

Mindfulness and Psychological Flexibility in Irritable Bowel Syndrome

(IBS): An Exploration of Associations and Relationships.

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Chapter 1

Introduction

Introductory Chapter

This thesis aims to examine the concepts of mindfulness and psychological flexibility in people with Irritable Bowel Syndrome (IBS), how they present, and how these may contribute to the alleviation of physical and / or mental distress caused by the condition. The thesis consists of two major sections: a systematic review and an empirical study. This introductory chapter presents a brief description of each section, how the sections are linked, and an overview of the thesis as a whole.

Chapter 1: Systematic Review

Irritable bowel syndrome (IBS) is a long-term, recurring health condition, with psychosocial stressors a significant risk factor in symptomatic periods (e.g. Choung, Locke, Zinsmeister, Schleck & Talley, 2009), and an associated impact on daily life and functioning (e.g. Hahn, Yahn & Strassels, 1999). Mindfulness, as part of the management of long-term physical health conditions, has increasingly been investigated within the clinical literature (e.g. with people with diabetes, cardiovascular disease, and chronic pain syndromes: Abbott, Whear, Rodgers, Bethel, Coon et.al., 2014; Lauche, Cramer, Dobos, Langhorst & Schmidt, 2013; van Son, Nyklícek, Pop, Blonk, Erdtsieck et.al., 2013). As such, interventions incorporating mindfulness training - fostering the ability to pay conscious attention to the present moment in an accepting and non-judgemental way (Kabat-Zinn, 1994, p.4) - may be an effective alternative or adjunct to medical treatment for IBS.

This review used systematic search strategies to establish the current status of empirical research into mindfulness-based interventions for people with IBS, and the associated impact on measures of physical and psychological health. A general trend for positive effects on both physical symptoms and some aspects of psychological health was reported. However, the mechanisms underlying how mindfulness training impacted on symptoms was unclear, and it

was noted that psychological measures utilised in these studies tended to focus on anxiety and mood. Discussion points and potential areas for future exploration were identified.

This review is intended for submission to 'Psychology and Health' and is written in accordance with the author guidelines for this journal, which follows the American Psychological Association (APA) publication manual, 6th Edition (2011) referencing style.

Chapter 2: Empirical Paper

In order to consider the presence of mindfulness in people with IBS more fully, the next section of this thesis incorporates an original empirical study exploring the impact of the different facets of trait mindfulness and psychological flexibility (Hayes, Luoma, Bond, Masuda & Lillis, 2006) in people with IBS. While mindfulness can be 'trained' through intervention and practice, it can also be conceptualised as a 'trait' or dispositional ability to be mindful in everyday life (Bao, Xue & Kong, 2015). More specifically, the study aimed to investigate if, and how, different facets of trait mindfulness and psychological flexibility are related and / or distinct, and whether they impact on measures of psychological health in a sample of people diagnosed with IBS. Rather than focus on anxiety and mood difficulties, however, the study assesses positively-framed facets of psychological health - participant's self-reported wellbeing and quality of life (Salvador-Carulla, Lucas, Ayuso-Mateos, & Miret, 2014). To the author's knowledge, this is the only study addressing the potential role of psychological flexibility, and measuring wellbeing, in the IBS population. Therefore, while acknowledging that the study is exploratory, it has potential value for informing clinical decision-making when considering potential interventions for physical and psychological difficulties associated with IBS.

Results indicated significant positive correlations between specific facets of trait mindfulness, wellbeing and quality of life, while significant inverse relationships between

facets of trait mindfulness, psychological flexibility and stress levels were found. The findings corroborate current literature on the related constructs of mindfulness and psychological flexibility, and suggest that interventions aimed at promoting mindful abilities may have a beneficial effect on physical health.

This empirical study is intended to be submitted to the 'British Journal of Health Psychology' and therefore it was written in accordance with the author guidelines for this journal, which again follow APA 6th Edition referencing guidelines.

Thesis Overview

This thesis delineates the different facets of mindfulness and psychological flexibility and explores how they impact on both physical and psychological health in a sample of people with IBS. The thesis as a whole adds to the literature on the value of mindfulness in the management of chronic health conditions, and develops the current understanding of psychological flexibility and its role in regulating physical and psychological distress caused by ill health. As a result, the thesis has implications for how clinicians consider the impact of IBS on the physical and psychological health of the individual, and recommend possible interventions to address these difficulties.

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Chapter 2

Systematic Review

A systematic review of the impact of mindfulness-based interventions on physical and psychological symptoms in people with Irritable Bowel Syndrome.¹

 $^{^{1}}$ To be submitted to the Psychology and Health journal, which does not have a word limit, although manuscripts must not exceed 30 pages.

Abstract

Objective: Irritable Bowel Syndrome (IBS) can significantly challenge physical and psychological health. Mindfulness training emphasises the development of skills in understanding and accepting experience, and may be a protective factor against aversive symptoms. This article aimed to review how mindfulness-based interventions impact on physical and psychological symptoms in people with IBS.

Design: Medline, ProQuest, PsychInfo, Scopus and Web of Science databases were searched for the period October to December 2014. IBS, mindfulness, and wellbeing were the key search terms. Studies were included if they examined mindfulness-based interventions in adults diagnosed with IBS. Non-IBS or paediatric populations, non-mindfulness-based interventions, reviews and protocols were excluded.

Main Outcome Measures: Physical symptoms, anxiety, mood, and quality of life were the main outcome measures.

Results: Ten studies were eligible for and included in the review. All studies reported broad improvements in physical symptoms and psychological symptoms as a result of the intervention. However, the extent of such changes varied. Methodological differences between studies ensured some difficulties in comparing results.

Conclusions: Mindfulness-based interventions appear to be moderately effective in reducing physical and some psychological aspects of IBS. However, the mechanisms underlying this are unclear and areas for future research are identified.

Keywords: Irritable bowel syndrome (IBS); mindfulness; intervention; symptoms

Introduction

Irritable Bowel Syndrome and associated impact

Irritable Bowel Syndrome (IBS) is one of a number of disorders collectively known as 'functional gastrointestinal disorders' (FGiDs). These are characterised by persistent and recurring gastrointestinal symptoms, caused by abnormal functioning of different parts of the gastrointestinal tract, and include functional dyspepsia, constipation and dysphagia (Longstreth, Thompson, Chey, Houghton, Mearin et.al., 2006).

IBS is defined by the presence of symptoms including abdominal discomfort and disordered bowel movements, recurrent over at least six months (Labus, Gupta, Gill, Posserud, Mayer et.al., 2013; Longstreth et.al., 2006). Estimated to affect between 10 and 20% of the UK population (NICE, 2008), it is a common and potentially debilitating condition. In addition to the impact on the individual, significant healthcare—related costs, such as repeated visits to general practitioners and specialist gastroenterology clinics, have been reported (e.g. Ahl, Mikocka-Walus, Gordon & Andrews, 2013).

No clear aetiology for IBS has to date been identified (De Palma, Collins & Bercik, 2014). Diagnosis is based on the presence of symptoms, yet may be a complicated process due to the necessity of excluding other potential organic contributory factors. However, with the recent reconceptualization of IBS as a bio-psychosocial, rather than a purely organic condition (Zernicke, Lawlor-Savage, Lounsberry, Zhong, Blustein et.al., 2012), the 'brain-gut axis theory' (Burnett & Drossman, 2005; Levy, Olden, Naliboff, Bradley, Francisconi et.al., 2006) has emerged in both the theoretical and empirical literature (e.g. Blanchard, Lackner, Jaccard, Rowell, Carosella et.al., 2008; Mayer, Naliboff, Chang & Coutinho, 2001). This theory posits that the central and enteric nervous systems impact on each other, thereby IBS symptoms may be caused and/or maintained by a combination of intestinal motor, sensory and central nervous system activity. It has been demonstrated that psychological arousal or stress

activates the autonomic nervous system, in turn resulting in gastro-intestinal changes (Mayer & Tillisch, 2011). Resulting symptoms such as stomach bloating, pain and discomfort may exacerbate psychological distress, including anticipatory anxiety, heightened awareness of bodily sensations, hopelessness or frustration (Spiegel, Gralnek, Bolus, Chang, Dulai et.al., 2004).

Debate over the most efficacious treatments for IBS has been ongoing (e.g. Tack, Fried, Houghton, Spicak & Fisher, 2006). If the brain-gut axis theory is valid and a bi-directional relationship between physical and psychological factors exists in FGiDs, the implication would be that both medical and psychological interventions may be warranted, within a wider understanding of the individual patient, their symptoms and circumstances. Medical and psychological interventions (changes to diet and lifestyle, medication, and psychotherapy), alongside alternative therapies (yoga and complementary therapies), have been examined within the research with varying degrees of efficacy (e.g. Chey, Maneerattaporn & Saad, 2011; Shen & Nahas, 2009). However, it has been suggested that neither form of intervention is superior: one study found that the crucial factor in successfully reducing IBS symptoms was the individual's acceptance of the need for treatment and their motivation to engage with the chosen treatment (Budavari & Olden, 2003).

Research into psychosocial factors in IBS, including mood and anxiety disorders, personality factors, and somatisation, has been prevalent in recent years (for a recent review see Fond, Loundou, Hamdani, Boukouaci, Dargel et.al., 2014). Compared with 'healthy' control samples, people with IBS have generally reported higher levels of anxiety and/or depression, stressful early life experiences and neuroticism (e.g. Chitkara, van Tilburg, Blois-Martin, & Whitehead, 2008). It would therefore appear that psychosocial factors are important in understanding the onset and maintenance of this condition, and subsequently in selecting and implementing specific interventions.

Mindfulness

While research into the psychosocial aspects of IBS and other FGiDs has become established, the focus of such studies has tended to be on the presence of anxiety and mood disorders, such as depression. The concept of *mindfulness* has become an integral part of 'third-wave' cognitive and behavioural therapeutic modalities, including Mindfulness-Based Stress Reduction (MBSR: Kabat-Zinn, 1992), Mindfulness-Based Cognitive Therapy (MBCT: Segal, Williams, & Teasdale, 2001) and Acceptance and Commitment Therapy (ACT: Hayes, Strosahl & Wilson, 1999). While the use of mindfulness techniques and amount of time devoted to practice of these varies in each of these approaches, the general aim of mindfulness training is to develop an understanding and acceptance of experience (both internal and external stimuli such as cognitions and emotions, as well as external stressors). This is in contrast with more traditional cognitive and behavioural approaches, which may focus on challenging or changing cognitions or emotions (e.g. Longmore & Worrell, 2007).

Mindfulness-based interventions have been utilised in a range of settings for both physical and psychological health difficulties. The concept of mindfulness has also been discussed with reference to non-clinical populations and is commonly found within general literature, such as the works of Jon Kabat-Zinn (1994) and Russ Harris (2008). Originating from the Buddhist tradition of non-striving and acceptance of experience, mindfulness has been defined as "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994, p.4). It may be viewed both as an innate, dispositional trait (the measured frequency of awareness and attention in the present moment: Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Brown & Ryan, 2003), and as a state-dependent, shifting construct (Lau, Bishop, Segal, Buis, Anderson et.al., 2006). Mindfulness (as both a psychological construct, and as part of a therapeutic intervention [e.g. MBSR, MBCT, ACT]) has been extensively researched within a range of physical health and long-

term conditions, including chronic pain syndromes and multiple sclerosis (Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013; Simpson, Booth, Lawrence, Byrne, Mair et.al., 2014).

Rationale for reviewing interventions

It has been demonstrated that increased levels of mindfulness, as a result of specific mindfulness training or intervention, is linked with reduced response to perceived stress (e.g. Evans, Ferrando, Carr & Haglin, 2010; Pradhan, Baumgarten, Langenberg, Handwerger, Gilpin et.al., 2007), in addition to other factors such as improved wellbeing and mood (De Palma et.al., 2014; Fond et.al., 2014). This is an important potential factor in the management of IBS and other FGiDs. As the brain-gut axis theory suggests, heightened biological response to psychological arousal or stress appears to be implicated in IBS recurrences. Increased mindfulness may reduce physiological and emotional stress, with subsequent beneficial effects on reported quality of life, mood and wellbeing. According to the brain-gut axis theory, these improved abilities to reduce physiological responses to perceived stressors may therefore be a focus of, or adjunct to, prescribed treatment of these disorders in future clinical practice. Mindfulness-based interventions may therefore have an important role in developing an individual's abilities in managing physiological and psychological stress.

