS
NHS Foundation Trust

UCLH Project ID number: 14/0190 Form version: 2
Patient Identification Number for this study:

CONSENT FORM

Title of project: Study into the effects of mindfulness on pain-related distress for hospital inpatients student study)

Name of Academic Supervisor/ Chief Investigator: Amanda Williams
Name of student researchers: Rebecca Ellis and Gareth Drake

Name of patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher (to be contacted if there are any problems)	Date	Signature

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top this consent form.

1 form for Patient;
1 to be kept as part of the study documentation,
1 to be kept with hospital notes