Objectives

The review aimed to examine and synthesise the research on the efficacy of mindfulness-based interventions, as compared with other therapeutic approaches and control groups, for people with IBS. IBS symptom severity and psychological health are the outcomes to be assessed. Intervention studies including randomized controlled trials are included. A protocol was drafted for the researcher's use during this review (see Appendix B).

Method

Electronic searches

Electronic searches of the following databases were conducted in October to December 2014: Medline (Ovid), PsychInfo, ProQuest, Scopus, Web of Science. These databases were chosen due to their perceived relevance to the topic and coverage of both medical and psychological material; ProQuest was included in an attempt to locate possible unpublished data.

Hand search

The monthly research update 'Mindfulness Research Monthly' (renamed the American Mindfulness Research Association [AMRA] in November 2014) was hand-searched from the first publication in January 2010 until December 2014.

Search Strategy

The following search strategy was developed for the Scopus database and adapted accordingly for subsequent databases.

Each database was searched within the date range 1990 to 2014 (months not specified), due to the fact that the first reported utilisation of mindfulness as a clinical intervention in western clinical settings was around 1990 (Kabat-Zinn, 1990; Kabat-Zinn, Massion, Kristeller, Peterson, Fletcher et.al., 1992). The key search terms were:

- I. "Irritable bowel syndrome" OR "IBS" OR "functional bowel disorder";
- II. mindfulness*;
- III. wellbeing.

The search terms were entered into each database in a stepwise manner: the first search term (IBS) was entered into the database; the second search term (mindfulness) was then searched for within those results, with the third (wellbeing) included only if the number of hits returned by the first two search terms was greater than 60, in order to identify the most relevant articles.

Eligibility criteria and study selection

Limits were set on the database, where possible, to include "English language", "human" and "humans". Additionally, PsychINFO gave the option to limit to "adulthood - 18 years and older" which was selected. Duplicates were removed in the preliminary screening of retrieved references. Study titles were then screened by the author to remove irrelevant material (example retrieved from ProQuest database: "Sexual function of women with chronic illness and cancer", Basson, 2010).

Stage two of the selection process then included scrutiny of the titles and abstracts of the remaining references using the exclusion criteria detailed below. If the full text of an article was unavailable this reference was excluded. The final stage of selection was determined by the application of the eligibility criteria outlined below.

Inclusion criteria

Studies were included if:

- I. the population were adults aged 18 years and older;
- II. the study population were diagnosed with IBS or another FGiD, such as functional dyspepsia;
- III. mindfulness-based interventions were the primary focus of intervention;
- IV. symptom severity and wellbeing were measured pre- and post-intervention;
- V. randomized controlled trials and other intervention methodologies were employed.

Exclusion criteria

Studies were excluded if:

I. they investigated a non-long term physical condition or non-FGiD population;

- II. they investigated populations with severe bowel disorders requiring more surgical intervention (inflammatory bowel disease, ulcerative colitis, Crohn's disease);
- III. they examined paediatric rather than adult populations;
- IV. mindfulness-based interventions were not investigated;
- V. the identified study was a protocol or a pilot for a future trial, if no intervention data was provided or no control group was included;
- VI. the article was a systematic review or meta-analysis.

A flowchart of search results is presented in Figure 1. The studies included in the review and their characteristics are reported in Table 1.

Results

Electronic database searches yielded two hundred and two articles, including fifteen duplicates. The hand-search yielded twenty-five articles, four of which were duplicates from the electronic search and were consequently removed. This left a total of two hundred and eight articles to be screened (for a flow diagram of study selection, see Figure 1).

Of the 208 articles screened, 174 were excluded on the basis of title alone. The remaining 34 article abstracts were then scrutinised using the inclusion criteria above.

Twenty-four articles were subsequently excluded, reasons included studies investigating non-clinical, non-IBS / FGiDs or paediatric populations, studies utilising non-mindfulness-based interventions, and protocols for future studies. One pilot study was excluded (Ljóttsen, Andréewitch, Hedman, Ruck, Andersson et.al., 2010), as no control group was utilised (Ljóttson, Falk Vesterlund, Hedman, Lindfors et.al., 2010). The remaining ten studies were included in this review. Characteristics of these are reported in Table 1.

Quality of Included Studies

Assessment of methodological quality

In order to assess the quality of the included studies, the 16-item Quality Assessment Tool for Studies with Diverse Designs (QATSDD – Sirriyeh, Lawton, Gardner & Armitage, 2012: see Table 2) was utilised. This scale covered the following areas: theoretical framework, aims, research setting, sample characteristics, data collection tools and procedure, 'fit' between research aims and data collection, analysis and critical reflections. Scores of 0 ("not at all"), 1 ("very slightly"), 2 ("moderately") or 3 ("complete") were allocated depending on the degree to which each aspect of methodology was met, with a maximum score of 42 achievable for quantitative studies.

Reliability of quality rating

A sample of papers were randomly selected and independently rated by another researcher using the same rating scale. There was one hundred percent agreement between raters on two of the four sampled papers; slight discrepancies on the remaining two papers generally focused around the justification given for particular assessment measures used and analytical methods chosen, and were resolved via a consensus meeting.

Risk of Bias

At individual study level, the ProQuest database and AMRA updates were included in the literature search in an attempt to locate the most recent and potentially unpublished studies. It is acknowledged that a language bias is present – the search was limited to those studies published in English. Other considerations of bias are included within the quality assessment. (Table 2).

 Table 1: Study Characteristics.

| Study Authors | Study Design | <u>Sample</u> | <u>N</u> | | <u>Gender</u> | | <u>Intervention</u> | <u>Follow Up</u> | Quality Rating |
|---|-------------------------------|---|---------------------|-----------------|-------------------|----------------------|--|---|----------------|
| | | | Experimental | Control | Experimental | Control | <u>Experimental</u> | | |
| Asadollahi et.al., 2014 | Quasi- experimental | Women with IBS | 10 | 10 | F (100%) | F (100%) | MBCT | 2 months | 19 |
| Fjorback et.al., 2013 | Randomized trial | Functional somatic syndromes (IBS 44%) | 59 | 60 | F (80%) | F (80%) | MBSR + CBT elements | 9 and 15 months | 35 |
| Gaylord et.al., 2011 | RCT | Women with IBS | 36 | 39 | F (100%) | F (100%) | MBSR tailored for IBS | 3 months | 32 |
| Kearney et.al., 2011 | Prospective study | Veterans, with and without IBS | With IBS: 43 | Without IBS: 49 | With IBS: M (79%) | Without IBS: M (71%) | MBSR | 2 and 6 months | 29 |
| Ljótsson et.al., 2010 | RCT | Individuals with IBS | 42 | 43 | F (83%) | F (86%) | CBT + mindfulness & acceptance training | 3 months intervention only | 36 |
| Ljótsson, Hedman, Andersson et.al., 2011 | RCT | Individuals with IBS | 98 | 97 | F (77.6%) | F (80.4%) | Internet-delivered CBT +, mindfulness training, exposure | 6 months | 31 |
| Ljótsson, Hedman, Lindfors et.al., 2011 | Follow-up from 2010 RCT | Individuals with IBS | 35 | 40 | Unclear | Unclear | CBT + mindfulness & acceptance training, exposure | 18 months intervention, 15 months control | 27 |
| Ljótsson, Andersson et.al., 2011 | RCT | Individuals with IBS | 30 | 31 | F (77%) | F (71%) | Internet-delivered CBT + mindfulness and acceptance training, exposure | 12 months | 35 |
| Ljótsson et.al., 2014 | Dismantling study | Individuals with IBS | 156 | 153 | F (75.2%) | F (77.3%) | Internet-delivered CBT + mindfulness and acceptance training, exposure | 6 months | 36 |
| Zernicke et.al., 2012 | RCT | Individuals with IBS | 43 | 47 | F (90.3%) | F (87.2%) | MBSR | 6 months | 36 |

Note. CBT = Cognitive Behavioural Therapy; IBS = Irritable Bowel Syndrome; MBCT = Mindfulness-Based Cognitive Therapy; MBSR = Mindfulness-Based Stress Reduction; RCT = Randomized Controlled Trial.

 Table 2: Quality Assessment Rating for the ten included studies

| Tubic 2: Quality Hosessment Hading 10 | Asadollahi | Fjorback et | Gaylord et | Kearney | Ljotsson et | Ljotsson | Ljotsson et | Ljotsson | Ljotsson et | Zernicke et |
|--|----------------|----------------|----------------|-----------------|----------------|------------------|----------------|------------------|----------------|----------------|
| | et al, 2014 | al., 2012 | al., 2011 | et al., 2011 | al., 2010 | et al., 2011a | al., 2011b | et al., 2011c | al., 2014 | al., 2012 |
| Explicit theoretical framework | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Statement of aims/objectives in main body of report | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Clear description of research setting | 3 | 2 | 2 | 3 | 2 | 1 | 2 | 2 | 2 | 2 |
| Evidence of sample size considered in terms of analysis | 0 | 3 | 0 | 0 | 3 | 3 | 0 | 3 | 3 | 3 |
| Representative sample of target group of a reasonable size | 1 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Description of procedure for data collection | 1 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 |
| Rationale for choice of data collection tool(s) | 2 | 2 | 3 | 2 | 2 | 2 | 1 | 2 | 2 | 2 |
| Detailed recruitment data | 1 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 3 | 3 |
| Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only) | 1 | 2 | 2 | 2 | 3 | 0 | 1 | 2 | 3 | 3 |
| Fit between stated research question and method of data collection (Quantitative) | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative) | | | | | | | | | | |
| Fit between research question and method of analysis | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Good justification for analytical method selected Assessment of reliability of analytical process (Qualitative only) | 0 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 3 | 3 |
| Evidence of user involvement in design | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Strengths and limitations critically discussed Total | 2 19 | 3 35 | 2 32 | 2 29 | 3 36 | 3 31 | 2 27 | 3 35 | 3 36 | 3 36 |

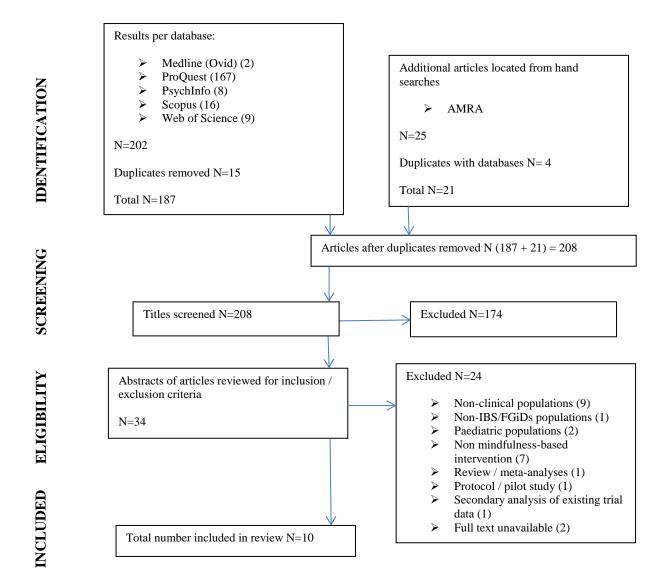


Figure 1. Flowchart of the study selection process

Range of Mindfulness Interventions

The range of mindfulness interventions utilised within these studies ensures that direct comparisons between the efficacy of results are difficult. The most common intervention utilised was Mindfulness-Based Stress Reduction (MBSR: Kabat-Zinn, 1982) - a manualised 8-week programme developed within the context of chronic pain management (see Table 1). Four of the ten studies adopted this programme (Fjorback, Arendt, Ørnbøl, Walach, Rehfelld et.al., 2013; Gaylord, Palsson, Garland, Faurot, Coble et.al., 2011; Kearney, McDermott

Martinez & Simpson, 2011; Zernicke, Campbell, Blustein, Fung, Johnson et.al., 2012), although one study tailored the MBSR programme to an IBS population (Gaylord et.al., 2011). One group of researchers developed a programme of cognitive-behavioural intervention incorporating elements of exposure, mindfulness and acceptance skills, which was used in four studies (Ljótsson, Hedman, Andersson, Hesser, Lindfors et.al., 2011; Ljótsson, Hedman, Lindfors, Hursti, Lindefors et.al., 2011; Ljótsson, Andersson, Andersson, Hedman, Lindfors et al., 2011; Ljótsson, Hesser, Andersson, Lackner, El Alaoui et.al., 2014). These researchers investigated the same intervention in both traditionally-delivered and internet-delivered formats (Ljótsson, Hedman, Andersson et.al., 2011). Only one study utilised Mindfulness-Based Cognitive Therapy (Asadollahi, Mehrabi, Neshatdoost, Kalantari, Afshar et.al., 2014), though it was noted that six other studies included elements of cognitive work (Fjorback et.al., 2013; Ljótsson et.al., 2010; Ljótsson Hedman, Andersson et.al., 2011; Ljótsson, Hedman, Lindfors et.al., 2011; Ljótsson, Andersson et.al., 2011; Ljótsson et.al., 2014).

The diverse nature of these interventions suggests that mindfulness may be evolving into an important component of interventions aside from the traditional MBSR (Kabat-Zinn, 1982; 1990) format frequently used in chronic or long-term health contexts.

Effects on IBS Symptoms

The findings of the included studies are summarised in Table 3. Effect sizes are reported using the Cohen's d calculation where possible.

Most studies included a measure of IBS symptoms: four (Asadollahi et.al., 2014; Gaylord et.al., 2011; Kearney et.al., 2011 & Zernicke et.al., 2012) used the well-validated IBS Symptom Severity Scale (IBS-SSS - Francis, Morris & Whorwell, 1997) as a primary outcome measure. In contrast, Ljótsson and colleagues (2010; 2011; 2011; 2011; 2014) used

the IBS version of the gastrointestinal symptom rating scale (GSRS-IBS -Wiklund, Fullerton, Hawkey, Jones, Longstreth et.al., 2003). A more general measure of health status (the SF-36: Ware, Campbell, Kosinski & Gandek, 1993) was used by Fjorback et.al. (2013), given that this study was not IBS-specific and was instead conducted with people with a range of functional somatic syndromes.

Overall, positive effects of mindfulness-based interventions on symptoms of IBS when compared with control groups were reported by the majority of studies. However, results differed in terms of the extent of change. Ljótsson et.al. (2010) reported large improvements on symptoms as a result of a CBT intervention with elements of mindfulness and acceptance training; these gains were maintained at 12- and 15-month follow-up (Ljótsson, Hedman, Lindfors et.al., 2011). Similarly, Zernicke et.al. (2012) reported clinically meaningful improvement in symptoms in the intervention group both post-treatment and at 6-month follow-up; however slow improvements within the control group were also noted. As the control group consisted of clients on a waiting list for MBSR, this finding was discussed in terms of individual expectations of the treatment programme. Corroborating the trend for positive effects, the results of a randomized controlled trial also reported decreased physical symptom severity (Gaylord et.al., 2011).

However, these positive results were balanced by some less positive findings. Kearney et.al. (2011) found statistically insignificant changes in IBS symptoms as a result of participation in an MBSR programme in a sample of military veterans, and no changes at six months follow-up. Fjorback et.al. (2013) found no changes in physical health status between the intervention and control groups at fifteen-month follow-up. These findings substantiate the results of Asadollahi et.al. (2014), who likewise reported no IBS symptom changes at two-month follow-up.

As previously noted, the variability in results on symptoms may reflect methodological issues, such as different interventions, different follow-up periods, and assessment methods adopted between studies. Given the recurrent nature of IBS symptoms, with periods of severe discomfort interspersed with periods of relative wellness, this may also reflect the natural course of the condition over time.

Effects on Psychological Sequelae

The ten studies included here tended to examine the effects of the mindfulness intervention on commonly-assessed psychological sequelae, most frequently quality of life and IBS-specific forms of anxiety. Wellbeing – as opposed to psychopathology – was not assessed with formal outcome measures in any of these studies, therefore this may indicate an area for future research with IBS populations.

Measures used ranged from IBS-specific instruments (such as the IBS-related quality of life scale [IBS-QOL: Patrick, Drossman, Frederick, DiCesare & Puder, 1998], and the Visceral Sensitivity Index [VSI: Labus, Bolus, Chang, Wiklund, Naesdal et.al., 2004], which assesses cognitive, emotional, attentional, and behavioural aspects relating to fear of IBS symptoms and associated situations), to more general mental health measures including the Hospital Anxiety and Depression Scale (HADS: Zigmond & Snaith, 1983) and the Symptom Checklist-90-Revised (Derogatis, 1994).

Eight studies included a measure of quality of life (all of these using an IBS-specific quality of life scale) and seven used the VSI scale (see Table 3). Interestingly, despite focusing on mindfulness-based interventions, levels of mindfulness pre- and post-intervention were only assessed in one trial (Gaylord et.al., 2011), although unsuccessful attempts were made to follow up continuing meditation practice in one other study (Zernicke et.al., 2012).

In general, these studies reported positive effects of the particular intervention on psychological functioning. Despite the fact that no changes to IBS physical symptoms were noted, Asadollahi et.al. (2014) reported that MBCT reduced levels of anxiety, including OCD, in their female sample. Gaylord et.al. (2011) reported significant differences in improvement, both on measures of general anxiety and on the VSI, between the intervention and control groups at three-month follow-up (effect sizes calculated from the reported means and standard deviations). Kearney et.al. (2011) also reported significant positive changes in IBS-related quality of life and on the VSI at 6 months follow-up, despite not finding significant results between intervention and control groups immediately post-treatment.

However, more mixed findings were reported by Ljótsson and colleagues. Significant improvements on IBS-related quality of life were found post-treatment and at long-term follow-up (Ljótsson et.al., 2010; Ljótsson, Hedman, Lindfors et.al., 2011), although only moderate improvements on the VSI were found. This might suggest that IBS-specific fears and attentional focus were not significantly impacted as result of the intervention. In support of this, a further trial found comparable reductions in IBS-related fear and avoidance measured by the VSI (Ljótsson, Andersson et.al., 2011).

A recent dismantling study examined the effects of a mindfulness intervention with and without exposure exercises in an IBS population; while both groups demonstrated improvements, the exposure group made larger gains on measures of IBS-specific quality of life, fear and avoidance, and general anxiety and depression (Ljótsson et.al., 2014). This suggests that exposure work, typically used in the management of anxiety disorders, is an important element in designing effective mindfulness interventions for people with IBS. While this makes intuitive sense due to the recurring nature and subjective impact of the condition, the role of mindfulness in and of itself is less clear.

Table 3. Summary of Study Outcomes

| Study authors | Assessed Outcomes | <u>IBS symptoms</u> | <u>Anxiety</u> | Mood | <u>Stress</u> | Quality of Life | |
|---|--|---|---|---|---|---|--|
| Asadollahi et.al, 2014 | IBS-SSS; Symptom Checklist-90-R | Improvement pre- to post-treatment; between groups effect size (<i>ES</i> =0.28) | Improvement pre- to post-treatment; between groups effect size (<i>ES</i> =0.45) | Improvement pre- to post-treatment; between groups effect size (<i>ES</i> =0.41) | Not assessed | Not assessed | |
| Fjorback et.al., 2013 | SF-36 Physical Component Summary; SF-36 pain and general health scales; Whitely-8 health anxiety scale; SCL-8 Somatization and anxiety and depression scales | No significant differences between groups; moderate effect pre- to post-treatment for intervention group (<i>d</i> =0.45) at 3 month follow-up | No significant differences between groups; moderate effect pre- to post-treatment for intervention group on health anxiety (<i>d</i> =0.62) at 3 month follow-up | No significant differences between groups; small effect preto post-treatment for intervention group for anxiety and depression SCL-8 (<i>d</i> =0.31) at 3 month follow-up | Not assessed | Not assessed | |
| Gaylord et.al., 2011 | IBS-SSS; IBS-QOL; FFMQ; CSQ; VSI; BSI-18 | Decreased symptom severity post-treatment in intervention group (e.g. pain severity d =0.76) | Improvement in anxiety post-treatment in intervention group (<i>d</i> =0.41) | Improvement in depression scores in intervention group post-treatment (<i>d</i> =0.15) | Not assessed | Improvement in IBS-related quality of life in intervention group post treatment (<i>d</i> =-0.58) | |
| Kearney et.al., 2011 | IBS-SSS; IBS-QOL; VSI;SF-8; PCL; FFMQ | For IBS only, moderate effect pretreatment to 6 month follow-up (<i>d</i> =-0.28). Between-groups effects not measured | For IBS only, moderate effect pre-treatment to 6 month follow up (<i>d</i> =-0.40). Between-groups effects not measured | Not assessed | Not assessed | For IBS only, small effect pre-treatment to month follow up (<i>d</i> =0.33). Betweengroups effects not measured | |
| Ljótsson et.al., 2010 | GI symptom diary; GSRS-IBS; IBS- QOL; VSI; MADRS-S; Sheehan Disability Scales | Significant between- group difference post- treatment (<i>d</i> =1.21) | Moderate between group difference post-treatment (<i>d</i> =0.64) | No significant difference pre- and post-treatment observed | Not assessed | Significant between- group difference post- treatment (<i>d</i> =0.93) | |
| Ljótsson, Hedman, Andersson et.al., 2011 | GSRS-IBS; IBS- QOL; VSI; CSFBD; PSS; HADS | Significant reduction in symptoms pre- to post-treatment; small between-group effect (<i>d</i> =0.38) | Significant reduction in gastrointestinal and general anxiety pre- to post-treatment; small between-group effect | Significant reduction in negative thoughts about symptoms and general mood improvement; small between-group | Significant reduction in stress pre- to post- treatment; no significant differences between | Significant improveme pre- to post-treatment; moderate between-groueffect (<i>d</i> =0.51) | |

| | | | (d=0.33 and d=0.04 respectively) | effects (d =0.32 and d =0.01 respectively) | groups (<i>d</i> =-0.02) | |
|---|--|---|--|---|--|---|
| Ljótsson, Hedman, Lindfors et.al., 2011 | GSRS-IBS; IBS- QOL; VSI; | Significant improvement maintained at 12-15 month follow-up (<i>d</i> =1.11) | Moderate improvement maintained at 12-15 month follow-up (<i>d</i> =0.79) | Not assessed | Not assessed | Significant improvement maintained at 12-15 month follow-up (<i>d</i> = 0.91) |
| Ljótsson, Andersson et.al., 2011 | GSRS-IBS; TIC-P; IBS-QOL; VSI; Sheehan Disability Scales | Significant improvement prepost-treatment; moderate betweengroup effect (<i>d</i> =0.77) | Significant improvement pre- to post-treatment; moderate betweengroup effect (<i>d</i> =0.73) | Not assessed | Not assessed | Significant improvement pre- to post-treatment; moderate between-group effect (<i>d</i> =0.79) |
| Ljótsson et.al., 2014 | GSRS-IBS; IBS- QOL; VSI; CSFBD; HADS | Significant improvement pre- and post-treatment; moderate betweengroup effect (<i>d</i> =0.47) | Significant improvement pre- and post-treatment; small between-group effect (<i>d</i> =0.30) | Significant improvement pre- and post-treatment; small between-group effect (<i>d</i> =0.18) | Not assessed | Significant improvement pre- and post-treatment; small between-group effect (<i>d</i> =0.26) |
| Zernicke et.al., 2012 | Health behaviours; meditation practice log; IBS-SSS; IBS- QOL; POMS; C- SOSI; FACIT-sp | Clinically significant improvement pre- to post-treatment; moderate betweengroup effect (<i>d</i> =0.50) | Not assessed | Significant improvement pre- to post-treatment; small between-group effect (<i>d</i> =0.21) | Significant improvement pre- to post-treatment; moderate betweengroup effect (<i>d</i> =0.60) | Significant improvement pre- to post-treatment; moderate between-group effect (<i>d</i> =0.49) |

Note. BSI-18 = Brief Symptom Inventory (18 items); CSFBD = Cognitive Scale for Functional Bowel Disorders; CSQ = Coping Strategy Questionnaire; C-SOSI = Calgary Symptoms of Stress Inventory; ES = Effect Size (statistic not reported); FACIT = Functional Assessment of Chronic Illness Therapy- Spiritual Wellbeing; FFMQ = Five Facet Mindfulness Questionnaire; GSRS-IBS = Gastrointestinal Symptom Rating Scale for IBS; HADS = Hospital Anxiety and Depression Scale; IBS-QOL = IBS-related Quality of Life Scale; IBS-SSS = IBS Symptom Severity Scale; MADRS-S = Montgomery Asberg Depression Rating Scale - Self report; PCL = Post-traumatic stress disorder Checklist; POMS = Profile Of Mood States; PSS = Perceived Stress Scale; SF-8 = Short Form (8 items); SF-36 = Short Form (36 items); TIC-P = Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry; VSI = Visceral Sensitivity Index.

Discussion

Summary of Evidence

The studies reviewed in this article suggest that cultivating levels of mindfulness can be potentially useful as a focus of, or adjunct to, interventions targeting psychological health in people with IBS. The interventions examined within these studies are broadly efficacious in terms of both IBS symptom presentation and some psychological sequelae, including perceived quality of life and IBS-related anxiety. This is in line with other reviews in the field; for example Lakhan & Schofield's (2013) review of mindfulness-based interventions for people with a range of somatization disorders reported the most consistent improvements on pain, symptom severity and quality of life in people with IBS.

Amongst the overall positive effects on physical and psychological symptoms, variation in the extent and maintenance of these positive changes were reported. Two studies (Ljótsson et.al., 2010; Zernicke et.al., 2012) found significant positive changes in both IBS symptom presentation and IBS-related quality of life, which were maintained at follow-up; both of these studies rated highly on the QATSDD, suggesting that their results may be valid. In contrast, others (Asadollahi et.al., 2014; Fjorback et.al., 2013; Kearney et.al., 2011) reported insignificant or no changes on IBS symptoms, IBS-related anxiety, mood or quality of life. Some of the variation in these results may be explained by issues within the study population or methodology. Asadollahi and colleagues (2014) exhibited many methodological and reporting issues and received the lowest quality rating (19/42) on the QATSDD, though whether this was due to error or difficulties with translation or cultural norms, it is unclear. Although both rated adequately on the QATSDD (35 and 29 respectively), Fjorback et.al. (2013) reported results for a group of individuals with IBS within a larger sample of functional somatic conditions, while Kearney et.al. (2011) looked at a veteran sample who may have had concurrent medical and / or psychological stressors. The findings on

psychological sequelae are of interest. Moderate to strong positive outcomes on quality of life and IBS-related anxiety were reported generally consistently. This is mirrored by the high consistency in the instruments used across studies: for example, eight of the ten studies used the same measure to assess IBS-related quality of life.

However, some more mixed findings were reported by Ljótsson and colleagues (2010; Ljótsson, Hedman, Lindfors et.al., 2011). Other aspects of psychological health such as non-IBS-specific anxiety and quality of life, perceived stress levels, or wellbeing, were not assessed. Research has suggested that people with IBS report higher levels of anxiety and mood disturbance compared with control groups (Chitkara et.al., 2008; Fond et.al., 2014); similarly, the brain-gut axis theory suggests that both physiological and psychological responses to stress may impact on IBS symptoms (Evans et.al., 2010; Pradhan et.al., 2007). It would therefore appear logical that mindfulness training can have a positive effect on both IBS physiological symptoms and psychological health. Future studies may investigate if reported wellbeing in people with IBS is higher or lower than control samples, and if mindfulness interventions can offer an effective treatment for this.

The dismantling study conducted by Ljótsson and colleagues (2014) posited the idea that exposure work – typically used in the management of anxiety disorders – is a salient factor in designing effective mindfulness interventions for people with IBS. The authors proposed that mindful acceptance of aversive inner experiences (such as IBS-related symptoms), combined with the practice of engaging in more flexible and functional behavioural responses to such experiences, can lead to increased psychological flexibility (Ljótsson, Andersson et.al., 2011). It is notable that both Ljótsson et.al. (2014) and Ljótsson, Andersson et.al. (2011) rated well on the QATSDD (36 and 35 respectively), suggesting that these results are valid. Given the fundamental aspects of acknowledging and accepting moment-to-moment experiences in mindfulness training, there is a theoretical rationale underpinning how relevant

this is for coping with the recurring nature and subjective impact of IBS. Mindfulness practice, when combined with exposure exercises, may also be consistent with the theory that the most significant factors in positive symptom change are the accepted need for and motivation to engage in the offered treatment, whatever that happens to be (Budavari & Olden, 2003). Despite this, the combined results from the other studies indicate that exposure elements are not necessary to effect change in psychological symptoms of IBS. It may also be argued that the inclusion of exposure exercises may detract from and confuse the role of mindfulness itself within this intervention.

Additionally, the premise that reduced physical symptom severity can mediate reports of improved quality of life and psychological distress appears logical and examination of these pathways of mediation may clarify how these factors interact. A secondary analysis on the data reported by Gaylord et.al. (2011) examining the therapeutic mechanisms of mindfulness training was conducted by Garland, Gaylord, Palsson, Faurot, Mann et.al. (2012). Results from this suggested that mindfulness training ameliorated symptoms of IBS by promoting non-reactivity to gut-focused anxiety and perceptions of abdominal symptoms, which in turn led to improvements in IBS-related quality of life. As such, this offers an interesting observation on the nature of mindfulness interventions and how they may 'work' for people with IBS.

It is notable that Ljótsson and colleagues developed and investigated a form of CBT incorporating both mindfulness and acceptance training; also, the general trend of positive effects on both IBS symptom severity and IBS-related quality of life (alongside other measures of general and specific anxiety and mood) in the interventions that emphasised acceptance of symptoms, suggests that acceptance, as a component of psychological flexibility (Hayes, Strosahl & Wilson, 1999) may have an important if unclear role (Ljótsson et.al., 2010; Ljótsson et.al., 2011; Ljótsson et.al., 2014).

It has been hypothesized that mindfulness and psychological flexibility are related constructs (e.g. Curtiss & Klemanski, 2014; Masuda, Price & Latzman, 2012), and psychological flexibility may influence psychological variables in a similar way to mindfulness, i.e. reduce subjective stress and, by implication, positively affect quality of life and perceived wellbeing. However, psychological flexibility has been under-researched to date, though it is emerging as a construct of interest within clinical health settings (e.g. examining activity levels in older adult populations - Kangasniemi, Lappalainen, Kankaanpaa, & Tammelin, 2014). Further research is warranted in clarifying the role that psychological flexibility may play in mediating IBS symptoms and their psychological impact.

Limitations

Individual Studies

As highlighted above, there are difficulties in generalising findings from the range of different interventions examined. While the manualised MBSR programme is established and replicable, adaptations have also been made (Gaylord et.al., 2011); similarly, one research group (the work conducted by Ljótsson and colleagues) has developed an intervention based on the tenets of CBT for IBS, focusing specifically on gastrointestinal anxiety and exposure to IBS-specific symptoms and situations, with mindfulness taught as a strategy to practice acceptance of these aversive experiences. This intervention has been tested and retested (Ljótsson et.al., 2010; Ljótsson, Andersson et.al., 2011), suggesting that this may be a useful addition to the range of mindfulness-based interventions for people with IBS.

It is perhaps surprising that levels of mindfulness were not formally assessed in these studies (with the exception of Gaylord et.al., 2011). The accurate measurement of mindfulness practice is acknowledged to be difficult (Zernicke et.al., 2013), however, preand post-treatment measures may have examined whether the intervention had any effect on

levels of state mindfulness. If higher levels of mindfulness are beneficial in coping with the physical and psychological demands of a recurrent health condition, this should be a priority for future researchers in this field.

The work of Fjorback et.al. (2011) was conducted on a population with a range of somatisation disorders that included, but was not limited to, people diagnosed with IBS. It is therefore difficult to generalise these findings to the wider IBS population. A final limitation may be the general bias towards 'Western' publications: with the exception of Asadollohi et.al. (2014), all of the studies reviewed here were conducted with European or North American sample populations. In both the studies reviewed here and in the wider research literature, the conceptualisation of mindfulness – which has come to general awareness in the affluent, secular Western cultures through such programmes as MBSR, MBCT and ACT—may differ from the 2500-year old Buddhist tradition of meditation (Fennell & Segal, 2011). Research conducted across cultural and secularity barriers may demonstrate different results.

Limits of Review

The conclusions of this review can add to the growing literature on the efficacy of mindfulness-based interventions in promoting positive physical and psychological outcomes for people with IBS (for example, see Aucoin et.al., 2014, for a recent meta-analysis of mindfulness-based interventions as a treatment for FGiDs). The selected studies included randomized controlled trials and are of adequate quality, as rated using the QATSDD tool (Sirriyeh et.al., 2011).

This review is not without its limitations. While the ProQuest database was searched, no theses or unpublished data met inclusion criteria for this review. It is impossible to state that all the available studies were scrutinized, therefore the generalizability of conclusions drawn is limited. While the term "functional bowel disorder" (FGiD) was searched for, only studies

examining IBS were located. This is unsurprising, as IBS is the most frequently-occurring FGiD and other disorders within this category – such as functional dyspepsia or dysphagia – may be under-researched. However, some caution must be exercised in generalising the review's findings on the efficacy of mindfulness-based interventions to other FGiDs.

The application of inclusion and exclusion criteria was conducted by the author alone and was not validated by independent researchers. Similarly, the choice of quality assessment tool (the QATSDD) may have impacted on the evaluation of the individual studies. The testretest and inter-rater reliability of the QATSDD have been reported to be good (Sirriyeh et.al., 2012, a finding which was echoed by the good level of agreement between raters in the present review), and the tool allows comparison of studies with different designs; however, given that no qualitative studies were located during the literature searches, more established quality assessment tools such as the Cochrane Collaboration Risk of Bias (Higgins, Altman, Gøtzsche, Jüni, Moher et.al., 2011) may have been more appropriate, and allowed a more rigorous evaluation of the study findings. The small number of studies which formed the basis for this review reflects the developing nature of this topic to date; with this in mind, the lack of qualitative studies examining people's experiences of such interventions on their physical and psychological health is perhaps surprising. Exploring the nature of people's experiences may provide greater depth of insight into strengths and limitations of these interventions for service users, and give clinically-relevant information for healthcare professionals and service providers.

Conclusions

This review has supported previous research on the utility of mindfulness-based interventions on both physical symptoms of IBS and psychological outcomes such as quality of life and anxiety. Future research may focus on the underlying mechanisms of how such interventions work. The impact on participant's concept of wellbeing may also be explored, as opposed to

measures of mood or anxiety. While MBSR programmes continue to be more widely-available in the USA rather than the UK, it is hoped that the current literature denoting the efficacy of mindfulness-based interventions for people with chronic health concerns may inform future service provision for these populations.

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Chapter 3

Empirical Study

Trait Mindfulness and Psychological Flexibility in Irritable Bowel Syndrome (IBS).²

² To be submitted to the British Journal of Health Psychology, which has a word limit of 5000 words.

Abstract.

Objectives: The study aims were twofold: to explore how facets of trait mindfulness and psychological flexibility were related or distinct, and to investigate if and how these two constructs impacted on health and wellbeing in people with IBS.

Design: A cross-sectional correlational, online study was employed.

Methods: One hundred and thirty-five participants were recruited through The IBS Network and completed measures assessing IBS severity (IBS-SSS: Francis, Morris & Whorwell, 1997), trait mindfulness (FFMQ-SF: Bohlmeijer, ten Klooster, Fleddereus, Veehof & Baer, 2011), IBS-specific psychological flexibility (IBSAAQ: Ferreira, Eugenicos, Morris & Gillanders, 2012), wellbeing (WEMWBS: Tennant, Hiller, Fishwick, Platt, Joseph et.al., 2007), quality of life (WHOQOL-BREF: Skevington, Lotfy & O'Connell, 2004), perceived stress (PSQ: Levenstein, Prantera, Varvo, Scribano, Berto et.al., 1993) and external life stressors.

Results: Correlational and regression analyses were conducted. Few correlations were found between aspects of trait mindfulness and psychological flexibility, suggesting they are distinct constructs within this population. One facet of trait mindfulness ('acting with awareness') and one of psychological flexibility ('activity engagement') were significant predictors of wellbeing and all domains of quality of life. Additionally, the 'non-reacting' and 'acting with awareness' facets of mindfulness significantly predicted perceived stress. IBS symptom severity was also found to be correlated with perceived stress.

Conclusions: Trait mindfulness and psychological flexibility appear to be important predictors of psychological and physical distress for people with IBS. While there is overlap, trait mindfulness and psychological flexibility appear to be distinct constructs. Clinical implications of developing both concepts are discussed.

Statement of Contribution.

What is already known on this subject?

- Mindfulness-based interventions are effective in reducing stress responses across physical and psychological outcomes
- Mechanisms of trait mindfulness and psychological flexibility and their contribution to wellbeing are unclear

What does this study add?

- Examination of relations between trait mindfulness and psychological flexibility in people with IBS
- Facets of trait mindfulness and psychological flexibility independently impact on IBS-related health outcomes

Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder, characterised by debilitating symptoms such as pain, disordered bowel function and bloating, and estimated to affect 10-20% of the general UK population (National Institute for Health and Care Excellence [NICE], 2008). IBS has been conceptualised as a biopsychosocial condition (Zernicke, Lawlor-Savage, Lounsberry, Zhong, Blustein et.al., 2012), with the 'brain-gut axis' theory hypothesising how the cyclical relationship between physical and psychological / environmental factors may both cause and maintain IBS symptoms (Burnett & Drossman, 2005; Levy, Olden, Naliboff, Bradley, Francisconi et.al., 2006; Mayer & Tillisch, 2011). In brief, the autonomic nervous system (ANS), when activated by stress, impacts on gastrointestinal functions. The resultant aggravation in abdominal and bowel symptoms in turn may contribute to heightened psychological distress, including anxiety, frustration and suffering (Mayer & Tillisch, 2011; Spiegel, Gralnek, Bolus, Chang, Dulai et.al., 2004; Zernicke et.al., 2012).

How we respond to stress may therefore have important ramifications for our health. Research has indicated that activation of the autonomic and neuroendocrine systems can impact on physical and mental health symptoms (e.g. Dunkel Schetter & Dolbier, 2013;

Juster, McEwan & Lupien, 2010). One approach to regulating stress responses is through mindfulness, defined as "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994, p.4). Mindfulness is considered to comprise of different facets, including non-reactivity, observing, acting with awareness, describing, and non-judging, all of which are characterized by an openness to and acceptance of internal and external experiences, whether pleasant or aversive (Baer, Smith, Hopkins, Krietemeyer & Toney, 2006).

Mindfulness has been conceptualized as both a transient, state-dependent construct that can be cultivated through practices such as meditation, and an innate psychological trait (the ability to be mindful in everyday life - Brown & Ryan, 2003). State mindfulness may thus be described as a competence that may be acquired through practice (Baer et.al., 2006), while trait, or dispositional, mindfulness may be referred to as a facet of personality that relates to the frequency of awareness and attention in the present moment (Baer et.al., 2006; Brown & Ryan, 2003). While both trait mindfulness, and state, as a result of mindfulness training, is associated with lowered stress responses in non-clinical populations (Bao, Xue & Kong, 2014; Laurent, Laurent, Nelson, Wright & Sanchez, 2014), it is unclear if trait mindfulness is being modified, or if effects are due to the proximity of mindful attentional states (Bishop, 2002; Brown & Ryan, 2003).

Mindfulness-based interventions such as Mindfulness-Based Stress Reduction (MBSR: Kabat-Zinn, 1982), Mindfulness-Based Cognitive Therapy (MBCT: Segal, Williams, & Teasdale, 2001), and Acceptance and Commitment Therapy (ACT: Hayes, Strosahl & Wilson, 1999) have been studied across a range of physical health domains (e.g. Cash, Salmon, Weissbecker, Rebholz, Bayley-Veloso et.al., 2014; Louckes, Britton, Howe, Eaton & Buka, 2014; Simpson, Booth, Lawrence, Byrne, Mair et.al., 2014). In a recent meta-analysis, Bohlmeijer, Prenger, Taal & Cuijpers (2010) reported small to medium effects of

MBSR on anxiety, depression and psychological distress in adults with a chronic medical condition. In a recent meta-analysis of IBS populations, Aucoin, Lalonde-Parsi & Cooley (2014) identified significant maintained improvements in both IBS symptom severity and quality of life as a result of mindfulness-based interventions, although the authors highlighted methodological flaws and high risk of bias within the reviewed studies. Lakhan & Schofield (2013) also reported small to moderate improvements in pain, symptom severity, mood disturbance, anxiety and quality of life in a review of somatization disorders, with subgroup analyses identifying mindfulness-based interventions as most efficacious in IBS populations.

Although the mechanisms underlying how mindfulness exerts a beneficial effect are unclear, it is hypothesized that an improved ability to observe and accept everyday experiences non-judgementally may act as a 'buffer' against stressors, in turn leading to healthier appraisals of and responses to stress (Brown, Bravo, Roos & Pearson, 2014; Creswell & Lindsay, 2014; Fledderus, Bohlmeijer, Smit & Westerhof, 2010; Laurent et.al., 2014). An alternative model has been posited by Shapiro, Carlson, Astin & Freedman (2006), in which mindfulness is proposed to act through a number of meta-mechanisms, including values clarification, exposure, and cognitive / behavioural flexibility, to exert a positive influence on health outcomes.

One factor that may interact with this process is 'psychological flexibility'. Originating in the work on ACT (Hayes et.al., 1999), psychological flexibility has been defined as the ability to be open, present-focused and aware with the present moment, and to change or persist in behaviours when doing so serves one's values and goals (Hayes et.al., 1999; Hayes, Luoma, Bond, Masuda & Lillis, 2006). Psychological flexibility has been conceptually linked with mindfulness, suggesting they are related yet distinct constructs (Curtiss & Klemanski, 2014; Masuda, Price & Latzman, 2012). As such, uncertainty exists around differentiating the roles each may play in mediating distress (Creswell & Lindsey, 2014; Kashdan &

Rottenberg, 2010). Whilst the construct of psychological flexibility has been discussed as a fundamental aspect of health (Kashdan & Rottenberg, 2010), difficulties are reported in its evaluation, partly due to a lack of consensus regarding its definition, its manifestation, and its overlap with other psychological processes, leading to fragmentation within the empirical literature (Kashdan & Rottenberg, 2010).

The brain-gut axis theory suggests heightened biological response to psychological arousal or stress appears to be implicated in IBS symptomatic periods (Burnett & Drossman, 2005; Levy et.al., 2006; Mayer & Tillisch, 2011). Trait mindfulness and / or psychological flexibility may reduce physiological and emotional stress, with subsequent beneficial effects on reported quality of life, mood and wellbeing in people with IBS.

Given the lack of consensus around conceptual interplay between mindfulness and psychological flexibility, the mechanisms underlying how they work, and how they present in people with IBS, this study was exploratory in nature. The aims of this study were twofold: to investigate whether particular facets of trait mindfulness and psychological flexibility are related constructs amongst an IBS population, and to explore if, and how, they may influence subjective wellbeing, perceived stress, and quality of life.

It was hypothesised that:

- Facets of trait mindfulness will be correlated with facets of IBS-specific psychological flexibility, wellbeing, and perceived stress;
- Facets of IBS-specific psychological flexibility will be correlated with wellbeing,
 IBS symptom severity and perceived stress;
- 3. Facets of trait mindfulness will emerge as predictors of wellbeing, quality of life and perceived stress, when confounding variables are controlled for;

4. Facets of IBS-specific psychological flexibility will emerge as predictors of wellbeing, quality of life and perceived stress, when confounding variables are controlled for.

Method

Participants.

One hundred and thirty-five adults completed the study between November 2014 and March 2015. Participants were eligible if they were aged 18 or over, were diagnosed with IBS, and understood written English.

Eighty-two percent of participants were female (N=111). Participants had a mean age of 46.06 years (SD 16.42), with a mean length of time since diagnosis of 13.86 years (SD 12.88). Sixty-six percent (N=89) of participants were married or in a relationship. Ninety-five percent (N=128) identified themselves as White British or from the UK. Twenty-two percent of participants were not currently taking any medication, with 74% either taking medication specifically for IBS, for another physical or mental health difficulty, or some combination of these three (five participants chose not to disclose this information). Seventy percent of participants did not currently engage in any intentional mindfulness practice. Demographic information is summarised in Table 4. Power calculations for linear multiple regression analysis indicated that 98 participants were needed to detect a medium effect ($f^2 = 0.15$ at a power of 0.80 and an alpha of 0.05).

Measures

Demographic information including age, gender, ethnicity, marital status, current and previous treatment for IBS (including medication), and details of any mindfulness practice was collected.

Table 4. Demographic characteristics of the sample (N= 135).

| Variable | M (SD) | Min / Max |
|---------------------------------------|---------------|-----------|
| Age | 48.06 (16.42) | 18 - 84 |
| Time since diagnosis (years) | 13.86 (12.88) | 0 - 70 |
| Variable | N | % |
| Gender | | |
| Male | 24 | 18 |
| Female | 111 | 82 |
| Marital Status | | |
| Married / Relationship | 89 | 66 |
| Single | 34 | 25 |
| Divorced / Other | 12 | 9 |
| Ethnicity | | |
| White British | 128 | 95 |
| Other | 7 | 5 |
| Current Medication | | |
| For IBS | 32 | 24 |
| For other physical health difficulty | 20 | 15 |
| For other mental health difficulty | 6 | 4 |
| Combination of the above | 42 | 31 |
| None | 30 | 22 |
| Prefer not to say | 5 | 4 |
| Current Mindfulness Practice | | |
| None | 95 | 70 |
| Some | 21 | 16 |
| Other e.g. yoga, relaxation exercises | 19 | 14 |

The IBS Symptom Severity Scale (IBS-SSS: Francis, Morris & Whorwell, 1997) is a 4-item measure assessing the severity of current IBS symptoms (i.e. over the preceding ten day period). Significant differences between patients and control samples (p=0.0001: Francis et.al., 1997), and high accuracy in predicting symptom severity (p<0.01: Francis et.al., 1997) have been reported, as have good reproducibility and sensitivity to change (p<0.001: Francis et.al., 1997), suggesting that the IBS-SSS is a reliable and valid measure of symptom severity. Normative means and standard deviations were reported as: mild IBS M= 133, (SD=33), moderate IBS M= 243 (SD=42), and severe IBS M=372 (SD=66 - Francis et. al., 1997).

The Five Factor Mindfulness Questionnaire – Short Form (FFMQ-SF: Bohlmeijer, ten Klooster, Fleddereus, Veehof & Baer, 2011) is a 24-item scale measuring five mindfulness facets. These facets, together with mean scores for each as reported by Bohlmeijer et.al.

(2011) are: observing (attending to inner and external stimuli: M= 13.86, SD= 3.21), describing (putting experience into words: M= 16.28, SD= 3.91), acting with awareness (attending to activity in the present moment: M= 13.19, SD= 3.32), non-judging (not evaluating or criticising inner experience: M= 14.09, SD= 3.63) and non-reacting (resisting impulsive reactions to experience: M= 13.47, SD= 3.07). The five facets of the FFMQ-SF have demonstrated small to moderate correlations with Acceptance [AAQ-II] across the five facets), indicating good construct validity, and the measure has good internal consistency (α >0.7, Bohlmeijer et.al., 2011). In this study Cronbach's alpha was .80.

Acceptance and Action Questionnaire - IBS version (IBSAAQ: Ferreira, Eugenicos, Morris & Gillanders, 2012) is derived from the Chronic Pain Acceptance Questionnaire-Revised (CPAQ-R: McCracken, Vowles & Eccleston, 2004), which was based on the Acceptance and Action Questionnaire (AAQ-II: Bond, Hayes, Baer, Carpenter, Guenole et.al., 2011). The IBSAAQ consists of 20 items across two subscales: IBS willingness (e.g. "feeling comfortable with IBS experiences": M=28.5, SD=9.4) and Activity Engagement (e.g. "getting on with living despite bowel discomfort": M=27.7, SD=12.2). Good convergent validity for total scores and each of the two subscales has been reported (correlations with the AAQ-II of 0.58, 0.55, 0.46 respectively: Ferreira et.al., 2012). Good internal consistency (α > 0.8) and test-retest reliability (all ps <0.001) have been reported (Ferreira et.al., 2012); in this study internal consistency was .85. Item 8 ("there are many activities I do when I feel bowel discomfort") was excluded from analysis, as per the original study (Ferreira et.al., 2012).

Social Readjustment Rating Scale – Revised (SRRS-R: Hobson, Kamen, Szostek, Nethercut, Tiedmann et.al, 1998) is a 51-item scale assessing the severity of a range of life events potentially experienced in the previous year. Each event is assigned a weighted Life Change Rating (LCR), with higher scores indicating increased likelihood of illness.

Normative data provided by Hobson & Delunas (2001) indicated a mean score of 248 (SD= 422) within a North American general population sample. The researchers found significant and meaningful differences in the way people evaluated the stressfulness of various life events (F [33.9, 1,467.3] = 329.67, p< .05), suggesting that the SRRS-R is a valid measure of life events (Hobson et.al., 1998).

Perceived Stress Questionnaire (PSQ: Levenstein, Prantera, Varvo, Scribano, Berto et. al., 1993) is a 30-item measure of perceived stress which has been validated for use with people with gastrointestinal disorders. A mean score of 0.41 (SD=0.17), alongside high internal consistency (α = .92) and good construct validity (e.g. correlation with self-rated stress: r= .56: Levenstein et.al., 1993), has been reported by the authors. In the current study internal consistency was similarly high (α = .94).

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS: Tennant, Hiller, Fishwick, Platt, Joseph et.al., 2007) is a 14-item scale assessing wellbeing and psychological functioning. All items are worded positively and address aspects of positive mental health. The WEMWBS has demonstrated good criterion validity (e.g. correlations of .71 to .77 with the PANAS-PA and the WHO-5: Tennant et.al., 2007), and internal consistency (α = 0.91), with a median score of 51 (95% CI=51-52: Tennant et.al., 2007) has been reported. In this study Cronbach's alpha was .94.

The World Health Organisation Quality of Life scale – BREF (UK centre - Skevington, Lotfy & O'Connell, 2004) is a 26-item measure assessing four domains of quality of life: physical (M=57.17, SD=19.46), psychological (M=54.90, SD=17.83), social (M=59.33, SD=22.51) and environmental (M=64.76, SD=16.55: Skevington & McCrate, 2011). The WHOQOL-BREF has demonstrated good concurrent validity across the four quality of life domains (e.g. correlations of .04 - .79, and .42 - .69 with Physical and Mental scores on the SF-36: Skevington et.al., 2004). Good internal consistency has been reported (α = 0.55 – 0.87

across the four domains in a UK sample - Skevington et.al., 2004). In this study Cronbach's alpha was .91.

Procedure

In order to minimise potential disruption to participants, an online study design was adopted. Ethical approval was granted by the University of Liverpool. Participation was voluntary, with an option to enter into a prize draw, as an acknowledgment of participation. The study was advertised through the website, newsletter, Twitter® and Facebook® accounts of The IBS Network, the largest UK charity for people with IBS. On accessing the study link, participants were directed to an information page detailing what the study involved. This was followed by a screening page which asked participants to confirm they met the inclusion criteria and to indicate informed consent. Participants were then directed to complete each measure in turn. The survey took approximately 30 minutes to complete. Upon completion, participants were directed to a study debriefing page, which included the researcher contact details, if required. Participants could also indicate if they wished to receive a copy of the final study report and / or to enter the prize draw.

Data Analysis

Data was exported to IBM SPSS Version 22 for analysis and screened for missing responses.

A complete dataset was obtained for N=135 participants.

Data analysis was completed in four steps. First, descriptive statistics were calculated (see Table 5). Independent t-tests were conducted to detect any significant differences between descriptive data: a significant difference between severity scores for males (M=262.08, SD-65.34) and females (M=311.80, SD=86.40); t (133) = 2.65, p=.009 was detected. Significant differences in severity scores between those who practice mindfulness (M=267.86,

SD=99.95) and those who don't (M=309.43, SD=80.80); t (133) = -2.08, p=.039 was also found.

Second, the assumptions of normality, linearity and homoscedasticity were checked. Scores were found to be non-normally distributed on the FFMQ-SF, SRRS-R, and WHOQOL-BREF measures. Non-parametric analyses were therefore chosen as a more conservative option for subsequent correlational analyses. Two extreme outliers were found on the SRRS-R, and three on the Environmental factor of the WHOQOL-BREF. In such cases it is recommended that a comparison of the means and trimmed means is made (Pallant, 2013: p.67). A significant difference between SRRS-R means was found (M= 164.58; Trimmed M= 148.16: see Table 4). Following a sensitivity analysis (Cook's distance maximum values<1.00), a decision was made to retain these outliers.

Third, non-parametric correlations (Spearman's rho) were completed to explore how trait mindfulness and IBS-specific psychological flexibility were related (Hypothesis 1). To reduce the likelihood of a Type 1 error due to multiple testing, Bonferroni corrections were applied. This resulted in an adjusted alpha value of p=.003. Lastly, Hypotheses 3 and 4 were examined using a hierarchical multiple regression. Regression residuals were checked for normality and homoscedasticity and these assumptions were met. IBS symptom severity, external life events, gender, and mindfulness practice were controlled for. Multicollinearity was checked (Tolerance values > 0.2 [Menard, 1995] and VIF values < 10 [Myers, 1990]) and was not found to be an issue in the study data.

Results

Participant flow through the study can be seen in Figure 2.

Descriptive Statistics

Means and standard deviations for the primary study variables are reported in Table 5.

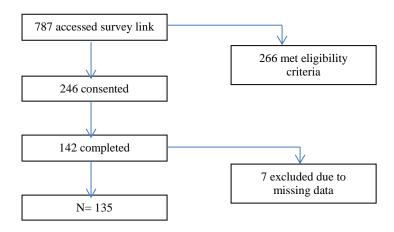


Figure 2. Flowchart of Study Participants.

Table 5. Means, standard deviations and range of scores for study variables.

| Variable | Mean (SD) | 95% CI | 5% Trimmed | Range |
|----------|-----------------|-----------------|------------|-------------|
| | , , | | Mean | J |
| FFMQ-SF | | | | |
| NR | 12.39 (4.06) | 11.70 - 13.08 | 12.34 | 5 - 22 |
| O | 14.05 (3.88) | 13.39 - 14.71 | 14.23 | 4 - 20 |
| AA | 16.02 (4.78) | 15.21 - 16.84 | 16.04 | 5 - 25 |
| D | 16.79 (4.21) | 16.07 - 17.50 | 16.81 | 5 - 25 |
| NJ | 14.93 (4.89) | 14.09 - 15.76 | 14.84 | 5 - 25 |
| IBSAAQ | 52.83 (15.45) | 50.20 - 55.46 | 52.87 | 12 - 95 |
| WEMWBS | 37.01 (12.34) | 34.91 - 39.11 | 36.98 | 14 - 66 |
| WHOQOL | | | | |
| Phys | 52.90 (20.70) | 49.37 - 56.42 | 53.14 | 0 - 100 |
| Psy | 48.58 (18.71) | 45.39 - 51.76 | 48.71 | 6 - 94 |
| Soc | 56.12 (23.69) | 52.09 - 60.15 | 56.51 | 0 - 100 |
| Env | 65.07 (16.36) | 62.28 - 67.85 | 65.48 | 13 - 94 |
| PSQ | 0.525 (0.19) | 0.49 - 0.55 | 0.526 | 0.05 - 0.96 |
| IBS SSS | | | | |
| Total | 302.96 (85.00) | 288.49 - 317.43 | 303.21 | 110 - 490 |
| Mild | 152.73 (19.02) | 139.95 – 165.51 | 154.14 | 110 - 170 |
| Moderate | 247.23 (32.09) | 238.64 - 255.83 | 248.17 | 180 - 295 |
| Severe | 373.16 (47.42) | 361.68 - 384.64 | 371.68 | 300 - 490 |
| SRRS-R | 164.58 (157.24) | 137.81 - 191.34 | 148.16 | 0 - 1005 |

Note. FFMQ-SF = Five Factor Mindfulness Questionnaire Short Form; NR = Non-reactivity; O = Observing; AA = acceptance; D = Describing; NJ = Non-judging; IBSAAQ = IBS Acceptance and Action Questionnaire; WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale; WHOQOL = WHO Quality of Life Scale; Phys = Physical; Psy = Psychological; Soc = Social; Env = Environmental; PSQ = Perceived Stress Questionnaire; IBSSSS = IBS Symptom Severity Scale; SRRS-R = Social Readjustment Rating Scale Revised.

Correlations between study variables

Table 6 presents correlations between the study variables. Four of the five facets of the FFMQ-SF (non-reacting, observing, acting with awareness, and describing) demonstrated small to moderate, statistically significant correlations with wellbeing (r=.290 to .475, p<0.003). In addition, non-reacting and acting with awareness, as well as the describing inner experience and non-judgement facets of the FFMQ-SF, demonstrated small to moderate, significant inverse correlations with perceived stress (r-.282 to -.544, p<.003). These findings suggest support for Hypothesis 1. The activity engagement facet of psychological flexibility was moderately, statistically significantly, positively correlated with wellbeing (r=.557, p<.003), and demonstrated moderate, significant negative correlations with both IBS severity and perceived stress (r=-.414 and -.320, p<.003 respectively), suggesting support for Hypothesis 2. The IBS willingness facet demonstrated the same pattern, though the correlations between this facet and wellbeing, perceived stress, and IBS severity, were smaller in size (r=.270, -.277, -.272, p<.003 respectively: see Table 6).

Correlations between trait mindfulness and psychological flexibility

Few correlations were found between the different facets of trait mindfulness and IBS-specific psychological flexibility. Statistically significant, but small, correlations were found between the non-reacting facet and both total IBSAAQ scores (r=.299, p<.003) and the activity engagement factor (r=.332, p<.003), and between the non-judging facet and the IBS willingness factor (r=.257, p<.003). These findings suggest support for Hypothesis 1, and imply that the two constructs are distinct.

While both psychological flexibility factors showed small but significant intercorrelations, there were relatively few inter-correlations identified between the facets of trait mindfulness. The non-reacting facet of mindfulness on the FFMQ-SF was significantly correlated with the observing facet; furthermore, the acting with awareness facet was significantly correlated with the observing, describing and non-judging facets (see Table 6), a pattern similar to that found by Bohlmeijer et.al. (2011). While internal consistency was good (α =0.8), the relative lack of inter-correlations suggests these mindfulness facets were more distinct in this sample.

Table 6. Spearman's correlations between study variables.

| Variable | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. | 10. | 11. | 12. | 13. | 14. | 15. | 16. |
|-----------------|-------|-------|-----------|-------|-------|------------------|---------------|-------|-------|-------|------|------|-------|-------|-------|------|
| 1. FFMQ NR | 1.00 | | | | | | | | | | | | | | | |
| 2. FFMQ O | .257* | 1.00 | | | | | | | | | | | | | | |
| 3. FFMQ AA | .178 | .255* | 1.00 | | | | | | | | | | | | | |
| 4. FFMQ D | .219 | .128 | .320* | 1.00 | | | | | | | | | | | | |
| 5. FFMQ NJ | .179 | .047 | .325* | .007 | 1.00 | | | | | | | | | | | |
| 6. PSQ | 544* | 187 | 449* | 282* | 298* | 1.00 | | | | | | | | | | |
| 7.IBSAAQ | .299* | .072 | .027 | .176 | .162 | 321 [*] | 1.00 | | | | | | | | | |
| 8. AE | .332* | .178 | .110 | .119 | .024 | 320* | .817 * | 1.00 | | | | | | | | |
| 9. IBSW | .198 | 021 | .005 | .179 | .257* | 272* | .790 * | .342* | 1.00 | | | | | | | |
| 10. WEMWBS | .359* | .306* | .475* | .290* | .130 | 569* | .488* | .557* | .270* | 1.00 | | | | | | |
| 11. IBSSSS | 262* | 165 | 104 | 126 | 069 | .287* | 408* | 414* | 277* | 250* | 1.00 | | | | | |
| 12.SRRS-R | 096 | 054 | 105 | 140 | 143 | .217 | 119 | 079 | 091 | 217 | 0.33 | 1.00 | | | | |
| 13. WHOQOL Phys | .296* | .116 | .218 | .018 | .140 | 361* | .524* | .555* | .314* | .536* | 526* | 181 | 1.00 | | | |
| 14. WHOQOL Psy | .420* | .326* | .483* | .251* | .231 | 627* | .535* | .573* | .355* | .755* | 459* | 255* | .651* | 1.00 | | |
| 15. WHOQOL Soc | .275* | .171 | .249 | .061 | .177 | 428* | .290* | .370* | .145 | .547* | 170 | 150 | .345* | .511* | 1.00 | |
| 16. WHOQOL Env | .326* | .229 | .285* | .194 | .175 | 496* | .447* | .524* | .232 | .566* | 385* | 296* | .615* | .659* | .464* | 1.00 |

Note. FFMQ = Five Factor Mindfulness Questionnaire- Short Form; NR = Non-reactivity; O = Observing; AA = acceptance; D = Describing; NJ = Non-judging; IBSAAQ = IBS Acceptance and Action Questionnaire; AE = Activity Engagement; IBSW = IBS Willingness; PSQ = Perceived Stress Questionnaire; WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale; WHOQOL = WHO Quality of Life Scale; Phys = Physical; Psy = Psychological; Soc = Social; Env = Environmental

^{*}p<.003 (Bonferroni corrected value)

Hierarchical multiple regression analyses

Regression analyses were conducted to test the predictive value of trait mindfulness and psychological flexibility for wellbeing, quality of life and perceived stress (while controlling for gender, mindfulness practice, IBS severity, and external stressors). IBS severity and SRRS-R scores, gender and mindfulness practice were therefore entered in Block 1; as the study was exploratory, the facets of trait mindfulness and psychological flexibility were entered in a stepwise fashion (Field, 2005, p.161), in order to determine which factors were the most significant. Results are summarised in Tables 7 -12 below.

The activity engagement facet of the IBSAAQ emerged as the most significant predictor for wellbeing, followed by the acting with awareness facet of the FFMQ-SF. This model as a whole was statistically significant, accounting for 55.2% of variance when gender, mindfulness practice, IBS severity and external stressors were controlled for: F(6, 128) = 26.333, p=.000. Similarly, the acting with awareness facet of trait mindfulness emerged as the most significant predictor of psychological quality of life, with the non-reacting facet the third most significant predictor: F(8, 126) = 27.030, p=.000. These findings lend support to Hypothesis 3, as facets of trait mindfulness are accounted as significant predictors in both models for wellbeing and psychological quality of life; the significance of psychological flexibility is also highlighted within this.

Only partial support for Hypothesis 4 was found. One facet of psychological flexibility (activity engagement) emerged as the most significant predictor of both physical and social quality of life domains. The acting with awareness facet of trait mindfulness was also significantly predictive of physical and social quality of life. However, neither facet of psychological flexibility was significantly predictive of perceived stress. Instead, the non-reactive and acting with awareness facets of trait mindfulness were the most significant factors.

Table 7. Hierarchical regression analyses predicting wellbeing

| | Unstandardised Coefficients | | Sta | andardised Co | efficiants | Model Sur | nmary | |
|----------------|------------------------------------|------|--------------|----------------|------------------|----------------|-------------------------|-----------------------|
| Steps in Model | В | SE B | ß | 95% Confi | idence Intervals | \mathbb{R}^2 | Adjusted R ² | R ² Change |
| _ | | | | L | U | | - | |
| 1 Gender | -1.83 | 2.69 | - .06 | - 7.14 | 3.49 | .157** | .131 | |
| Practice | -7.62 | 2.81 | 22** | -13.18 | - 2.06 | | | |
| Severity | 03 | .01 | 24** | - .06 | - .01 | | | |
| Life events | 02 | .01 | 21* | - .03 | 00 | | | |
| 2 Gender | 65 | 2.31 | 02 | - 5.22 | 3.91 | .386 | .362 | 22.9%** |
| Practice | -6.57 | 2.41 | 19** | - 11.35 | - 1.80 | | | |
| Severity | 00 | .01 | - .03 | - .03 | .02 | | | |
| Life events | 01 | .01 | 17* | - .03 | 00 | | | |
| AE | .68 | .10 | .53** | .49 | .88 | | | |
| 3 Gender | -1.07 | 1.98 | 03 | - 4.99 | 2.85 | .552 | .531 | 16.7%** |
| Practice | -6.97 | 2.07 | 21** | - 11.06 | - 2.87 | | | |
| Severity | 00 | .01 | - .01 | 02 | .02 | | | |
| Life events | 01 | .01 | 13* | 02 | 00 | | | |
| AE | .64 | .08 | .49** | .47 | .81 | | | |
| FFMQAA | 1.07 | .16 | .41** | .76 | 1.37 | | | |

^{*} *p*<.05; ***p*<.01

Table 8. Hierarchical regression analyses predicting physical quality of life

| | Unstandard | dised Coefficients | Standardise | d Coefficiants | | Model Sum | Model Summary | | | | |
|----------------|------------|--------------------|-------------|-----------------------|---------------|----------------|-------------------------|-----------------------|--|--|--|
| Steps in Model | В | B SE B | ß | 95% Conf Intervals | idence | \mathbb{R}^2 | Adjusted R ² | R ² Change | | | |
| | | | | L | U | | | | | | |
| 1 Gender | .04 | 4.01 | .00 | - 7.89 | 7.97 | .332** | .311 | | | | |
| Practice | -10.53 | 4.20 | 19* | -18.83 | - 2.23 | | | | | | |
| Severity | 12 | .02 | 49** | - .15 | 08 | | | | | | |
| Life events | 03 | .01 | 19* | - .04 | - .01 | | | | | | |
| 2 Gender | 1.56 | 3.60 | .03 | - 5.56 | 8.68 | .469 | .449 | 13.7%** | | | |
| Practice | -9.18 | 3.76 | 16* | -16.62 | - 1.74 | | | | | | |
| Severity | 08 | .02 | 32** | - .11 | - .04 | | | | | | |
| Life events | 02 | .01 | 16* | - .04 | 00 | | | | | | |
| AE | .88 | .15 | .41** | .58 | 1.19 | | | | | | |
| 3 Gender | 1.35 | 3.56 | .03 | - 5.70 | 8.39 | .485 | .461 | 1.6%* | | | |
| Practice | -9.38 | 3.72 | 17 * | -16.74 | -2.02 | | | | | | |
| Severity | 08 | .02 | 31** | - .11 | - .04 | | | | | | |
| Life events | 02 | .01 | 15* | - .04 | 00 | | | | | | |
| AE | .86 | .15 | .40** | .56 | 1.16 | | | | | | |
| FFMQAA | .55 | .28 | .13* | .00 | 1.10 | | | | | | |
| 4 Gender | 1.97 | 3.50 | .04 | - 4.96 | 8.90 | .508 | .481 | 2.3%* | | | |
| Practice | -10.34 | 3.67 | 18** | - 17.61 | -3.08 | | | | | | |
| Severity | 08 | .02 | 32** | - .11 | 04 | | | | | | |
| Life events | 02 | .01 | 15* | 04 | 00 | | | | | | |
| AE | .89 | .15 | .41** | .59 | 1.18 | | | | | | |
| FFMQAA | .82 | .29 | .19** | .24 | 1.40 | | | | | | |
| FFMQD | 82 | .34 | 17* | - 1.49 | - .16 | | | | | | |

^{*} p<.05; **p<.01

Table 9. Hierarchical regression analyses predicting psychological quality of life.

| | Unstandardi | sed Coefficients | Standardised | Coefficients | | Model Sumi | mary | |
|----------------|---------------|------------------|--------------|---------------|-----------------|----------------|-------------------------|-----------------------|
| Steps in Model | В | SE B | ß | 95% Confi | dence Intervals | \mathbb{R}^2 | Adjusted R ² | R ² Change |
| _ | | | | L | U | | - | _ |
| 1 Gender | 2.83 | 3.70 | .06 | -4.50 | 10.15 | .303** | .282 | |
| Practice | -8.90 | 3.87 | 17* | -16.56 | -1.24 | | | |
| Severity | - .09 | .02 | 42** | 13 | 06 | | | |
| Life events | 03 | .01 | 24** | 05 | 01 | | | |
| 2 Gender | 2.28 | 3.19 | .05 | - 4.03 | 8.60 | .487 | .467 | 18.4%** |
| Practice | - 9.42 | 3.34 | 18** | -16.02 | -2.82 | | | |
| Severity | - .09 | .02 | 38** | 11 | 06 | | | |
| Life events | 02 | .01 | 20** | 04 | 01 | | | |
| FFMQAA | 1.69 | .25 | .43** | 1.20 | 2.19 | | | |
| 3 Gender | 3.60 | 2.82 | .07 | -1.98 | 9.17 | .605 | .587 | 11.8%** |
| Practice | -8.25 | 2.95 | 16** | -14.08 | -2.42 | | | |
| Severity | 05 | .01 | 23** | 08 | 02 | | | |
| Life events | 02 | .01 | 18** | 03 | 01 | | | |
| FFMQAA | 1.60 | .22 | .41** | 1.16 | 2.03 | | | |
| AE | .74 | .12 | .38** | .51 | .98 | | | |
| 4 Gender | 2.98 | 2.79 | .06 | -2.54 | 8.50 | .620 | .599 | 1.5%* |
| Practice | - 7.72 | 2.91 | 15** | -13.48 | - 1.96 | | | |
| Severity | 05 | .01 | 22** | 08 | 02 | | | |
| Life events | 02 | .01 | 16** | 03 | 01 | | | |
| FFMQAA | 1.53 | .22 | .39** | 1.10 | 1.96 | | | |
| AE | .68 | .12 | .35** | .43 | .92 | | | |
| FFMQNR | .62 | .28 | .14* | .07 | 1.17 | | | |
| 5 Gender | 2.47 | 2.77 | .05 | -3.01 | 7.94 | .632 | .608 | 1.2%* |
| Practice | - 7.56 | 2.88 | 15** | -13.25 | -1.87 | | | 1,2 / 0 |
| Severity | 04 | .01 | 20** | 07 | 02 | | | |
| Life events | 02 | .01 | 15** | - .03 | 00 | | | |
| FFMQAA | 1.56 | .22 | .40** | 1.13 | 1.98 | | | |
| AE | .60 | .13 | .31** | .36 | .85 | | | |
| FFMQNR | .59 | .28 | .13* | .04 | 1.13 | | | |
| - | | | | | | | | |
| IBSW | .25 | .13 | .12* | .00 | .50 | | | |

^{*} p<.05; **p<.01

Table 10. Hierarchical regression analyses predicting social quality of life

| | Unstandardised Coefficients | | St | andardised Co | efficiants | Model Summary | | | |
|----------------|------------------------------------|------|--------------|----------------|-----------------|----------------|-------------------------|-----------------------|--|
| Steps in Model | В | SE B | ß | 95% Confi | dence Intervals | R ² | Adjusted R ² | R ² Change | |
| - | | | L | U | | - | _ | | |
| 1 Gender | - 4.83 | 5.39 | 08 | -15.49 | 5.83 | .079* | .051 | | |
| Practice | - 8.77 | 5.64 | - .14 | - 19.92 | 2.38 | | | | |
| Severity | - .05 | .03 | 18* | - .10 | 00 | | | | |
| Life events | - .03 | .01 | - .16 | 05 | .00 | | | | |
| 2 Gender | - 3.38 | 5.13 | 06 | - 13.53 | 6.78 | .175 | .143 | 9.6%** | |
| Practice | - 7.48 | 5.37 | - .12 | - 18.09 | 3.14 | | | | |
| Severity | - .01 | .03 | - .04 | - .06 | .04 | | | | |
| Life events | - .02 | .01 | - .14 | 05 | .00 | | | | |
| AE | .84 | .22 | .34** | - 13.71 | 1.28 | | | | |
| 3 Gender | - 3.78 | 5.02 | 06 | -18.24 | 6.15 | .218 | .181 | 4.3%** | |
| Practice | - 7.86 | 5.25 | - .12 | - .06 | 2.52 | | | | |
| Severity | - .01 | .03 | - .03 | - .04 | .04 | | | | |
| Life events | - .02 | .01 | - .12 | .38 | .01 | | | | |
| AE | .80 | .21 | .32** | .27 | 1.23 | | | | |
| FFMQAA | 1.04 | .39 | .21** | -13.71 | 1.82 | | | | |

^{*} *p*<.05; ***p*<.01

Table 11. Hierarchical regression analyses predicting environmental quality of life

| | Unstandardised Coefficients | | Sta | andardised Co | efficiants | Model Summary | | | |
|----------------|------------------------------------|------|--------------|----------------|-----------------|----------------|-------------------------|-----------------------|--|
| Steps in Model | В | SE B | ß | 95% Confi | dence Intervals | R ² | Adjusted R ² | R ² Change | |
| _ | | | L | U | | - | | | |
| 1 Gender | 3.14 | 3.33 | .07 | -3.46 | 9.73 | .261** | .238 | | |
| Practice | - 5.80 | 3.49 | - .13 | -12.70 | 1.10 | | | | |
| Severity | - .07 | .02 | 37** | - .10 | - .04 | | | | |
| Life events | - .03 | .01 | 28** | - .05 | - .01 | | | | |
| 2 Gender | 4.39 | 3.00 | .10 | -1.53 | 10.32 | .411 | .388 | 15.0%** | |
| Practice | - 4.68 | 3.13 | - .10 | -10.88 | 1.52 | | | | |
| Severity | - .04 | .02 | 19* | - .07 | - .01 | | | | |
| Life events | - .03 | .01 | 25** | - .04 | - .01 | | | | |
| AE | .73 | .13 | .43** | .48 | .98 | | | | |
| 3 Gender | 4.15 | 2.92 | .10 | - 1.64 | 9.93 | .444 | .418 | 3.3%** | |
| Practice | - 4.91 | 3.06 | - .11 | - 10.96 | 1.14 | | | | |
| Severity | - .04 | .01 | 18* | - .06 | - .01 | | | | |
| Life events | - .02 | .01 | 23** | - .04 | - .01 | | | | |
| AE | .71 | .13 | .41** | .46 | .95 | | | | |
| FFMQAA | .63 | .23 | .19** | .18 | 1.08 | | | | |

^{*} *p*<.05; ***p*<.01

Table 12. Hierarchical regression analyses predicting perceived stress

| | Unstandardised Coefficients | | Sta | andardised C | oefficiants | Model Summary | | |
|----------------|------------------------------------|------|--------------|--------------|-------------------|----------------|-------------------------|-----------------------|
| Steps in Model | В | SE B | ß | 95% Con | fidence Intervals | \mathbb{R}^2 | Adjusted R ² | R ² Change |
| _ | | | | L | U | | | |
| 1 Gender | 03 | .04 | 05 | 11 | .06 | .148** | .121 | |
| Practice | .05 | .05 | .09 | - .04 | .14 | | | |
| Severity | .00 | .00 | .27** | .00 | .00 | | | |
| Life events | .00 | .00 | .22** | .00 | .00 | | | |
| 2 Gender | - .01 | .04 | - .01 | .86 | 08 | .329 | .303 | 18.1%** |
| Practice | .03 | .04 | .05 | .47 | - .05 | | | |
| Severity | .00 | .00 | .16* | .04 | .00 | | | |
| Life events | .00 | .00 | .16* | .03 | .00 | | | |
| FFMQNR | - .02 | .00 | 45** | .00 | - .03 | | | |
| 3 Gender | 00 | .04 | - .01 | - .07 | .07 | .437 | .411 | 10.9%** |
| Practice | .04 | .04 | .07 | - .04 | .11 | | | |
| Severity | .00 | .00 | .15* | .00 | .00 | | | |
| Life events | .00 | .00 | .13 | .00 | .00 | | | |
| FFMQNR | - .02 | .00 | 40** | - .03 | - .01 | | | |
| FFMQAA | - .01 | .00 | 34** | 02 | - .01 | | | |

^{*} *p*<.05; ***p*<.01

Discussion

This study aimed to explore how different facets of trait mindfulness and psychological flexibility were conceptually related, and to investigate if and how they impacted on psychological health and wellbeing in people with IBS.

Facets of both trait mindfulness and psychological flexibility significantly predicted wellbeing, different domains of quality of life, and perceived stress. Aspects of trait mindfulness and IBS-specific psychological flexibility were both significantly predictive of psychological quality of life; specifically, the activity engagement and acting with awareness factors were significantly predictive of both physical and social quality of life, as predicted. This finding has been previously reported for trait mindfulness facets (e.g. Boden, Irons, Feldner, Bujarski & Bonn-Miller, 2014), but psychological flexibility has not previously been examined in relation to its utility in predicting quality of life domains. In addition, the acting with awareness facet emerged as the second most significant predictor of wellbeing (Hypothesis 1), in line with previous research which suggested that facets of mindfulness, such as acting with awareness, are implicated in wellbeing (e.g. Carmody & Baer, 2007; Ciarrochi, Kashdan, Leeson, Jordan & Heaven, 2011). The non-reacting and acting with awareness facets of the FFMQ-SF were also significant predictors of perceived stress (Hypothesis 4), however, neither psychological flexibility factor manifested as a significant predictor.

Four of five facets of trait mindfulness demonstrated small to moderate, significant correlations with wellbeing. The small to moderate, significant correlations of the psychological flexibility factors with wellbeing were expected (Hypothesis 2), however, the activity engagement factor's emergence as the most significant predictor was noted. The presence of psychological inflexibility has been considered a feature of psychopathology

(Kashdan & Rottenberg, 2010); this finding therefore suggests that psychological flexibility is also a significant factor in perceived wellbeing.

In general, research reports the absence or reduction in negative outcomes, which may not necessarily equate with greater wellbeing, and specific measures of wellbeing are not consistently utilised (Kashdan & Rottenberg, 2010). Small to moderate, significant inverse correlations were found between four of the five facets of trait mindfulness and perceived stress (Hypothesis 1); as were similar correlations between stress and both factors of psychological flexibility (Hypothesis 2). Dispositional mindfulness has been reported to be negatively correlated with perceived stress in diverse populations including older adults (Prakash, Hussain & Schirda, 2014), adults with multiple sclerosis (Senders, Bourdette, Hanes, Yadav & Shinto, 2014), and breastfeeding mothers (Perez-Blasco, Viguer & Rodrigo, 2013), all of which suggests support for the 'stress-buffering' effects of mindfulness (Brown et.al., 2014; Creswell & Lindsay, 2014; Fledderus et.al., 2010; Laurent et.al., 2014).

Few inter-correlations between facets of trait mindfulness and psychological flexibility were found. The small but statistically significant correlations identified between the activity engagement and non-reacting facets, and the IBS willingness and non-judging factors, suggest that trait mindfulness and psychological flexibility are more distinct than related entities, albeit with some overlap on certain aspects (Curtiss & Klemanski, 2014; Masuda et. al., 2012). It may be that particular aspects of the non-reactive and non-judgement facets of mindfulness are theoretically related to those of psychological flexibility. A recent study has discussed the differential relevance of the facets of trait mindfulness in predicting avoidance behaviour in a sample of people with colorectal cancer (Reynolds, Consedine & McCambridge, 2014). These authors discussed the importance of the non-reacting and non-judging facets in this process, as they facilitate the detachment of experience from behaviour, allowing the individual to act in ways that are not necessarily dictated by their thoughts or

emotions. This is consistent with the definition of psychological flexibility (full and willing contact with the present moment, and changing or persisting in behaviours in line with one's values: Hayes et.al., 2006), and lends support to the inter-connectedness of these constructs.

Descriptively, the IBS-severity subgroup means and standard deviations are within the ranges reported by Francis et.al. (1998), suggesting the sample here are somewhat representative of the IBS population. Facet scores on the FFMQ-SF were broadly similar to those previously reported (Bohlmeijer et.al., 2011), while scores on the IBSAAQ, WEMWBS and WHOQOL-BREF were slightly lower than previous studies (Ferreira et.al., 2012; Skevington & McCrate, 2011; Tennant et.al., 2007). Conversely, self-reported stress levels were higher than those found by Levenstein et.al. (1993).

Collectively, these findings suggest that both trait mindfulness and psychological flexibility are important attributes in promoting positive perceptions of wellbeing and quality of life and, possibly, involved in 'buffering' distressing or stressful aspects of IBS in some way. This is in line with current literature on the beneficial effects of mindfulness on psychological and physical outcomes, both in IBS and other physical health populations (e.g. Aucoin et.al., 2014; Bao et.al., 2014; Lakhan & Schofield, 2014; Laurent et.al., 2014; van Son, Nyklíček, Nefs, Speight, Pop et.al., 2014). However, the significance of psychological flexibility has been less explicit: while positive effects on psychological health (Fledderus et.al., 2010) and occupational stress and burnout (Lloyd et.al., 2013) have been reported, psychological flexibility has not been overtly examined in an IBS population. Given that both were found to be significant in this study, this lends weight to the consideration of mindfulness and psychological flexibility operating as complementary processes. A recent study with overweight adults posited that mindfulness and psychological flexibility comprise an overarching regulatory process of accepting and non-judging experience, while the individual engages in values-driven, meaningful action (Sairanen, Tolyanen, Karhunen,

Kolehmainen, Järvela et.al., 2015). Similarly, Shapiro et.al.'s (2006) model of the mechanisms underpinning the positive effects of mindfulness may also be tapping into components of psychological flexibility. The present study suggests that both may be important constructs in predicting psychological distress in people with IBS.

Moreover, this study's findings offer broad support for the brain-gut axis theory (Burnett & Drossman, 2005; Levy et.al., 2006; Mayer & Tillisch, 2011). This is illustrated by the significant positive correlations between IBS severity scores and perceived stress, and the strong inverse relationships between severity and all aspects of quality of life. This is consistent with the proposition that stress activates the ANS, leading to a worsening of gastrointestinal symptoms, in turn impacting on psychological distress (Mayer & Tillisch, 2011; Spiegel et.al., 2004; Zernicke et.al., 2012). However, given the correlational nature of the study, it is impossible to extrapolate the origins or direction of these relationships between physical, psychological and environmental factors.

Clinical Implications.

Given the potential significance of both trait mindfulness (specifically the acting with awareness and non-reacting facets) and psychological flexibility in influencing wellbeing, it would appear that these features provide plausible targets for intervention in IBS management. However, if the distinctions between these constructs are not clearly defined, interventions may not necessarily foster change for those who may benefit.

An intervention such as Acceptance and Commitment Therapy (ACT: Hayes et.al., 1999), which targets both mindfulness skills and psychological flexibility, may lend itself to IBS populations. To the best of the author's knowledge, there is no current evidence to support the use of ACT for people with IBS, beyond a doctoral thesis (the application of an ACT model to the conceptualisation and treatment of IBS: Ferreira, Gillanders, Morris &

Eugenicos, 2011), and a brief discussion of its potential value in one review paper (Naliboff, Frese & Rapgay, 2008). Previous research has demonstrated that mindfulness training (i.e. the cultivation of a mindful 'state') can lead to increases across all five facets of trait mindfulness (e.g. Carmody & Baer, 2007, who noted the largest increases in the observing and non-reacting facets). This would imply that the ability to notice, yet not judge or react to experiences, is a skill which may be amenable to change through intervention.

The utility of mindfulness-based interventions for a range of chronic health conditions, including IBS, has been extensively reviewed: moderate positive results of interventions were found for people with IBS (Cross, unpublished thesis), while more significant positive results have been reported elsewhere (Aucoin et.al., 2014; Lakhan & Schofield, 2013). Despite the recent publication of NICE guidance, no updates to psychological intervention have been included. Current guidelines recommend "Referral for psychological interventions (cognitive behavioural therapy [CBT], hypnotherapy and/or psychological therapy) should be considered for people with IBS who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile" (NICE, 2015, p.17). The research evidence for mindfulness-based interventions has not translated into current recommended practice. Given the importance of individual reaction to and management of stress responses (Creswell & Lindsay, 2014; Laurent et.al., 2014), and the subsequent impact on both physical and psychological status in people with IBS (Aucoin et.al., 2014; Burnett & Drossman, 2005; Lakhan & Schfield, 2013; Levy et.al., 2006; Mayer & Tillisch, 2011), it would appear that psychological aspects of health are equally worthy of consideration.

Understanding and delineating the mechanisms of how such interventions work is central to the effective implementation of evidence-based research to clinical practice. Finally, although an internet-based questionnaire format was employed, the level of qualitative information provided by participants was unexpected. Throughout the demographics

questionnaire many respondents gave significant amounts of detail about their experiences of IBS and its' ongoing impact on their everyday lives. While purely speculative, there is perhaps a desire for people with this particular condition to relate their experiences and feel 'heard' in some sense.

Limitations

The current study had several methodological limitations. The correlational design ensured that causality cannot be inferred. Participants were self-selected, the sample was female-dominated and ethnically homogeneous in nature. This may be indicative of the prevalence of IBS, or may be representative of the geographical location of the majority of studies (Lovell & Ford, 2012). Other factors such as socio-economic status (while not explicitly assessed, all participants had access to a computer and the internet) and severity of IBS symptoms (the majority of participants rated their IBS as moderate to severe) set limitations on the generalisability of the findings. The presence of other confounding variables not assessed for in this study may have also impacted on results (e.g. specific physical or psychiatric difficulties that interplay with physical or psychological symptoms).

Another limitation was the lack of a control group. Operational difficulties, such as matching controls on some characteristics of an IBS sample who were generally older, had had the illness for significant periods of time, and who were on a range of medications, meant that this was beyond the scope of the current study. Additionally, the investigation of psychological flexibility as an under-researched area could have been bolstered by the inclusion of a general psychological flexibility measure such as the Acceptance and Action Questionnaire (Bond et.al., 2011). This may have allowed comparisons between participants' IBS-specific and more general ratings, alongside further investigation of the relationship with trait mindfulness.

Conclusions and future directions

The findings of this exploratory study offer some support to the current literature around trait mindfulness and effects on psychological health, specifically wellbeing, quality of life, and subjective stress, for individuals with IBS. The presence of psychological flexibility also appears worthy of further analysis. Future research could include replicating this study with a control group in order to test the findings more rigorously; alternatively, a hypothetical model of the mechanisms underpinning trait mindfulness and psychological flexibility could be tested on a larger population of people with IBS using structural equation modelling.

It is also possible that future directions could follow a qualitative methodology investigating people's experiences of IBS and impact on their daily lives and functioning. Judging by the anecdotal information given by participants, it is apparent that people with IBS wish to talk openly about the condition and how advice and treatment could be improved. Service users should be included in the design of future studies, in order to guide specific research questions: stakeholder involvement in research is currently recommended (e.g. Craig, Dieppe, Macintyre, Michie, Nazareth et.al., 2008), and such insights could offer a valuable source of guidance for healthcare practitioners.

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